



Department of Health and Human Services

# Semiannual

Report to Congress

April 1, 2007-September 30, 2007



OIG

Office of Inspector General

## OIG COMPONENTS

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

OAS

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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.

# Semiannual

Report to Congress



**April 1, 2007-September 30, 2007**



Department of Health and Human Services  
Office of Inspector General

# 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, 2007.

As detailed in this report, OIG's investigations, audits, and evaluations continue to generate record savings and expected recoveries and also produce recommendations to ensure efficient and effective program operations. We also highlight in this report significant cases leading to Federal health care program exclusions of individuals and entities and criminal or civil prosecutions in State and Federal courts across the Nation; such cases play a vital role in protecting HHS programs and beneficiaries.

Our record of achievement in HHS program protection has required the commitment of OIG's more than 1,500 dedicated professionals. Not only have they contributed their own talents and energy to our mission, but they have also worked to effect productive interdisciplinary partnerships with others who share our objective of ensuring the quality and integrity of HHS programs. For example, we have worked closely with fellow Department employees involved in program integrity efforts, Department of Justice personnel, State antifraud and audit officials, vigilant beneficiaries, and many others in Government and the wider health care community.

As we look to build on the work summarized for this reporting period, we will continue to concentrate our resources where the challenges are greatest and the benefits most advantageous to taxpayers and beneficiaries. Such challenges include continued attention to Medicare Part D; Medicare, Medicaid, and SCHIP payment integrity; Medicaid administration; quality of care; public health emergency preparedness and response; food, drug, and medical device safety; grants management; information technology systems and infrastructure; and ethics program oversight and enforcement.

I want to express my sincere appreciation to Congress as well as to the Department for their support over the past 6 months. I would like to thank in particular the many executives and officials within the Department, our authorizing and appropriating committees in Congress, our examiners within the Office of Management and Budget, and our audit and evaluation colleagues at the Government Accountability Office for helping to support and advance our important mission.

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



# External Activities

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

## **President's Council on Integrity and Efficiency**

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

## **Congressional Testimony**

OIG officials provided testimony to Congress on several occasions:

- On April 18, 2007, Deputy Inspector General for Evaluation and Inspections, Stuart Wright, testified before the House Committee on Energy and Commerce, Subcommittee on Health, regarding OIG's work related to Medicare integrity and efficiency. The testimony focused on such areas as appropriateness of Medicare payments and prices for items and services, access and quality-of-care issues for beneficiaries, and fraud and abuse vulnerabilities associated with durable medical equipment suppliers.
- On June 26, 2007, Regional Inspector General for Evaluation and Inspections, Robert A. Vito, testified before the House Committee on Ways and Means, Subcommittee on Health, regarding OIG's continuing work on the pricing of end stage renal disease (ESRD) drugs. The testimony featured findings from a June 2007 report (summarized in the Medicare section of this report), which determined that dialysis facilities could acquire the majority of ESRD drugs at prices 4 to 32 percent less than the Medicare reimbursement amount during the third quarter of 2006.
- On June 27, 2007, Chief Counsel to the Inspector General, Lewis Morris, submitted a Statement for the Record to the Senate Special Committee on Aging on OIG activities related to pharmaceutical fraud. The Statement addressed OIG's efforts to promote industry's voluntary compliance with program requirements, enforcement accomplishments in the area of pharmaceutical manufacturer fraud, and future OIG guidance to address the interactions between physicians and pharmaceutical and medical device manufacturers.
- On July 18, 2007, Assistant Inspector General for Legal Affairs, Gregory Demske, testified before the Senate Special Committee on Aging regarding OIG's work related to identifying and preventing the abuse of the elderly. The testimony described the spectrum of activities, enforcement actions, and

initiatives OIG has undertaken to identify cases of elder abuse, ensure that those who would harm the elderly are prosecuted to the fullest extent of the law and/or prevented from continuing to participate in Federal health care programs, identify where programs and systems involved in the oversight of quality of care may be strengthened, and promote practices that will help prevent elder abuse.

The full texts of testimony provided at these hearings can be found on the Internet at <http://oig.hhs.gov/testimony.html#1>.

### **Speeches**

On April 23, 2007, the IG served as the keynote speaker for the Health Care Compliance Association's Annual Compliance Institute. He discussed the evolution and future of OIG's compliance activities and also discussed OIG's recently published "Protecting Public Health and Human Services Programs: A 30-Year Retrospective." Principal Deputy Inspector General (PDIG), Larry Goldberg, also spoke at this conference focusing on OIG's review of State False Claims Acts and work related to Medicare supplier fraud and quality of care.

### **Events**

OIG officials participated in the following events:

- On April 23, 2007, the IG spoke to the newly established Chicago Chapter of the Association of Health Care Journalists at the Columbia College School of Journalism. The PDIG and OIG senior staff from the Chicago Regional Office also participated. The IG spoke about OIG's relationship with health care media and discussed OIG's history and accomplishments related to the recently published "Protecting Public Health and Human Services Programs: A 30-Year Retrospective."
- On May 30, 2007, OIG sponsored a Conflict of Interest and Ethics Violations Summit that brought together over 200 individuals from the oversight, ethics program and policy, and enforcement communities to discuss a variety of issues related to operation of Government ethics programs and violations of Federal conflict of interest statutes. U.S. Securities and Exchange Commissioner Annette L. Nazareth welcomed all participants to the program. The IG provided the keynote address, and speakers included senior officials from OIG; the Securities and Exchange Commission, Office of Government Ethics; U.S. Department of Justice; HHS; and the Chief Investigative Counsel, Senate Committee on Health, Education, Labor, and Pensions.

### **External Organizations**

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

# Highlights

## Summary of Accomplishments

For fiscal year (FY) 2007, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported savings and expected recoveries of over \$43 billion: \$39 billion in implemented recommendations and other actions to put funds to better use, \$1.9 billion in audit receivables, and \$2.18 billion\* in investigative receivables.

Also for this FY, OIG reported exclusions of 3,308 individuals and entities for fraud or abuse involving Federal health care programs and/or their beneficiaries; 447 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 262 civil actions, which include False Claims Act (FCA) and unjust enrichment suits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters.

### **Purdue Companies and Three Executives To Pay Nearly \$635 Million for Fraudulently Marketing OxyContin**

As part of a global criminal, civil, and administrative settlement agreement, the Purdue Frederick Company, Inc., and Purdue Pharma L.P. (collectively, the Purdue Companies), and three top executives agreed to pay almost \$635 million to resolve a variety of Federal, State, and private liabilities. Specifically, the agreement resolved allegations that the Purdue Companies waged a fraudulent and deceptive marketing campaign aimed at convincing doctors nationwide that OxyContin, because of its time-release formula, was less prone to abuse and that it was less likely to cause addiction or to produce other narcotic side effects than competing immediate release opioids. The Purdue Frederick Company, Inc. is subject to a 25-year exclusion; Purdue Pharma L.P. agreed to enter a 5-year corporate integrity agreement (CIA) with OIG. (Details on pp. 27-28.)

### **South Florida Medicare Fraud**

OIG has employed a multifaceted approach to fight Medicare fraud in South Florida. Along with our partners and the U.S. Attorney's Office for the Southern District of Florida, we developed innovative methods to identify and prosecute fraud in a timely manner, resulting in \$54.3 million in investigative receivables and a number of indictments. Additionally, we analyzed the claims patterns of HIV/AIDS infusion therapy providers and beneficiaries in three South Florida counties and determined that in the last half of 2006, these counties accounted for half of the total amount, and 79 percent of the amount for drugs, billed nationally for Medicare beneficiaries with HIV/AIDS. We also found that the approaches CMS and its contractors have used to control these aberrant billing practices have not proven effective. We recommended that CMS treat South Florida as a high-risk area, mandate site visits for certain providers, adjust contractor standards for processing new applications, modify the Statement of Work for

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

the jurisdiction that includes South Florida, review all reassignments in high-risk areas, and strengthen revocations. (Details on pp. 3 and 28-29.)

### **FDA's Oversight of Clinical Trials Through Its Inspection Processes**

We identified data limitations and other factors that affect the Food and Drug Administration's (FDA) ability to effectively manage the Bioresearch Monitoring (BiMo) program. For example, FDA is unable to identify all clinical trials and institutional review boards (IRB), and it lacks a single database for tracking its own inspections. Furthermore, the three FDA centers and the Office of Regulatory Affairs inconsistently classify some inspections. In addition, FDA's guidance and regulations do not reflect current clinical trials practices. Finally, we estimate that FDA inspected about 1 percent of clinical trials for the fiscal year 2000–2005 period. We recommended that FDA take the following steps to improve its information systems and processes: (1) develop a clinical trial database that includes all clinical trials, (2) create an IRB registry, (3) create a cross-center database that enables complete tracking of BiMo inspections, (4) establish a mechanism to provide feedback to BiMo investigators on their inspection reports and findings, and (5) seek legal authority to provide oversight that reflects current clinical trial practices. (Details on pp. 37-38.)

### **Eligibility for the State Children's Health Insurance Program**

We found that California, Florida, and New York made some State Children's Health Insurance Program (SCHIP) payments on behalf of beneficiaries who did not meet Federal and State eligibility requirements and did not adequately document all determinations of eligibility. Florida, for example, paid an estimated \$19 million to \$33 million in Federal funds for ineligible beneficiaries. We recommended that the States use our results to help ensure compliance with applicable requirements. Most importantly, beneficiaries should be reminded of the need to provide accurate and timely information, and employees should be required to verify and document eligibility determinations. (Details on pp. 21-22.)

### **Maximus, Inc., Entered Into a \$42.65 Million Settlement**

Maximus, Inc., a revenue maximization consulting business for State and local jurisdictions throughout the country, entered into a \$42.65 million settlement agreement with the Government to resolve its liability under the FCA. Maximus allegedly filed false claims for Medicaid-funded targeted case management services, which assist foster children with their medical, social, and educational needs. As part of the global settlement agreement, Maximus entered into a 5-year CIA and into a 24-month deferred prosecution agreement. In a novel provision, the CIA requires that OIG's Office of Audit Services perform the claims and contract reviews that are ordinarily performed by an Independent Review Organization. (Details on p. 28.)

### **Certification and Oversight of Medicare Hospices**

We found that, as of July 2005, 86 percent of Medicare hospices were certified by State agencies within 6 years, as required at that time, and 14 percent averaged 3 years past due. In addition, health deficiencies were cited for 46 percent of the hospices surveyed and for 26 percent of hospices investigated for complaints and many deficiencies related to patient care. CMS and State agencies rarely use methods other than certification

surveys and complaint investigations to monitor or enforce hospice performance. We recommended that CMS (1) provide guidance to State agencies and CMS regional offices regarding analysis of existing data and identification of at-risk hospices; (2) include hospices in Federal comparative surveys and annual State performance reviews; (3) seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification; and (4) seek legislation to establish enforcement remedies, in addition to termination, for poor hospice performance. (Details on p. 7.)

### **Outpatient Outlier Payment Adjustments**

We determined that CMS's practice of not retroactively adjusting erroneous outpatient outlier payments creates vulnerabilities in the outpatient outlier program and is inconsistent with CMS's general policy on revisiting incorrectly calculated payments, as well as CMS's policy of retroactively adjusting inpatient prospective payment system outlier payments. Medicare makes outlier payments to health care providers for extremely costly cases. Prior OIG reviews found that some providers received significant outpatient outlier overpayments as a result of fiscal intermediaries' and providers' errors and providers' manipulation of charge data. CMS did not adjust these overpayments, resulting in substantial losses to the Medicare trust fund and payment inequities among providers. We recommended that CMS issue regulations to require retroactive adjustments of outpatient outlier payments within appropriately established thresholds. (Details on p. 7-8.)

### **Advanced Neuromodulation Systems, Inc., Entered into a \$2.95 Million Settlement**

To resolve its liability under the CMPL, Advanced Neuromodulation Systems, Inc. (ANS), a medical device manufacturer, paid \$2.95 million and entered into a 3-year CIA to settle allegations that it engaged in a marketing program in which physicians were paid kickbacks for patient referrals. Specifically, ANS allegedly paid illegal remunerations for the purchase or lease of its medical devices and for patient trials using ANS's spinal cord simulator. (Details on p. 25.)

### **Use of Health Information Technology in State Medicaid Programs**

We found that 12 State Medicaid agencies have implemented 16 health information technology (HIT) initiatives for Medicaid beneficiaries and participating providers, including claims-based electronic health records initiatives, electronic prescribing initiatives, remote disease-monitoring initiatives, and personal health records initiatives. We also found that 25 State Medicaid agencies are currently involved in planning and developing statewide health information exchange (HIE) networks. Lastly, we found that 13 State Medicaid agencies are incorporating the Medicaid Information Technology Architecture (MITA) into their HIT and HIE planning. We recommended that CMS continue to support the goals of MITA, collaborate with other Federal agencies and offices to assist State Medicaid agencies with developing privacy and security policies, and continue to work with the Office of the National Coordinator for HIT to ensure that State Medicaid initiatives are consistent with national goals. (Details on p. 15.)

### **Unobligated Funds Provided for HIV/AIDS Services**

We found that the Health Resources and Services Administration (HRSA) did not fully comply with applicable requirements or use its offset authority in managing unobligated

funds provided to the States for HIV/AIDS services under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Unobligated funds in 10 States totaled more than \$60 million in grant year 2002. Had HRSA used its offset authority, it could have carried over unobligated balances from the prior year and offset the amount of current-year funds needed for grant awards. This action would have made more current-year funds available to address certain States' unmet program needs. We recommended that HRSA monitor the States' compliance with CARE Act requirements, comply with carryover policy, examine the reasons for some States' large unobligated balances, and analyze each State's unobligated balance in light of its offset authority. (Details on p. 37.)

# Hurricane-Related Activities

In response to the Gulf Coast hurricanes of 2005, OIG launched a coordinated oversight effort to ensure that the Department's response and recovery funds are spent appropriately, that those attempting to defraud the Government are brought to justice, and that the individuals responsible for the relief efforts are wise stewards in assisting those affected by the hurricanes and their aftermath.

We continue to work with Federal, State, and local partners in this effort, including participating as a member of the President's Council on Integrity and Efficiency's (PCIE) Homeland Security Roundtable and the Disaster Relief Working Group, which are coordinating the oversight activities of the Federal Inspectors General (IG). We took the lead in developing information related to State and local liaisons as part of a comprehensive Hurricane Action Plan developed by the Homeland Security Roundtable. In addition, along with other members of the IG community, we are a member of the Department of Justice Fraud Task Force in Baton Rouge. That task force is investigating allegations of fraud related to Federal outlays in connection with Hurricane Katrina.

We have initiated extensive audit, evaluation, and investigative activities related to the oversight of HHS's hurricane recovery efforts. A list of recently completed and ongoing projects follows:

## **Department Accounting for Federal Emergency Management Agency Assignments**

As of September 30, 2007, the remaining spending authority for HHS missions assigned by the Federal Emergency Management Agency totaled almost \$43.7 million. This spending authority is contained within 23 individual open mission assignments with different magnitudes and objectives. OIG's audits are designed to determine whether HHS is appropriately accounting for these costs.

## **Auditing Hurricane-Related Procurements**

We are auditing all HHS hurricane-related contractual procurements over \$100,000. These audits focus specifically on the methods of procurement. As of August 31, 2007, we issued 51 audit reports with an audited value of \$79.5 million. Of the 51 reports, 48 concluded that the awarding agencies had complied with procurement requirements. The remaining three reports had administrative findings.

We also audited costs billed to the largest contract awarded by HHS to assist hurricane victims. This contract provided \$21 million to transport returning evacuees requiring en route medical care.

## **Emergency Response to Hurricane Katrina: Use of the Government Purchase Card**

OIG recently issued a final report analyzing purchase card transactions by HHS personnel deployed in response to Hurricane Katrina. The purchase card program was designed to save the Government money by avoiding costly paperwork and expediting the process of making purchases. Our review of HHS's Hurricane Katrina purchase card transactions found that 15 percent did not meet selected purchasing requirements. We recommended

that the Assistant Secretary for Administration and Management (ASAM) provide additional written guidance on emergency purchasing procedures, require training on such procedures, and develop a tracking system for monitoring Government purchase card transactions during emergency situations. ASAM agreed with the recommendations and stated that it had established a course of action to strengthen the purchase card program, including additional written guidance for training in emergency purchasing procedures and a tracking system for monitoring purchases during emergency situations.

#### **Medicaid Payments and Services Under Hurricane-Related Demonstration Projects**

OIG recently issued two reports analyzing Medicaid payment and services provided to hurricane evacuees under HHS demonstration projects. Because of Hurricanes Katrina and Rita, beneficiaries of HHS programs who resided in the Gulf Coast States were evacuated to various places around the United States or otherwise significantly affected. In response and in an effort to ensure that victims of Katrina and Rita received needed health care, HHS used Section 1115 waiver and expenditure authority to expand Medicaid coverage criteria. We found that for eight selected States, Medicaid paid \$716 million for medical services and prescription drugs under the hurricane-related demonstration projects. Nearly two-thirds, \$448 million, was paid for medical services; the remainder, \$268 million, was paid for prescription drugs. In addition, a greater percentage of evacuees received medical services and prescription drugs than nonevacuees, but average total payment per evacuee was less.

#### **Investigations of Health Care Fraud, Quality-of-Care Lapses, and Other Issues**

As of the end of this reporting period, OIG had five open investigations involving allegations of health care fraud, poor quality of care, and patient abandonment and is assisting in investigations of circumstances surrounding the deaths of nursing home residents and hospital patients. OIG is also involved in two other cases that include allegations of individuals fraudulently obtaining benefits based on false information.

# Table of Contents

<b>External Activities</b> .....	<b>iii</b>
<b>Highlights</b> .....	<b>v</b>
<b>Hurricane-Related Activities</b> .....	<b>ix</b>
<b>The Centers for Medicare &amp; Medicaid Services</b> .....	<b>1</b>
<b>Reports Related to CMS’s Programs</b> .....	<b>3</b>
<b>Medicare-Related Reports</b> .....	<b>3</b>
Aberrant Billing in South Florida for Beneficiaries With HIV/AIDS.....	3
Medical Equipment and Supplies for Beneficiaries in Skilled Nursing Facilities .....	3
Quality Concerns Identified Through Quality Improvement Organization Medical Record Reviews.....	4
Fiscal Integrity of Quality Improvement Organizations .....	4
Consecutive Medicare Stays Involving Inpatient and Skilled Nursing Facilities .....	5
Inpatient Rehabilitation Facility Admissions .....	5
Transition Stays at Inpatient Psychiatric Facilities.....	6
Certification and Oversight of Medicare Hospices .....	7
Impact of Not Retroactively Adjusting Outpatient Outlier Payments .....	7
Intravenous Immune Globulin: Medicare Payment and Availability .....	8
Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007 .....	8
Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006.....	9
Costs To Administer and Purchase Cancer Drugs .....	9
Medicare Payments for 2003 Part B Mental Health Services: Medical Necessity, Documentation, and Coding .....	10
Medicare Payments for Surgical Debridement Services.....	10
Medicare Payments for Negative Pressure Wound Therapy Pumps.....	11
Provider Enrollment, Chain and Ownership System: Early Implementation Challenges.....	11
Retail Pharmacy Participation in Medicare Part D Prescription Drug Plans in 2006 .....	12
Medicare’s Program Safeguard Contractors: Activities To Detect and Deter Fraud and Abuse .....	12
<b>Medicaid-Related Reports</b> .....	<b>13</b>
States’ Use of New Drug Pricing Data in the Medicaid Program .....	13
Examining Fluctuations in Average Manufacturer Prices .....	13
Medicaid Outpatient Drug Expenditures in Iowa.....	14
Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Payment Limits .....	14

Use of Health Information Technology in State Medicaid Programs .....	15
Medicaid Disproportionate Share Hospital Payments .....	15
Medicaid Payments and Services Related to Hurricanes Katrina and Rita .....	16
Medicaid Community Mental Health Center Provider Services in Indiana .....	17
Medicaid Reimbursement Rate for School-Based Health Services in Maryland .....	17
Medicaid Reimbursement for Graduate Medical Education in Missouri .....	18
State Claims for the Costs of Family Planning Services Provided Through Medicaid Managed Care Programs .....	18
Medicaid Pharmacy Claims Billed as Family Planning .....	19
Abortion-Related Laboratory Claims Billed as Family Planning .....	19
Missouri’s Provider Tax .....	20
<b>State Children’s Health Insurance Program-Related Reports .....</b>	<b>20</b>
Fraud and Abuse Safeguards in Separate State Children’s Health Insurance Programs .....	20
State Children’s Health Insurance Program Eligibility .....	21
<b>Outreach .....</b>	<b>22</b>
Advisory Opinions .....	22
Provider Self-Disclosure Protocol .....	22
<b>Federal and State Partnership: Joint Audits of Medicaid .....</b>	<b>23</b>
<b>Office of Inspector General Administrative Sanctions .....</b>	<b>23</b>
Program Exclusions .....	24
Civil Monetary Penalties Law .....	25
Patient Dumping .....	26
<b>Criminal and Civil Enforcement .....</b>	<b>27</b>
Pharmaceutical Companies .....	27
Billing Consultant .....	28
Durable Medical Equipment Suppliers .....	28
Hospitals .....	29
Home Health .....	29
Clinics .....	30
Practitioners .....	30
Group Homes .....	31
<b>Medicaid Fraud Control Units .....</b>	<b>31</b>
Investigations .....	32
OIG Reviews of MFCUs .....	32

<b>Public Health and Human Service Programs and Departmentwide Issues .....</b>	<b>35</b>
<b>Reports Related to Public Health Programs .....</b>	<b>37</b>
Unobligated Funds Provided by the Ryan White Comprehensive AIDS Resources Emergency Act .....	37
FDA’s Oversight of Clinical Trials Through Its Inspection Processes.....	37
Unobligated Balances of Funds Awarded Under the Bioterrorism Hospital Preparedness Program .....	38
Graduate Student Compensation Costs Charged to National Institutes of Health Research Grants.....	39
Safeguards Over Controlled Substances at Indian Health Service Facilities .....	39
Indian Health Service’s Resolution of Audit Recommendations .....	40
Security of Stockpile Sites .....	40
<b>Actions and Investigations Related to Public Health Programs.....</b>	<b>40</b>
Health Education Assistance Loan Defaults.....	40
Public Health-Related Investigations.....	41
<b>Reports Related to Human Service Programs .....</b>	<b>42</b>
Enrollment Levels in Head Start.....	42
Aid to Families With Dependent Children Overpayment Recoveries.....	43
Costs Claimed for the Statewide Automated Child Welfare Information System in California .....	43
Undistributable Child Support Collections in Indiana .....	44
<b>Child Support Enforcement.....</b>	<b>44</b>
Task Forces.....	44
Child Support Investigations.....	45
Misuse of ACF Grant Funds .....	46
<b>Reports Related to Departmentwide Issues.....</b>	<b>46</b>
Departmental Processes for Awarding Hurricane Contracts .....	46
Hurricane-Related Costs Billed to a Contract .....	46
Emergency Response to Hurricane Katrina: Use of the Government Purchase Card .....	47
Non-Federal Audits .....	47
<b>Resolving Recommendations .....</b>	<b>48</b>
Table 1: Reports With Questioned Costs.....	49
Table 2: Funds Recommended To Be Put to Better Use .....	50
<b>Legislative and Regulatory Review and Development .....</b>	<b>51</b>
Regulatory Review Functions.....	51
Regulatory Development .....	51
<b>Employee Fraud and Misconduct.....</b>	<b>51</b>

<b>Appendixes .....</b>	<b>53</b>
<b>Appendix A: Savings Achieved Through Implementation of Recommendations in Audits and Evaluations for Fiscal Year 2007 .....</b>	<b>55</b>
<b>Appendix B: Notes to Tables 1 and 2 .....</b>	<b>63</b>
Notes to Table 1.....	63
Notes to Table 2.....	67
<b>Appendix C: Reporting Requirements of the Inspector General Act of 1978, as Amended .....</b>	<b>69</b>
<b>Appendix D: Status of Public Proposals for New and Modified Safe Harbors to the Anti-Kickback Statute .....</b>	<b>71</b>
<b>Appendix E: Summary of Sanction Authorities.....</b>	<b>75</b>
Program Exclusions.....	75
Patient Dumping.....	75
Civil Monetary Penalties Law.....	76
Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities .....	76
<b>Appendix F: Acronyms and Abbreviations.....</b>	<b>79</b>

Please note: Numerical information in this report is rounded.

# The 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 old or older, people younger than 65 years old with certain disabilities, and people of any age with end stage renal disease (ESRD). In fiscal year (FY) 2006, Medicare served 43 million beneficiaries at a cost of \$337 billion. Medicare has four parts: Hospital Insurance (Part A), which helps cover inpatient care in hospitals, including critical access hospitals, skilled nursing facilities (SNF), and hospice and certain home health care; Supplementary Medical Insurance (Part B), which helps pay for physician services and outpatient care; Medicare Advantage (MA), which offers a range of prepaid managed health care choices; and the Medicare Prescription Drug Benefit (Part D), which provides an optional prescription drug benefit to individuals enrolled in Medicare, generally through private prescription drug plans.
- Medicaid, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. In FY 2006, the enrollment for Medicaid was estimated at 47 million people; total Federal and State outlays were \$317 billion, of which the Federal share was \$180 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 2006, SCHIP served 6.9 million beneficiaries at a Federal cost of \$5.5 billion.

OIG's focus on these health care programs reflects the spending of the Department of Health and Human Services (HHS): CMS expenditures have accounted for about 80 percent of the Department's budget over the last several years. This focus is also rooted in legislative mandates and funding sources, including the following:

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. 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, Pub. L. No. 109-171) provides OIG annual funding of \$25 million from FY 2006 through FY 2010 to undertake fraud and abuse control activities related to the Medicaid program.

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

# Reports Related to CMS's Programs

## Medicare-Related Reports

### **Aberrant Billing in South Florida for Beneficiaries With HIV/AIDS**

We found that CMS has had limited success controlling the aberrant billing practices of infusion therapy providers in South Florida. Our analysis focused on the claims patterns of HIV/AIDS infusion therapy providers and beneficiaries in three South Florida counties. In the last half of 2006, these three counties accounted for half of the total amount—and 79 percent of the amount for drugs—billed nationally for Medicare beneficiaries with HIV/AIDS. Examples of improper billing by these providers in these counties in recent years included billing for allowable diagnosis codes rather than the diagnosis found in the medical records and billing for services that were never provided. CMS and its contractors tried to control inappropriate payments to these providers in these three South Florida counties using various tools, including payment suspensions, prepayment reviews, provider number revocations, claims processing edits, and onsite investigations of existing providers. We determined that these efforts have not been effective because aberrant HIV infusion providers have adjusted their billing patterns and circumvented controls.

We recommended that CMS treat South Florida as a high-risk area; mandate announced and unannounced site visits for certain infusion therapy providers; give contractors more time to review new provider applications; modify the statement of work for the jurisdiction that includes South Florida to require enhanced efforts to fight fraud and abuse (such as claims-editing activities); require extensive review of all reassignments in high-risk areas to confirm they are legitimate; and strengthen revocations to prevent further fraud and abuse (such as shortening the notice given to providers before revocations are enforced). CMS generally concurred with our recommendations. In its comments on our draft report, CMS noted that it had incorporated our recommendations regarding provider enrollment into a demonstration project, announced on August 20, 2007, that targets South Florida infusion fraud. CMS is in the process of investigating additional enrollment safeguards to help reduce the fraudulent activity within Medicare. (OEI-09-07-00030)

### **Medical Equipment and Supplies for Beneficiaries in Skilled Nursing Facilities**

Our review found that Medicare Part B overpaid suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) on behalf of beneficiaries in skilled nursing facilities (SNF) stays. Because the cost of furnishing DMEPOS during SNF stays is generally included in the SNF's Medicare Part A payments, Part B payments to suppliers for such items are overpayments.

Medicare Part B's durable medical equipment regional carriers (DMERC) made \$100.8 million in potential overpayments to DMEPOS suppliers in calendar years (CY) 1999–2002 on behalf of beneficiaries in Part A-covered SNF stays. These

overpayments occurred because CMS did not have Common Working File edits in place to prevent such overpayments; as a result, DMERCs were unable to initiate recovery actions. For CY 2003, after edits were in place in the Common Working File, our computer match identified potential DMEPOS overpayments valued at \$15.4 million. Our statistical sample showed that DMERCs had not recovered approximately 69 percent of these overpayments. Two of the four DMERCs had not implemented procedures to process and recover the backlog of overpayments created by the new Common Working File edits; we projected that, as a result, the DMERCs did not recover \$11.2 million of the \$15.4 million in potential CY 2003 overpayments.

We recommended that CMS direct the DMERCs to review the \$100.8 million in potential overpayments for CYs 1999–2002 and make appropriate recoveries and to initiate recovery of the estimated \$11.2 million in CY 2003 overpayments and ensure that all DMERCs have established proper controls to recover overpayments that the Common Working File edits identify. CMS agreed with our recommendations. (A-01-05-00511)

### **Quality Concerns Identified Through Quality Improvement Organization Medical Record Reviews**

Our review of Quality Improvement Organizations (QIO), which are under contract with CMS to oversee and enhance the quality of care provided to Medicare beneficiaries, raised questions about the effectiveness of medical records reviews. QIOs have a statutory and contractual obligation to conduct such reviews to ensure that the care provided to Medicare beneficiaries meets professional standards. We found that, of the 318,018 cases QIOs selected for review between February 2003 and January 2006, QIOs completed full quality-of-care reviews on 34,768 of these cases and confirmed one or more quality concerns in 6,439 (19 percent) of those with full quality-of-care reviews. QIOs assigned the two lowest classifications to more than 80 percent of the cases with confirmed quality concerns. QIOs imposed no corrective actions in 1,794 cases (28 percent) with confirmed quality concerns and, in 70 percent of the cases with corrective actions, recommended the least severe corrective action available.

These findings raise questions for CMS to consider in its administration of the QIO program, including whether CMS should revisit its guidance regarding classifications of confirmed quality concerns and corrective actions. CMS indicated that it was reviewing the QIO case review process for reviewing and classifying quality-of-care concerns and had implemented a revised array of quality improvement activities for QIOs to recommend to providers. (OEI-01-06-00170)

### **Fiscal Integrity of Quality Improvement Organizations**

At the request of the Senate Finance Committee, we assessed the fiscal integrity of QIOs in nine States with respect to the following specified areas: board member and executive staff compensation and travel, legal fees, administrative and equipment charges, business relationships and conflicts of interest, and contract modifications. During the reporting period, we issued the first two reports of this series.

■ **Missouri** – The QIO in Missouri provided adequate documentation to support costs claimed in the specified fiscal integrity areas. Between February 2003 and January 2006,

the QIO received \$18.2 million in Federal reimbursement and incurred total costs of approximately \$23 million to support all lines of business, including the QIO contract. We reviewed a sample of approximately \$4.5 million of the \$23 million of costs incurred in the areas of interest to the Committee. We did not make any recommendations. (A-07-06-01036)

■ **Rhode Island** – The QIO in Rhode Island provided adequate documentation to support costs claimed in the fiscal integrity areas. Between November 2002 and October 2005, the QIO received \$11.2 million in Federal reimbursement and incurred total costs of approximately \$14.6 million to support all lines of business, including the QIO contract. We reviewed a sample of approximately \$3.7 million of the \$14.6 million of costs incurred in the areas of interest to the Committee. We did not make any recommendations. (A-01-06-00507)

### **Consecutive Medicare Stays Involving Inpatient and Skilled Nursing Facilities**

Our review of consecutive Medicare stays involving inpatient facilities and SNFs in CY 2004 found that 35 percent of consecutive stay sequences, for which Medicare paid an estimated \$4.5 billion, were associated with quality-of-care problems (that is, medical errors and accidents) and/or fragmentation of services. For the purposes of this review, we defined “consecutive stay sequence” as a sequence of three or more individual inpatient and SNF stays for the same Medicare beneficiary for whom the admission date for each successive stay occurred within 1 day of the discharge date for the preceding stay. In addition, we found that 11 percent of individual stays within these sequences, for which Medicare paid an estimated \$1.4 billion, were associated with problems involving quality of care, admissions, treatments, or discharges that contributed to the need for multiple stays and that 20 percent of individual stays, for which Medicare paid an estimated \$3.1 billion, lacked documentation sufficient for reviewers to determine whether appropriate care was rendered.

We recommended that CMS take the following actions: (1) direct QIOs to monitor for fragmentation and quality of care across consecutive stay sequences and the quality of care provided during the individual stays within those sequences; (2) encourage both QIOs and fiscal intermediaries to monitor the medical necessity and appropriateness of services provided within these consecutive stay sequences; (3) collaborate with providers to improve systems of care based on review results; and (4) reinforce efforts to educate medical providers on their responsibility for ensuring that medical records provide such information as may be necessary to determine the quality, medical necessity, and medical appropriateness of care. CMS concurred with our recommendations. (OEI-07-05-00340)

### **Inpatient Rehabilitation Facility Admissions**

We found that two hospitals submitted numerous inpatient rehabilitation facility (IRF) claims in CY 2003 that did not meet Medicare requirements. An IRF provides specialized care for patients recovering from conditions requiring intensive inpatient rehabilitation therapy.

- Of 100 claims sampled at a hospital in Massachusetts, 47 were determined by medical reviewers to be unallowable. The unallowable claims involved

beneficiaries who were capable of significant practical improvement but could have received rehabilitation services in a less intensive setting, such as an SNF or an outpatient facility, and beneficiaries who were not capable of significant practical improvement as a result of therapy or were medically unable to participate in intensive treatment. As a result, we projected a total overpayment by Medicare to the hospital of approximately \$4.8 million.

- Of 100 claims sampled at a hospital in New Hampshire, 44 were determined by medical reviewers to be unallowable. The unallowable claims involved beneficiaries with conditions similar to those found in the Massachusetts hospital. As a result, we projected a total overpayment to the hospital of approximately \$1.7 million.

We recommended that both hospitals refund to the Medicare program the estimated overpayments; identify and refund any overpayments for subsequent years' IRF claims that did not meet Medicare requirements; and strengthen their preadmission screening procedures to provide reasonable assurance that beneficiaries admitted for IRF services require treatment at the IRF level of care, are capable of significant practical improvement, and are able to participate in intensive rehabilitation. The hospitals disagreed with our findings and recommendations. (A-01-04-00531, A-01-04-00530)

#### **Transition Stays at Inpatient Psychiatric Facilities**

We found that inpatient psychiatric facilities did not always properly submit claims for transition stays paid in CY 2005 by a Medicare fiscal intermediary. Under Medicare's inpatient psychiatric facilities prospective payment system (IPF PPS), these facilities must submit a single discharge bill for an entire inpatient stay. Under CMS instructions, if a beneficiary's stay begins before and ends on or after the date on which the facility becomes subject to the PPS (herein called a transition stay), the fiscal intermediary should base its payments to the facility on prospective payment rates and rules.

For 76 of the 100 claims sampled, inpatient psychiatric facilities incorrectly split the beneficiary's stay by submitting claims under two separate payment periods, rather than submitting 1 claim for the entire inpatient stay. These claims occurred because the facilities did not have adequate controls to ensure that claims submitted during their transition to the IPF PPS complied with Medicare requirements. Based on our sample results, we estimated that Medicare overpaid the facilities \$2.17 million for incorrectly billed claims for transition stays in 2005.

We recommended that the intermediary make the appropriate adjustments to the sampled claims that resulted in overpayments of \$341,000, review our information on the additional claims with potential overpayments estimated at \$1.83 million and recover any overpayments, and analyze postpayment data from claims submitted after our review to ensure that they were billed properly and paid correctly. The intermediary agreed with our recommendations. (A-01-07-00500)

### **Certification and Oversight of Medicare Hospices**

We found that, as of July 2005, 86 percent of Medicare hospices were certified by State agencies within 6 years, as required at that time, and 14 percent averaged 3 years past due. In addition, we found that 46 percent of the hospices surveyed were cited for at least one health deficiency, such as care planning for patients, and 15 percent received repeat citations for the same deficiency during previous surveys. CMS and State agencies rarely used methods other than certification surveys and complaint investigations to monitor and enforce hospice performance. Other available methods include Federal comparative surveys, annual State performance reviews, and analysis of hospice performance data. We also found that CMS rarely used its only enforcement remedy for noncompliant hospices, which is termination from the Medicare program; only one hospice was terminated as a result of severe problems during an initial survey.

To strengthen oversight of the Medicare hospice program to better protect both the program and its beneficiaries, we recommended that CMS provide guidance to State agencies and CMS regional offices regarding analysis of existing data and identification of at-risk hospices; include hospices in Federal comparative surveys and annual State performance reviews; seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification; and seek legislation to establish additional enforcement remedies, apart from termination, for poor hospice performance.

CMS agreed to provide increased guidance and include hospices in State performance reviews. However, because of resource constraints, it did not agree with greater inclusion of hospices in Federal comparative surveys and establishing frequency requirements for hospice certification. CMS indicated it will continue to consider the recommendation to seek legislation to establish additional enforcement remedies for poor hospice performance. (OEI-06-05-00260)

### **Impact of Not Retroactively Adjusting Outpatient Outlier Payments**

We determined that CMS's practice of not retroactively adjusting erroneous outpatient outlier payments creates vulnerabilities in the outpatient outlier program and is inconsistent with CMS's general policy on revisiting incorrectly calculated payments, as well as CMS's policy of retroactively adjusting inpatient PPS outlier payments. Under the outpatient PPS, CMS reimburses outpatient providers, including hospital outpatient departments and community mental health centers (CMHC), based on predetermined fixed payment amounts. CMS may make additional payments, called outlier payments, if the cost of care is extraordinarily high in relation to the average cost of treating comparable conditions or illnesses. CMS's fiscal intermediaries determine whether claims qualify for outlier payments after reviewing the cost and charge data in providers' annual cost reports. Although inpatient outlier claims are subject to retroactive adjustments, CMS considers outpatient outlier payments, estimated at \$2.73 billion for CYs 2001 through 2007, as final payments not subject to such adjustments.

Using the results of four earlier reviews of outpatient outlier payments to CMHCs, we calculated that the CMHCs received net overpayments totaling \$24.4 million. In response to our earlier recommendations to collect the overpayments, the fiscal

intermediaries stated that they were not authorized to do so. CMS's practice of not adjusting erroneous outpatient outlier payments contributes to substantial net losses to the Medicare trust fund and payment inequities among CMHCs. Although our work was specific to CMHCs, similar vulnerabilities may exist in the overall outpatient outlier program.

We recommended that CMS issue regulations to require adjustments of outpatient outlier payments at final cost report settlement, retroactive to the beginning of the cost report period, and retroactive adjustments of outpatient outlier payments when an error caused by the fiscal intermediary or provider is identified after the cost report is settled. CMS stated that it would explore the feasibility and cost effectiveness of implementing our recommendations. (A-07-06-04059)

### **Intravenous Immune Globulin: Medicare Payment and Availability**

For the third quarter of 2006, we found that there were improvements relative to previous quarters in the ability of hospitals and physicians to purchase intravenous immune globulin (IVIG) at prices below the Medicare payment amounts but that there were problems with the availability of IVIG. IVIG is a plasma-derived product administered to patients with poorly functioning immune systems. In terms of payments, OIG found that, during the third quarter of 2006, 56 percent of IVIG sales to hospitals and 59 percent to physicians by the three largest distributors occurred at prices below the Medicare payment amounts. This represented a dramatic shift from the previous quarters, when the percentage of sales at prices below Medicare payment rates for IVIG was as low as 23 percent for hospitals and 4 percent for physicians. In terms of availability, OIG found that most physicians and distributors reported problems with IVIG availability in 2005 and 2006 and that these availability problems were related to Medicare payment.

CMS stated that the report, which had no recommendations, provided initial information on the availability and pricing of IVIG and set the stage for further review of certain issues, such as off-label use, payment lags, and distributor markups. (OEI-03-05-00404)

### **Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007**

In our third review comparing ASPs to AMPs, we identified 39 of 326 Healthcare Common Procedure Coding System (HCPCS) codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2006. Pursuant to section 1847A(d)(3) of the Social Security Act (the Act), OIG must notify the Secretary of HHS if the ASP for a particular drug exceeds the drug's AMP by a threshold of 5 percent. If that threshold is met, the Act grants the Secretary authority to disregard the ASP pricing methodology for that drug and substitute the payment amount for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP.

Of the 39 codes, 4 have met the threshold for price adjustments in all three of OIG's studies comparing ASPs and AMPs. An additional eight HCPCS codes were also previously eligible for price adjustments as a result of OIG's second report, which used data from the fourth quarter of 2005. If reimbursement amounts for all 39 codes had

been based on 103 percent of the AMP during the first quarter of 2007, we estimate that Medicare expenditures would have been reduced by \$13 million.

We recommended that CMS adjust Medicare reimbursement amounts for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act. CMS may want to focus on those drugs that, according to the three OIG reports, have ASPs that consistently meet this threshold. In response, CMS expressed a desire to better understand fluctuating differences between ASPs and AMPs, with the intent to develop a process to adjust payment amounts based on the results of OIG's pricing comparisons. (OEI-03-07-00140)

### **Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006**

We found that, on average, independent and hospital-based dialysis facilities responding to this OIG study could acquire the majority of selected separately billable ESRD drugs for less than the Medicare reimbursement amounts in the third quarter of 2006. This review is the third in a series of OIG reviews examining separately billable ESRD drugs and Medicare reimbursement in dialysis facilities.

Effective January 1, 2006, CMS promulgated several significant changes to the drug reimbursement methods used for dialysis facilities, including paying all dialysis facilities 106 percent of the ASP for all separately billable ESRD drugs and biologicals (with the exception of vaccines, blood, and blood products).

We found that, among responding independent dialysis facilities, the average acquisition cost for 9 of the 11 drugs under review was between 7 and 32 percent less than the Medicare reimbursement amounts; for the remaining 2 drugs, average acquisition costs ranged from 3 to 9 percent above the Medicare reimbursement amount. We also found that overall drug acquisition costs among independent chain facilities were somewhat less than those of independent nonchain facilities. And, among responding hospital-based dialysis facilities, the average acquisition cost for 6 of the 11 drugs under review was between 4 and 29 percent less than the Medicare reimbursement amount; for the remaining 5 drugs, average acquisition costs ranged from 1 to 8 percent above the Medicare reimbursement amount.

We concluded that acquisition costs for the same drug may vary based on the type and chain affiliation of the facility, causing some dialysis facilities (especially hospital-based facilities) to potentially experience greater gaps in reimbursement than others. We suggested that CMS continue to monitor the situation closely to ensure that all facilities are reimbursed appropriately. CMS stated that our findings in this report, which did not have recommendations, provided useful information that will be helpful in the agency's monitoring efforts. (OEI-03-06-00590)

### **Costs To Administer and Purchase Cancer Drugs**

Nine of the twelve practices that we reviewed could generally purchase drugs related to 15 selected payment codes for the treatment of cancer patients at or below the MMA-established reimbursement rates from April through June 2005. Only three practices paid prices above the reimbursement rates for at least half of the

payment codes related to the drugs purchased. Also, 11 of the 12 physician practices that we reviewed did not have (nor were they required to have) procedures to track, by procedure code, the costs associated with administering drugs to cancer patients. Without such procedures, the practices could not determine whether Medicare reimbursement for each code was sufficient to cover the costs of providing drug administration services.

We recommended that CMS consider the results of our review in any future evaluations of Medicare Part B reimbursement of costs associated with the administration and purchase of drugs for the treatment of cancer patients. CMS agreed. (A-09-05-00066)

### **Medicare Payments for 2003 Part B Mental Health Services: Medical Necessity, Documentation, and Coding**

We determined that 47 percent of the Part B mental health services allowed by Medicare in 2003 did not meet program requirements, resulting in a projected \$718 million in improper payments. Miscoded and undocumented services accounted for 26 and 19 percent of all mental health services in 2003, respectively. Medically unnecessary services and services that violated the “incident to” rule each accounted for 4 percent of all mental health services. Some services had more than one error.

We recommended that CMS revise, expand, and reissue its 2003 Program Memorandum on Part B mental health services with an increased emphasis on proper documentation coding and the requirements for services billed “incident to.” CMS agreed with the recommendation and stated it would consolidate existing guidance for providers of mental health services. (OEI-09-04-00220)

### **Medicare Payments for Surgical Debridement Services**

In our review of Medicare Part B payments for surgical debridement services in 2004, we found that 64 percent of these services did not meet Medicare requirements, resulting in improper payments of approximately \$64 million. Surgical debridement is the removal of dead or unhealthy tissue from a wound with the use of a sharp instrument. Medicare paid for 3 million surgical debridement services claims totaling \$188 million in 2004. We found that 39 percent of these surgical debridement services were billed with codes that did not accurately reflect the services provided, 29 percent had no or insufficient documentation to determine whether the services were medically necessary or were coded accurately, and 1 percent was not medically necessary. We also found that most carriers had local coverage determinations and edits in place but conducted limited medical review of the procedures.

We recommended that CMS strengthen program safeguards to prevent improper payments for surgical debridement services by developing more uniform policy guidance, instructing carriers to conduct additional medical reviews and education, and working with one particular carrier to ensure that its policy is consistent with current Medicare coding guidelines. CMS generally agreed with the recommendations. (OEI-02-05-00390)

### **Medicare Payments for Negative Pressure Wound Therapy Pumps**

Of the \$90 million that Medicare paid for negative pressure wound therapy pumps (pump) in 2004, we found that 24 percent of the claims for these pumps did not meet Medicare coverage criteria. This resulted in approximately \$21 million in improper payments and an additional \$6 million in improper payments for supplies associated with these claims. The pump, which Medicare covers under Part B as DME, is a portable or stationary device used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. Specifically, our review found that 15 percent of all pump claims in 2004 did not have sufficient documentation to determine whether the claims met Medicare coverage criteria, 6 percent of the claims were undocumented, and 3 percent were not medically necessary.

We recommended that CMS ensure that claims for the pump meet Medicare coverage criteria and are paid appropriately. We provided specific options to consider, such as conducting additional medical reviews, educating suppliers and wound care providers about the appropriate use of the pump, and establishing advance coverage determinations of pump claims from suppliers that have a high number of claims that have been denied or have a pattern of overutilization. CMS concurred with our recommendations for medical review and education activities but did not concur with the five additional options that we presented. (OEI-02-05-00370)

### **Provider Enrollment, Chain and Ownership System: Early Implementation Challenges**

We assessed the early implementation of CMS's Provider Enrollment, Chain and Ownership System (PECOS), which serves as the repository of enrollment records for Medicare providers, and found the following regarding delayed application processing:

- For Medicare Part A, 66 percent of the provider applications to the PECOS enrollment process that had been identified as late as of July 31, 2005, had not actually exceeded timeframes for enrollment processing established by CMS. This misclassification occurred because of contractors, which verify and enter the provider information into the PECOS, improperly retaining certain applications in a pending inventory or failing to correctly update the status in the PECOS.
- For Medicare Part B, the provider applications that were reported as exceeding timeframes as of July 31, 2005, were the result primarily of one contractor's backlog and providers' failure to respond to requests for information.
- More than half (25 of 41) of all contractors reported difficulty in accessing the PECOS and obtaining and recertifying user identification (ID) numbers.

We provided several suggestions to CMS to improve the provider application process. These included conducting updated training for Part A contractor staff to ensure consistent understanding of application-processing policy, addressing issues with system

access and user IDs that could lead to future delays in application processing, and determining the need for increased system capacity to ensure that periods of limited access to the PECOS will not reoccur as other planned initiatives are implemented. CMS indicated in its comments that the information in the report will assist in its ongoing management of the PECOS but CMS believed that the startup issues noted in our report have been resolved. (OEI-07-05-00100)

### **Retail Pharmacy Participation in Medicare Part D Prescription Drug Plans in 2006**

We found that, as of October 2006, 97 percent of the 58,768 retail pharmacies throughout the country participated in at least one Medicare prescription drug plan (PDP). We also found that retail pharmacies in metropolitan and nonmetropolitan counties participate at similarly high rates and that 70 percent of participating retail pharmacies offer beneficiaries the choice of all available PDPs in their region. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. No. 108-173) requires at least two plans offered by different sponsors to be available in every region. PDP sponsors contract with pharmacies to create pharmacy networks that provide Part D coverage to beneficiaries in their plans.

The high percentage of retail pharmacy participation suggests that beneficiaries' access to retail pharmacies that dispense Part D-covered drugs does not appear to be limited by any lack of willingness on the part of retail pharmacies to participate in PDPs. In response to the report, which had no recommendations, CMS stated that it was pleased with OIG's findings. (OEI-05-06-00320)

### **Medicare's Program Safeguard Contractors: Activities To Detect and Deter Fraud and Abuse**

We found that Program Safeguard Contractors (PSC) differed substantially in the number of new investigations and case referrals to law enforcement; some had minimal activity in these primary workload categories. Neither the size of a PSC's budget nor its oversight responsibility (dollar amount of Medicare paid claims) was strongly correlated with the number of new investigations or the number of new case referrals produced in 2005. We also found that most PSCs had minimal results from proactive data analysis. In addition, we found no consistency across PSCs regarding the level of detail about proactive data analysis included in the monthly status reports. We recommended that CMS review PSCs with especially low volumes of activity in investigations and case referrals for Medicare Parts A and B. In addition, we recommended that CMS should require PSCs to provide more detailed explanations of their investigations, case referrals to law enforcement, and proactive data analysis activities in their monthly reports.

CMS concurred in part with our first recommendation, stating that direct comparisons between PSC task orders are difficult to make. CMS concurred with our second recommendation and stated that it has revised the monthly reporting system to collect more information and to improve reporting consistency across PSCs. (OEI-03-06-00010)

## Medicaid-Related Reports

### States' Use of New Drug Pricing Data in the Medicaid Program

We found that as of September 2006, many States had not yet decided whether to use AMP data and/or retail sales price (RSP) data to calculate the amount their State Medicaid programs reimburse for prescription drugs. States' use of this data has the potential to reduce Medicaid prescription drug expenditures, which reached \$41 billion in 2005. Although the DRA requires CMS to provide AMP and RSP data to the States, the States are not required to use the data. In our early assessment, we found that States are anticipating CMS's final regulations to clearly explain how the AMP will be defined and calculated. States raised concerns about the AMP data files that they had received from CMS, indicating that the AMP units appeared to be inconsistent with typical unit definitions of drug products and requesting that the drug unit definitions be included in the data files. They also questioned whether the vendors that already provide drug-pricing information for claims processing could have access to AMP data.

To ensure that AMP and RSP data are accurate, reliable, and accessible, we recommended that CMS explicitly detail AMP's definition and calculation, including the definition of retail pharmacy class of trade when promulgating new AMP regulations; furnish States with interim guidance and/or information regarding AMP data; and explicitly detail the RSP's definition, calculation, and method of collection when distributing RSP data to States. CMS generally agreed with the recommendations and stated that it had taken several steps toward addressing them. (OEI-03-06-00490)

### Examining Fluctuations in Average Manufacturer Prices

In a review of fluctuations in the AMPs of pharmaceuticals, we found that AMPs did not fluctuate substantially from the second quarter of 2005 to the second quarter of 2006 and that roughly equal numbers of AMPs decreased as increased. Overall, 39 percent of the AMPs stayed the same between the quarters, and an additional 16 percent changed by less than 2 percent. However, AMPs for single-source drugs (that is, brand name products for which there are no generics) were more prone to increases between quarters.

The DRA requires CMS to make AMP data available to States as of July 1, 2006, for optional use in setting the reimbursement amounts paid to pharmacies that dispense prescription drugs to Medicaid beneficiaries. States' use of AMPs is expected to help reduce Medicaid prescription drug expenditures; prior to 2006, States lacked access to AMP data and have used reimbursement rates that have little relationship to market prices.

Industry representatives raised concerns that the AMP was too volatile to serve as a payment basis and may result in pharmacies having to absorb price increases in the period between AMP reporting and the establishment of reimbursement amounts. Although the increases tended to be relatively small, we would advise States to take into account the potential effects of AMP increases during the lag period when developing any AMP-based formulas.

CMS stated that the report, which had no recommendations, shows that AMPs can be used appropriately to set Medicaid payment to pharmacies. It noted, however, that our findings may not be comparable to actual experience once a new definition of the AMP is implemented. (OEI-03-06-00350)

### **Medicaid Outpatient Drug Expenditures in Iowa**

Of the \$466 million in Federal Medicaid funds that Iowa claimed for outpatient drug expenditures for FYs 2003 and 2004, \$154,000 represented expenditures for drugs that were not eligible for Medicaid coverage because the coverage terminated before the drugs were dispensed. An additional \$1 million represented expenditures for drugs that were not listed as covered. Contrary to CMS guidance, the State did not verify whether those drugs were eligible for Medicaid coverage; therefore, the expenditures may not be allowable for Medicaid reimbursement.

We recommended that Iowa (1) refund \$154,000 to the Federal Government, (2) work with CMS to resolve \$1 million in payments for drugs that were not listed as covered and that may not have been eligible for Medicaid coverage, and (3) strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. Iowa partly agreed with the recommendations. (A-07-06-04062)

### **Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Payment Limits**

In our preliminary assessment of the expected impact of certain provisions of the DRA on Medicaid upper payment limits, we found that Federal upper limit amounts are likely to decrease substantially as a result of the DRA. The Federal upper payment limits help ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs. Beginning January 1, 2007, pursuant to the DRA, Medicaid Federal upper limits are to be based on 250 percent of the lowest AMP rather than 150 percent of the lowest price published in the national compendia.

This preliminary assessment, which focused on the 521 drugs on the Federal upper limit list in the second quarter of 2006 and 25 selected drugs with the highest total Medicaid expenditures in 2005, found the following:

- For 23 of the 25 high-expenditure drugs reviewed, Federal upper limit amounts set under the previous calculation method were more than double the average pharmacy costs in the second quarter of 2006.
- Federal upper limit amounts would decrease for 492 of the 521 drugs under the new calculation set forth in the DRA.
- Of the 25 high-expenditure drugs reviewed, only 6 had estimated average pharmacy acquisition costs that would be below the new Federal upper limit amount.
- The AMP used to set a new Federal upper limit amount may be substantially lower than other AMPs associated with a drug.

- Among the 25 high-expenditure drugs reviewed, examining the volume-weighted AMPs helped identify instances in which pharmacy acquisition costs may exceed the new Federal upper limit amount.

We recommended that CMS take steps to identify when a new Federal upper limit amount may not be representative of a drug's acquisition cost to pharmacies and, in those situations, determine the proper course of action (working with Congress, if necessary). CMS disagreed with the findings concerning the effect of the DRA-related changes to the Federal upper limit calculation. (OEI-03-06-00400)

### **Use of Health Information Technology in State Medicaid Programs**

We found that 12 State Medicaid agencies have implemented a total of 16 health information technology (HIT) initiatives for Medicaid beneficiaries and participating providers, including claims-based electronic health records initiatives, electronic prescribing initiatives, remote disease-monitoring initiatives, and personal health records initiatives. We also found that 25 State Medicaid agencies are currently involved in planning and developing statewide health information exchange (HIE) networks. Lastly, we found that 13 State Medicaid agencies are incorporating the Medicaid Information Technology Architecture (MITA) into their HIT and HIE planning. MITA is a framework developed by CMS to help States modernize their Medicaid information systems.

In recent years, both the President and the Secretary of the Department of HHS have promoted the goal of developing interoperable HIT and HIE initiatives. We recommended that CMS continue to support the goals of MITA to help facilitate future State Medicaid HIT and HIE initiatives, assist State Medicaid agencies with developing privacy and security policies regarding the use of Medicaid health care information in HIT and HIE initiatives, and continue to work with the Office of the National Coordinator for HIT to ensure that State Medicaid initiatives are consistent with national goals. (OEI-02-06-00270)

### **Medicaid Disproportionate Share Hospital Payments**

In our review of disproportionate share hospital (DSH) payments to hospitals, we found that two States claimed a total of \$45.3 million in unallowable Federal payments. The Social Security Act requires that States make Medicaid DSH payments to hospitals that serve disproportionately large numbers of low-income patients. The Omnibus Budget Reconciliation Act of 1993 limits these payments to a hospital's uncompensated care costs, which are the annual costs incurred to provide services to Medicaid and uninsured patients less payments received for those patients. This limit is known as the hospital-specific DSH limit.

■ **New Hampshire** – Of the \$194.1 million that New Hampshire claimed in DSH payments for FY 2004, \$70.6 million (\$35.3 million Federal share) was unallowable. The State did not comply with the hospital-specific DSH limits for 24 of the 28 DSH hospitals because it did not properly determine the hospitals' allowable costs in accordance with the Medicare principles of cost reimbursement, as CMS guidance

requires. Specifically, the cost-to-charge ratios that the State used in determining allowable costs were inflated because they overstated costs by including unallowable costs and understated charges by using net, rather than gross, patient services revenue.

We recommended that the State (1) refund \$35.3 million to the Federal Government, (2) work with CMS to review DSH payments claimed after our audit period and refund any overpayments, and (3) establish policies and procedures to ensure that it complies with Federal requirements and the State plan in calculating future hospital-specific DSH limits. The State disagreed with our finding and recommendations. (A-01-05-00001)

■ **New Jersey** – Our review of DSH payments to two New Jersey hospitals identified unallowable payments. As a result of a State consultant’s erroneous calculation of the hospital-specific DSH limits, these hospitals received millions of dollars in additional DSH payments.

DSH payments to one hospital from July 1995 through June 2001 exceeded the hospital-specific limits by \$20 million (\$10 million Federal share). The consultant erroneously included nonreimbursable costs that were not DSH eligible in its calculations, and the State claimed some duplicate DSH expenditures. We were unable to determine the reasonableness of another \$9.9 million (\$4.9 million Federal share) because the consultant included in the hospital-specific DSH limits an undetermined amount of costs for patients with private insurance coverage. We recommended that the State (1) refund \$10 million to the Federal Government, (2) work with CMS to resolve \$4.9 million in set-aside costs, (3) adhere to Federal law and State plan requirements when submitting DSH claims subsequent to June 2001 for Federal reimbursement, and (4) review all work performed by consultants to ensure the veracity of future Medicaid claims to the Federal Government. The State partially agreed with the recommendations. (A-02-04-01024)

DSH payments to the other hospital exceeded the hospital-specific limits by \$2.2 million (\$1.1 million Federal share) from November 1996 through June 2001. In its calculations of the limits, the consultant improperly included \$2.2 million of costs applicable to patients with private insurance coverage. We recommended that the State (1) refund \$1.1 million to the Federal Government, (2) adhere to Federal law and State plan requirements when submitting DSH claims subsequent to June 2001 for Federal reimbursement, and (3) review all work performed by consultants to ensure the veracity of future Medicaid claims to the Federal Government. Again, the State partially agreed. (A-02-05-01007)

### **Medicaid Payments and Services Related to Hurricanes Katrina and Rita**

We found that for eight selected States, Medicaid paid \$716 million for medical services and prescription drugs under the hurricane-related demonstration projects initiated in response to Hurricanes Katrina and Rita. Nearly two-thirds—\$448 million—was paid for medical services; the remainder, \$268 million, was paid for prescription drugs. In addition, a greater percentage of evacuees received medical services and prescription drugs than nonevacuees. Overall and in each State, the average total payment per

evacuee was less than that per nonevacuee for medical services and prescription drugs. However, in a few specific categories, the average payment per evacuee exceeded that per nonevacuee by 50 percent or more. All States except Louisiana provided services to both evacuees and affected individuals; Louisiana did not enroll anyone into its Medicaid programs as evacuees.

We made no specific agency recommendations; however, we concluded that further investigation may be warranted for categories in which the average payment per evacuee exceeded that per nonevacuee by 50 percent or more. (OEI-05-07-00300, primary report, and OEI-05-06-00140, data compendium)

### **Medicaid Community Mental Health Center Provider Services in Indiana**

We estimated that Indiana overpaid CMHC providers at least \$33.4 million (\$21.3 million Federal share) in reimbursement for Medicaid Rehabilitation Option (MRO) services provided during FY 2003. Under the MRO services program, clinical mental health services are provided to individuals, families, or groups living in the community who need aid intermittently for emotional disturbances or mental illness. Of 200 randomly selected MRO services provided by CMHCs, 64 did not meet Federal and State reimbursement requirements.

We recommended that Indiana refund the Federal share of the overpayment and strengthen its internal controls over the monitoring of MRO services by furnishing written notification to CMHC providers that reminds them to prepare and retain complete documentation to fully support Federal and State claiming provisions. Indiana agreed with our second recommendation and partly agreed with our first recommendation. (A-05-05-00057)

### **Medicaid Reimbursement Rate for School-Based Health Services in Maryland**

We found that Maryland had not complied with reimbursement provisions specified in its CMS-approved State Medicaid plan for school-based health services; as a result, it received substantial overpayments between State FYs 2002 and 2004. Medicaid covers the costs of school-based health services, such as physical therapy, speech pathology/therapy services, and psychological counseling that are provided to children under the Individuals with Disabilities Education Act. Although the State's Medicaid plan required claims to be based on cost, the State instead used an unsupported reimbursement rate of \$82 per service. We determined that Maryland's use of the \$82 rate resulted in overpayments totaling \$65.5 million (\$32.8 million Federal share).

Because the State could not provide documentation to show that the \$82 rate was based on the cost of services, we used special education cost data for State FYs 2002 through 2004 and calculated the difference between the reimbursement claimed and the amount of allowable claims. Our newly calculated rates were significantly lower than the \$82 rate used by the State: \$42.40 in FY 2002 up to \$48.64 in FY 2004.

We recommended that the State refund \$32.8 million to the Federal Government for unallowable costs in FYs 2002 through 2004, determine the unallowable costs for

FY 2005 and make the appropriate refund, and continue to work with CMS to develop more accurate school-based health service rates and make revisions to the State plan. The State agreed with our finding that the \$82 rate was too high but did not agree on a refund amount. (A-03-05-00206)

### **Medicaid Reimbursement for Graduate Medical Education in Missouri**

We found that Missouri's claims for Medicaid reimbursement of graduate medical education (GME) payments to one private teaching hospital did not fully comply with Federal law or the approved State plan. According to the State, its share of these payments consisted of certified public expenditures. These expenditures represented city funds provided to the hospital for the care of indigent children.

Of the \$5.7 million (\$3.4 million Federal share) claimed for Medicaid reimbursement, \$2.2 million (\$1.4 million Federal share) was not allowable. Specifically, the State was not entitled to claim certified public expenditures because the city did not certify the funds before the State agency claimed Federal reimbursement and because the hospital did not certify the funds for all years audited. In addition, we were unable to determine what portion of the certified public expenditures related to the provision of GME.

We recommended that the State (1) refund to the Federal Government the \$1.4 million in GME overpayments to the hospital during State FYs 1999–2001, (2) follow Federal requirements and the State plan when claiming GME costs in the future, and (3) review claims for GME subsequent to our audit period and refund any portion that did not comply with Federal requirements and the State plan. The State partly agreed with the recommendations. (A-07-04-03058)

### **State Claims for the Costs of Family Planning Services Provided Through Medicaid Managed Care Programs**

In a review of seven States' claims for the cost of family planning services provided through Medicaid managed care programs, we found that six States had inflated the factors or rates used to claim reimbursement at the enhanced 90-percent rate or did not provide documentation to support their calculation as required. CMS defines family planning services as those services that prevent or delay pregnancy or otherwise control family size. States may claim enhanced 90-percent Federal funding for the cost of these services.

For the \$302.9 million in claims reviewed (Federal share), six of the seven States claimed unallowable costs totaling \$21.7 million. We attributed the unallowable claims to CMS's lack of specific guidance and controls to ensure that data used by the States conformed to their proposed methodologies.

We recommended that CMS issue specific guidance to States, consistent with current Medicaid regulations, to quantify a reasonable portion of the capitation payments attributable to family planning services, establish controls in its review process to ensure that the data States use to quantify family planning costs conform to the proposed methodologies for claiming the enhanced family planning rate, and specify retention requirements for base-year data. CMS supported the collection of funds improperly

claimed by four States in the review and agreed to issue guidance as specified in the first recommendation. CMS also confirmed that States should be required to maintain base-year data as long as they are using these data to support their claims.

(A-03-06-00200)

### **Medicaid Pharmacy Claims Billed as Family Planning**

We found that two States improperly received enhanced Federal Medicaid funds for prescription drug claims billed as family planning services.

■ **New Jersey** – New Jersey improperly received \$2.2 million in Federal Medicaid funds for prescription drug claims that did not qualify as family planning services. The overpayment occurred because the State had incorrectly designated 227 National Drug Codes (NDC) as related to family planning in its Medicaid Management Information System (MMIS). We recommended that the State (1) refund \$2.2 million to the Federal Government; (2) review all NDCs presently coded as family planning in the MMIS to verify that they are related to family planning; (3) periodically review all NDCs to ensure that they are appropriately coded in the MMIS; and (4) determine the amount of Federal Medicaid funds improperly reimbursed at the enhanced rate for non-family-planning NDCs, both prior and subsequent to our audit period, and refund that amount to the Federal Government. New Jersey concurred with our recommendations.

(A-02-05-01019)

■ **New York** – New York State improperly received \$6.1 million in Federal Medicaid funds for prescription drug claims that did not qualify as family planning services because the State had incorrectly designated 246 NDCs as related to family planning in its MMIS. We recommended that the State (1) refund \$6.1 million to the Federal Government; (2) review all NDCs presently coded as family planning in the MMIS to verify that they are related to family planning; (3) periodically review all NDCs to ensure that they are appropriately coded in the MMIS; and (4) determine the amount of Federal Medicaid funds improperly reimbursed at the enhanced rate for non-family-planning NDCs, both prior and subsequent to our audit period, and refund that amount to the Federal Government. The State generally concurred with our recommendations.

(A-02-05-01018)

### **Abortion-Related Laboratory Claims Billed as Family Planning**

We found that New York State improperly received Federal reimbursement for unallowable abortion-related services and was improperly reimbursed at the enhanced 90-percent rate for allowable abortion-related laboratory services that did not qualify as family planning services. Medicaid funds are available for abortion-related services only when the life of the mother would be endangered if the fetus were carried to term.

Of the 100 claims in our sample, 98 either did not qualify as family planning services and were not reimbursable at the enhanced 90-percent Federal matching rate or were abortion-related laboratory services that were not eligible for Medicaid reimbursement at all. As a result, we estimate that the State improperly received \$3.2 million in Federal Medicaid funds for CYs 2000 through 2003. However, we have set aside this amount for

consideration by CMS and the State because no medical review was performed on the 100 sampled claims.

We recommended that the State (1) work with CMS to resolve \$3.2 million in set-aside claims; (2) reemphasize that abortion-related services are not considered family planning and that Medicaid claims must be properly coded when an abortion-related service is provided; (3) strengthen system edits to identify abortion-related laboratory claims that are ineligible for Federal funding; and (4) determine the amount of Federal Medicaid funds improperly reimbursed at the 90-percent rate for ineligible abortion-related laboratory services, both prior and subsequent to our audit period, and work with CMS to determine the amount to be refunded to the Federal Government. The State concurred with our recommendations. (A-02-05-01009)

### **Missouri's Provider Tax**

We found that Missouri's provider tax for State FY 2004 did not comply with the requirements for a permissible provider tax outlined in Federal laws and regulations and the Medicaid Partnership Plan, which was negotiated between the State and CMS in 2002 to provide a stable funding mechanism for the State's Medicaid program. We found that the State received \$23 million in Federal matching funds as a result of using \$13 million in provider taxes not permitted under Federal regulations and the Medicaid Partnership Plan. However, because of certain limitations imposed by Federal regulations, we questioned only an estimated \$8 million. We also found that Missouri lacked policies and procedures to ensure that its provider tax program complied with Federal laws and regulations and the partnership plan; as a result, the State's provider tax may have been impermissible.

We recommended that (1) Missouri submit to CMS a separate waiver test for each class of service that would permit waiver of the uniform tax requirement for FY 2004, (2) refund more than \$8 million to the Federal Government, (3) submit to CMS a separate waiver test for each class of service for State FYs 2005 and 2006, (4) refund Federal reimbursement for the unallowable tax amounts paid by the hospitals not included in the audit and for unallowable Federal reimbursement for State FYs 2005 and 2006, (5) notify CMS of any State changes to the provider tax program, and (6) develop policies and procedures to ensure that the provider tax program complies with all Federal and negotiated requirements for provider taxes when completing the waiver tests. Missouri disagreed with our findings and recommendations. (A-07-06-01029)

## **State Children's Health Insurance Program-Related Reports**

### **Fraud and Abuse Safeguards in Separate State Children's Health Insurance Programs**

We found that State Children Health Insurance Programs (SCHIP) in six States had, as of September 2005, established methods and procedures to meet Federal requirements for protecting the programs against fraud and abuse. One State, however, had not met the Federal requirements for investigating suspected cases of fraud and referring cases to law enforcement. We also found that even though there were common State oversight

mechanisms addressing Federal requirements, these mechanisms did not always enable States to know the extent of fraud and abuse safeguarding activities on the part of the States' contractors, such as health plans.

To address the noncompliance by the one State identified in this report, we recommended that CMS direct the noncompliant State to institute procedures to meet Federal requirements for investigating cases of suspected SCHIP fraud and abuse and for referring cases to law enforcement. To make other improvements, we also recommended that CMS strengthen Federal and State oversight of separate SCHIPs' fraud and abuse safeguards. CMS agreed with our findings and recommendations. (OEI-06-04-00380)

### **State Children's Health Insurance Program Eligibility**

We found that all three States reviewed (1) made some SCHIP payments on behalf of beneficiaries who did not meet Federal and State eligibility requirements and (2) did not always adequately document eligibility determinations. In each State, we reviewed a statistical sample of payments from January 1 through June 30, 2005.

■ **California** – Based on a statistical sample, we projected that the State made payments totaling between \$2 million and \$14.2 million (Federal share) on behalf of ineligible beneficiaries. We also projected that case file documentation did not adequately support eligibility determinations for additional payments totaling \$5 million to \$21 million (Federal share).

We recommended that the State use the results of this review to help ensure compliance with Federal and State SCHIP eligibility requirements by (1) reemphasizing to beneficiaries the need to provide accurate and timely information and (2) requiring contractor and county employees to verify eligibility information and maintain appropriate documentation in all case files. The State agreed to do so. (A-09-06-00022)

■ **Florida** – Based on a statistical sample, we projected that the State made payments totaling between \$19 million and \$33 million (Federal share) on behalf of ineligible beneficiaries. We also projected that case file documentation did not adequately support eligibility determinations for additional payments totaling \$4.1 million to \$11.6 million (Federal share).

We recommended that the State use the results of this review to help ensure compliance with Federal and State SCHIP eligibility requirements by (1) reemphasizing to contractor employees the need to adequately verify eligibility information, (2) minimizing the time period between determination of Medicaid eligibility and disenrollment of the applicant from SCHIP, and (3) reemphasizing to contractor employees the need to maintain appropriate documentation in all case files. We also recommended that the State work with CMS to resolve the estimated improper payments identified in our review. In its comments, the State did not specifically address our recommendations. (A-04-06-00021)

■ **New York** – New York State operated both a separate children's health program (Child Health Plus B) and an expanded Medicaid program through March 2005. Beginning

April 2005 and for the remainder of the audit period, the State transitioned children in the expanded Medicaid program to the Child Health Plus B program.

Based on a statistical sample, we projected that the State made Child Health Plus B payments totaling between \$17.7 million and \$32.9 million (Federal share) and expanded Medicaid payments totaling between \$3.1 million and \$13.5 million (Federal share) on behalf of ineligible beneficiaries. We also projected that case file documentation did not adequately support eligibility determinations for payments totaling between \$9.5 million and \$20.2 million (Federal share).

We recommended that the State use the results of this review to help ensure compliance with Federal and State SCHIP eligibility requirements by (1) reemphasizing to beneficiaries the need to provide accurate and timely information and (2) requiring employees of managed care organizations to verify eligibility information and maintain appropriate documentation in all case files. We also recommended that the State work with CMS to resolve the estimated improper Child Health Plus B payments identified in our review. The State disagreed with our findings. (A-02-06-01003)

## **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, 2007, OIG received 27 advisory opinion requests and issued 7 advisory opinions. OIG advisory opinions are available on the Internet at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

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

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abuse practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The guidelines, entitled "Provider Self-Disclosure Protocol," give providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation may entail if fraud is uncovered. In doing so, the self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from doing business with Federal health care programs. The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that appear to constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in

overpayments). After making an initial disclosure, the provider or supplier is expected to undertake a thorough internal investigation of the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action.

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

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

During this reporting period, self-disclosure cases resulted in \$1.99 million in HHS receivables. For example:

■ **Massachusetts** – To settle a matter reported under OIG’s Provider Self-Disclosure Protocol, Tri-City Mental Health Center, Inc. (Tri-City), a community-based not-for-profit mental health provider, agreed to pay \$557,000 to resolve its liability under the False Claims Act (FCA). In addition, Tri-City entered into a 3-year certification of compliance agreement. Tri-City disclosed that as a result of improper actions taken by one of its employees, it billed Medicaid and the Massachusetts Department of Mental Health for services that were not supported by documentation or not provided at all. Tri-City terminated the employee who was allegedly responsible for the improper billings.

## **Federal and State Partnership: Joint Audits of Medicaid**

Another major OIG outreach initiative has been to work closely with State auditors in reviewing the Medicaid program. To this end, a partnership plan was developed to foster joint reviews and provide broader coverage of the Medicaid program. The partnership approach has helped ensure more effective use of scarce audit resources by both the Federal and the State audit sectors. To date, partnerships have been developed in 25 States.

Reports issued to date have resulted in identification of more than \$263 million in Federal and State savings and have led to joint recommendations for savings at the Federal and State levels, as well as improvements in internal controls and computer system operations.

## **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 participating in Federal health care programs and imposing civil monetary penalties 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 2,051 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 2,030 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:

■ **Georgia** – Martin Bradley, III, owner of a pharmaceutical wholesale distributor, was excluded for a minimum period of 70 years based on his conviction related to a racketeering scheme involving prescription drugs that were unlawfully obtained and diverted from 1996 to 2003. Bradley was sentenced to 20 years of incarceration and ordered to pay over \$27 million in restitution.

■ **Texas** – Doris Blake, owner of a billing company, was excluded for a minimum period of 50 years based on her conviction related to a Medicaid fraud scheme. Blake billed the Medicaid program from September 2001 to December 2003 for chemical dependency counseling services that were never rendered. She was sentenced to 50 years of incarceration and ordered to pay \$1 million in restitution.

■ **Florida** – Thomas Merrill, an osteopath, was excluded for a minimum period of 50 years based on his conviction for wire fraud, health care fraud resulting in death, health care fraud and unlawful dispensing of numerous controlled substances. From about January 2000 to about May 2004, Merrill submitted claims for medical services and procedures that were not provided or medically necessary. In addition, he wrote prescriptions for controlled substances outside the usual course of professional practice, resulting in patient deaths. He was sentenced to life in prison and ordered to pay approximately \$115,000 in restitution.

■ **Pennsylvania** – Joseph Davidson, a chiropractor, was excluded for a minimum period of 40 years based on his conviction related to submitting false claims to private insurers for services that were double-billed, upcoded, or not provided. In addition, Davidson and a codefendant agreed to stage phony automobile accidents to allow patients to falsely claim injuries and pursue fraudulent personal injury settlements. Davidson was sentenced to 63 months of incarceration and ordered to pay approximately \$7 million in restitution.

■ **Colorado** – Brian O’Connell was excluded for a minimum period of 20 years based on his conviction for the illegal practice of medicine, perjury, theft, assault (recklessly causing bodily harm), and criminally negligent homicide. O’Connell did not have a license to practice as a doctor of naturopathic medicine, yet he treated patients with illegal and unapproved substances and employed unapproved procedures for more than 30 months. His actions caused the death of a patient. O’Connell was sentenced to 8 years of incarceration.

### **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 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 over \$6 million in civil monetary penalties and assessments. The following are among the civil monetary penalties actions resolved during this reporting period:

■ **Texas** – Advanced Neuromodulation Systems, Inc. (ANS), a medical device manufacturer, paid \$2.95 million and entered into a 3-year CIA to resolve its liability under the CMPL to resolve allegations of paying kickbacks to physicians. OIG alleged that from January 1999 through January 2005, ANS offered and paid remuneration to potential and existing referral sources in exchange for referrals to ANS for the purchasing, leasing, ordering, arranging for or furnishing of medical devices manufactured by ANS that were payable by a Federal health care program. Specifically, ANS allegedly paid physicians \$5,000 for every five patients who were retriaged with ANS’s spinal cord stimulator as part of the Renew Retrial program. In addition, OIG alleged that ANS provided physicians with sports tickets, free trips, free dinners, grants, and other gifts. During the investigation, ANS was purchased by St. Jude Medical, Inc., a publicly traded company headquartered in St. Paul, Minnesota.

■ **Illinois** – To resolve its CMPL liability, Midwest Medical Laboratory, Inc. (Midwest) agreed to pay \$711,000 and to be excluded from participating in all Federal health care programs for 5 years. OIG alleged that Midwest submitted claims to Medicare Part B for services rendered to beneficiaries residing in SNFs. These services were already covered as part of the beneficiaries’ Medicare Part A stay. Medicare requires that outside suppliers providing services to beneficiaries in SNFs during stays covered by Medicare Part A bill only the SNFs, not Medicare. Midwest also allegedly billed the same services under both its Illinois and Florida provider numbers.

■ **Missouri** – Two nursing facilities entered into settlements with OIG to resolve their CMPL liability for allegedly employing an excluded nurse. Ashland Nursing and Rehab, LLC, doing business as Ashland Healthcare, agreed to pay \$88,000, and Fulton Manor, Inc., doing business as Fulton Manor Care Center, agreed to pay \$24,000. Both entities agreed to enter into 3-year Certification of Compliance Agreement under which they will certify that screening and training policies are in place to preclude the hiring of ineligible persons. The nurse was excluded in December 2004 after a conviction relating to improper treatment of disabled children in her care.

■ **New York** – Candita Catucci, M.D., and Juan Carlos Acosta agreed to pay \$75,000 and enter into a 5-year Integrity Agreement to resolve their liability under the CMPL for allegedly violating the anti-kickback statute. Catucci has a small internal medicine practice and Acosta, her husband, acts as her office manager. An investigation found that from February 28, 2005, to November 25, 2005, the two solicited and received remuneration in exchange for referring Medicare patients to a diagnostic imaging facility. They allegedly received \$100 for each MRI referral and \$50 for each CT referral.

### **Patient Dumping**

Of the civil monetary penalties cases OIG collected between April 1 and September 30, 2007, some were pursued under the Emergency Medical Treatment and Labor Act (EMTALA), a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of settlements involving alleged violations of that statute:

■ **Arizona** – Tempe St. Luke’s Hospital paid \$70,000 to resolve several allegations that it failed to meet its obligations under the EMTALA, including the failure to provide the services of an on-call specialist to two patients in need of such services. One patient presented with acute onset of leg pain and extensive leg arterial occlusions and another was pregnant, complaining of vaginal bleeding, cramps, and decreased fetal movement.

■ **Indiana** – St. Mary’s Medical Center paid \$40,000 to resolve allegations that it engaged in patient dumping. A 46-year-old uninsured man came to the hospital’s emergency department by ambulance and in an unresponsive state. The on-call neurosurgeon was at the hospital but did not treat the patient. Instead, he directed the emergency department physician to transfer the patient over 180 miles away. The transfer was performed without stabilizing treatment, and the patient arrived at the second hospital “brain dead.”

■ **Wisconsin** – St. Joseph Regional Medical Center paid \$40,000 to resolve an allegation that it failed to provide an adequate screening or stabilization to a patient who presented to the emergency department following a motor vehicle accident. She had loss of memory and severe abdominal, hip, and thigh pain. She was discharged with little evaluation and presented later that day to another hospital, where it was determined that she had a badly broken hip. She underwent a 4-hour surgery and was hospitalized for 8 days.

■ **Texas** – Medical Center of Arlington paid \$30,000 to resolve allegations that it failed to adequately screen and stabilize a pregnant patient who presented to the hospital’s emergency department in labor. Instead, she was inappropriately transferred to another hospital 21 miles away.

■ **Kansas** – Western Plains Medical, paid \$25,000 to resolve allegations that it failed to provide an appropriate medical screening examination, stabilizing treatment, or an appropriate transfer of a teenager who came to its emergency department seeking treatment for seizures. A nurse instructed the patient to see her doctor in Wichita,

Kansas. Her family drove for 3 hours to get her to the Wichita hospital, where she was admitted to the pediatric intensive care unit.

## **Criminal and Civil Enforcement**

One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal health care programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, in appropriate cases, under the civil FCA. A description of these enforcement authorities can be found in Appendix E.

The successful resolution of false claims often involves the combined investigative efforts and resources of OIG, the Federal Bureau of Investigation (FBI), Medicaid Fraud Control Units (MFCU), and other law enforcement agencies. OIG has the responsibility of assisting DOJ in bringing and settling cases under the FCA. Many providers elect to settle their cases prior to litigation. As part of their settlements, providers often agree to enter into 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 2007, the Government's enforcement efforts resulted in 302 criminal actions and 255 civil actions against individuals or entities that engaged in health-care-related crimes. These efforts resulted in \$2.17 billion in HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal health care programs. Some of these notable enforcement actions are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

### **Pharmaceutical Companies**

■ **Virginia** – As part of a global criminal, civil, and administrative settlement agreement, the Purdue Frederick Company, Inc., and Purdue Pharma L.P. (collectively, the Purdue Companies), and three top executives agreed to pay almost \$635 million to resolve a variety of Federal, State, and private claims for fraudulently marketing OxyContin, a controlled-release formulation of Oxycodone, a powerful pain medication. The investigation revealed that from December 1995 through June 2001, Purdue Frederick effectively undertook a fraudulent and deceptive marketing campaign aimed at convincing doctors nationwide that OxyContin, because of its time-release formula, was less prone to abuse and that it was less likely to cause addiction or to produce other narcotic side effects than competing immediate release opioids. Purdue Frederick, along with its former president, Michael Friedman; Chief Legal Officer, Howard Udell; and former Chief Medical Officer, Paul Goldenheim, were sentenced for criminal violations of the Federal Food Drug and Cosmetic Act for the misbranding of the drug OxyContin.

Each executive was sentenced to 3 years of probation, ordered to perform 400 hours of community service in a drug abuse or drug treatment program and pay a \$5,000 fine.

Purdue Frederick was sentenced to 5 years of probation. Pursuant to their plea agreements, the executives will pay a total of \$34.5 million in penalties. The Purdue Companies will pay a total of almost \$600 million in settlement and restitution costs and pay a maximum statutory fine of \$500,000. Purdue Frederick will be subject to a 25-year exclusion; Purdue Pharma L.P. agreed to enter a 5-year CIA with OIG.

■ **Massachusetts** – Pharmacia & Upjohn Company, Inc., a subsidiary of Pfizer Inc., was ordered to pay a \$19.7 million criminal fine for its guilty plea to offering a kickback to a pharmacy benefit manager (PBM). The investigation revealed that Pharmacia offered to make payments on a distribution contract to a subsidiary of a PBM in the expectation of obtaining improved formulary positioning and improved ancillary benefits from the PBM for Pharmacia’s drug products.

Also in Massachusetts, another Pfizer subsidiary, Pharmacia & Upjohn Company LLC, entered into a deferred prosecution agreement and will pay a \$15 million penalty related to its illegal promotion and distribution of Genotropin for uses not approved by FDA. To avoid prosecution, Pharmacia must comply with the 36-month deferred prosecution agreement which includes its cooperation in ongoing investigations related to its human growth hormone product, Genotropin.

### **Billing Consultant**

■ **District of Columbia** – Maximus, Inc., a revenue maximization consultant, entered into a \$42.65 million settlement agreement with the United States to resolve that company’s liability under the FCA. Maximus allegedly filed false claims for Medicaid-funded targeted case management services, which assist foster children in obtaining needed medical, social and educational, and other services. Maximus submitted 26,683 claims for Medicaid reimbursement that were not supported by documentation. The Federal Government contends that these services were never rendered. As part of the global resolution of the case, Maximus also entered into a 5-year CIA with OIG, as well as a 24-month deferred prosecution agreement with the U.S. Attorney’s Office. In a novel provision, the CIA requires that OIG’s Office of Audit Services perform the claims and contract reviews that are ordinarily performed by an Independent Review Organization.

### **Durable Medical Equipment Suppliers**

■ **Florida** – As part of the South Florida Initiative, Operation Equity Excise, also known as Operation Whack-a-Mole, was the first phase in a multiorganizational, multi-disciplinary project to prevent, identify and prosecute health care fraud. Through the operation, clinics and DME companies were identified and suspicious providers were investigated resulting in receivables totaling over \$50.1 million.

The second phase of the Initiative, Operation Equity Excise 2, represents criminal investigations seeking indictments and convictions against providers that were identified through the investigative efforts in phase 1 of the Initiative. During this reporting period,

nine DME providers and the owner of a billing company have been charged for defrauding Medicare.

In March 2007, the Intensive Medicare Fraud Strike Task Force was initiated. It was designed specifically to combat Medicare fraud through the use of real-time analysis of Medicare billing data. The strike force identified fraudulent schemes involving clinics and DME suppliers. As a result of this strike force, a DME company owner, Gisela Valladares, was convicted after a 3-day trial. As part of the scheme, Valladares paid Medicare beneficiaries for the use of their Medicare information to fraudulently bill Medicare. In addition, five defendants have been charged for defrauding Medicare, and \$4.1 million was ordered to be returned or was returned.

■ **Florida** – A \$21 million default judgment and permanent injunction was entered in favor of the Government against Q & Y Medical Equipment, Inc. As part of the default judgment, approximately \$300,000 previously frozen by the court was released to the Government. An investigation revealed that the DME company was created for the sole purpose of committing fraud. The investigation found that Q & Y billed Medicare for wound care products and power pressure-reducing mattresses that were not prescribed by physicians or provided to beneficiaries.

■ **Florida** – Rene Rodriguez, owner of DC Medical Services, Inc., was sentenced to 4 years in prison and ordered to pay \$2.2 million in restitution for health care fraud. From March 2006 to July 2006, Rodriguez's DME company billed Medicare for DME and supplies that had not been ordered by doctors or supplied to beneficiaries. As a result of the investigation, approximately \$1.4 million was seized from bank accounts. At sentencing, the judge ordered that the seized money be forfeited to the Government.

## Hospitals

■ **New Jersey** – Raritan Bay Medical Center (RBMC) agreed to pay \$7.5 million and enter into a 5-year CIA to resolve its liability for allegedly submitting false claims to Medicare and TRICARE from January 1998 to August 2003. The Government alleged that RBMC artificially inflated its cost-to-charge ratio through its cost reports, triggering outlier payments to which it was not entitled.

■ **California** – Loma Linda University Behavioral Medicine Center (LLUBMC) and its related party, Loma Linda University Medical Center, agreed to pay \$2 million plus interest to settle allegations that LLUBMC, a Medicare-certified inpatient psychiatric hospital, falsified its cost reports for fiscal years 1992 through 1996. The Government alleged that the cost reports sought reimbursement for services unrelated to patient care, such as an employee assistance program.

## Home Health

■ **California** – A licensed vocational nurse, Sonia Ogbeni, was sentenced to 78 months in prison and ordered to pay \$4.2 million in restitution for her health care fraud scheme. Investigation revealed that Ogbeni caused Medicare to pay for false or fraudulent home

health services between October 2001 and March 2005. A review of records showed that Ogbeni, who worked for multiple home health agencies, submitted records that purported that she saw 58 patients on a single day, personally made visits that lasted from 30 to 45 minutes each, saw patients every single day during a 2-year period, and saw multiple patients in different locations at the same time.

■ **Georgia** – Colquitt County Hospital Authority, Colquitt Regional Health, Inc., both doing business as Colquitt Regional Medical Center, and administrators Coleen Grimsley and James Lowry, (collectively, Colquitt), agreed to pay \$475,000 to resolve their FCA liability. The Government alleged that between January 2001 and December 2005, Colquitt’s home health agency located in Sylvester, Georgia, certified and recertified home health care patients for original and additional home health care episodes that patients did not need or for patients who were not home bound and upcoded initial certification diagnoses.

### **Clinics**

■ **New Jersey** – Chidi Ikeh, the owner of two physical therapy clinics, was sentenced to 54 months in prison and ordered to pay almost \$3.79 million in restitution for his guilty plea to health care fraud and wire fraud. Ikeh, a resident of Texas, admitted that he defrauded the Government by billing for fraudulent physical therapy services. From February 2002 through August 2005, Ikeh billed Medicare for physical therapy services that were not provided, were not supervised by a licensed physician, and/or were not performed by a qualified individual. In fact, none of Ikeh’s employees had any qualifications or were licensed to provide physical therapy services.

■ **California** – Comprehensive Cancer Centers, Inc. (CCC), agreed to pay \$900,000 to resolve its FCA liability for claims submitted to Medicare for services provided at its outpatient cancer facility located at the Desert Regional Medical Center (DRMC). The investigation revealed that between 1997 and 2003, CCC allegedly used incorrect diagnostic codes and billing modifiers related to screening mammograms and diagnostic mammograms. In addition, CCC allegedly caused DRMC to submit cost reports to Medicare that sought reimbursement for unreasonable management fees paid to CCC.

### **Practitioners**

■ **Tennessee** – East Tennessee Heart Consultants, P.C. (ETHC), a practice group of cardiology physicians, agreed to pay \$1.7 million and enter into a 5-year CIA for allegedly failing to return overpayments owed to various payors, including Medicare and Medicaid. In addition, ETHC entered into a pretrial diversion agreement whereby ETHC agreed to pay an additional \$1.21 million in restitution. Investigation revealed that ETHC had a long-standing policy of failing to return overpayments, which were allegedly created through data entry errors, deliberate manipulation of patient ledgers, double billing, or coordination of benefits errors.

■ **New Jersey** – Laxmipathi Garipalli, M.D., agreed to pay the Government \$564,000 to resolve his liability under the FCA, the Stark statute, and certain common law causes of

action. From March 2003 through June 2006, Garipalli, a cardiologist, allegedly received remuneration from a hospital in the form of a salary in exchange for referrals of cardiac patients to the hospital. The investigation found that the physician's salary was ostensibly for clinical faculty services that he did not perform.

■ **Maine** – Dr. Mark Shinderman, a psychiatrist, was sentenced to 6 months' confinement and 6 months' home detention and ordered to pay \$36,000 in restitution and fines. In July 2006, a jury found Dr. Shinderman guilty of various charges relating to prescription drug fraud at a for-profit methadone clinic. The investigation revealed that the psychiatrist wrote prescriptions for controlled substances using the name and Drug Enforcement Administration (DEA) registration number of another physician. In addition, the psychiatrist created false prescription logs and progress notes indicating that another physician provided health care services to patients when, in fact, he provided the services himself.

### **Group Homes**

■ **Pennsylvania** – In a joint State and Federal investigation, Nancy Whary, the final defendant in the Federal case, was sentenced for her guilty plea to misprision of a felony. Whary was prosecuted for her knowledge of health care fraud and patient abuse and neglect that took place at a group home formerly operated by her daughter and son-in-law, Tina and Clifford Fake. The couple and others conspired to defraud health care benefit programs; diverted prescription drugs that were intended for dependent persons in the group home; and concealed the fraud, neglect, and abuse from family members of the dependent persons under their care. The investigation was initiated after a resident was taken to the hospital with broken bones and bruising over 60 percent of his body. The joint investigation revealed that more than 20 residents were abused and/or neglected. Residents were beaten, financially exploited, fed from items taken from waste receptacles, and forced to stuff inserts into newspapers. Since 2000, three residents of the group home have died. In early 2007, Clifford and Tina Fake were sentenced in Federal court to 218 months and 136 months in prison, respectively, and ordered to pay over \$236,000 in restitution. As a result of State charges, the couple received prison sentences, which will run concurrently with their sentence imposed in the Federal investigation. In total, eight defendants were sentenced in the Federal case.

## **Medicaid Fraud Control Units**

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. State MFCUs were created in 49 States and the District of Columbia pursuant to the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 (Pub. 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 2007, OIG provided oversight for and administration of approximately \$169 million in Federal grants that were distributed to the 50 MFCUs.

### **Investigations**

Examples of cases worked jointly by OIG with MFCUs during this semiannual period include the following:

■ **Texas** – The Scooter Store, Inc. (TSS) entered into a settlement agreement with the Government to resolve its FCA liability. In the agreement, TSS agreed to pay \$4 million and relinquish its right to approximately \$13 million in claims initially denied for payment by CMS. The Government alleged that TSS submitted false claims to Medicare and Medicaid for power wheelchairs that beneficiaries did not want, did not need, or could not use; submitted claims for used power wheelchairs, scooters, and accessories as though the equipment were new; submitted claims for power wheelchair accessories that were not ordered by a physician; and improperly induced beneficiaries by promising free mobility equipment. TSS and its individual owner, Douglas Harrison, agreed to enter into a 5-year CIA. The investigation involved OIG, the Texas MFCU, and the FBI, with the support of CMS and its contractors.

■ **Virginia** – Rebecca Conyer, the owner of a home health agency, and Donna Bates, her office manager, were sentenced for defrauding the Medicaid program. Conyer was sentenced to 30 months' incarceration and ordered to pay \$923,000 in restitution. Bates received a 24-month prison sentence and was held responsible for paying \$713,000, a portion of the total restitution amount. The investigation revealed that personal care services billed to the Medicaid program were either not performed at all, were not performed according to Medicaid standards, or were performed by personal care aides who were not adequately trained. The investigation involved OIG, the Virginia MFCU, the FBI, and the U.S. Postal Inspection Service.

■ **Oregon** – The Medford School District agreed to pay \$830,000 to resolve its liability for allegedly submitting fraudulent claims to the Medicaid program from January 1998 through December 2001. The school district allegedly submitted claims for school-based health services and transportation expenses that were not adequately documented. The Government also alleged that claims submitted were for services that did not qualify for reimbursement or were for services that students did not actually receive. Previously, two other school districts entered into similar settlements for a total recovery of \$2.25 million. The investigation involved OIG and the Oregon MFCU.

### **OIG Reviews of MFCUs**

During FY 2007, OIG conducted 12 onsite reviews of MFCUs' compliance with the following: (1) 42 CFR Part 1007, entitled "State Medicaid Fraud Control Units," containing OIG's regulations for MFCUs; (2) 45 CFR Part 92, entitled "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local

Governments,” establishing uniform administrative rules for Federal grants; and (3) the 12 MFCU performance standards developed jointly by OIG and the National Association of Medicaid Fraud Control Units.

Examples of unmet requirements OIG found during these reviews include the following:

- MFCU professional staff were not permanent employees working full-time on Medicaid provider fraud and patient abuse and neglect matters.
- The MFCU was not a single identifiable entity of the State government.
- The MFCU did not employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner.
- The MFCU was not organized to promote the effective and efficient conduct of its activities.

As part of the onsite review process, OIG also made recommendations and suggestions to improve operation of MFCUs.



# Public Health and Human Service Programs and Departmentwide Issues

The Office of Inspector General (OIG) allocates about 20 percent of its resources to reviews of the Department of Health and Human Service's (HHS) 300 public health and human service programs and to departmentwide issues that affect more than one program. OIG has discretion in allocating most of these resources. However, a portion of these resources is used for mandatory reviews, including financial statement audits conducted pursuant to section 405(b) of the Government Management Reform Act (GMRA) of 1994 and the Chief Financial Officers Act of 1990 (CFO Act) and information systems reviews required by the Federal Information Security Management Act (FISMA).

This chapter describes OIG's work related to 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 are low-income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.
- The Indian Health Service (IHS) provides or funds health care services for 1.6 million American Indians and Alaska Natives.
- The National Institutes of Health (NIH) supports medical and scientific research examining the causes of and treatments for diseases such as cancer and HIV/AIDS.

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

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

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

This chapter summarizes OIG's reports related to public health and human service programs and departmentwide issues, including the efforts to respond to Hurricanes Katrina and Rita. 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

### **Unobligated Funds Provided by the Ryan White Comprehensive AIDS Resources Emergency Act**

We found that, during grant years 1999–2002, HRSA did not fully comply with applicable requirements or use its offset authority in managing millions of dollars in unobligated grant funds. Pursuant to Title II of the Ryan White Comprehensive AIDS Resources Act (CARE Act, Pub. L. No. 101-381), HRSA provides funds to States to pay for medications and support services for people who have HIV/AIDS and who have no health insurance or are underinsured.

Contrary to the CARE Act, HRSA did not recoup \$10.6 million in Title II funds from States that had not obligated at least 75 percent of their grant awards within 120 days and reallocated those funds to other States in proportion to their original grants. Contrary to HHS policy, HRSA authorized States to carry over \$48.7 million in unobligated Title II funds beyond one budget period. Additionally, HRSA did not use the offset authority provided by the CARE Act and HHS grants policy to manage States' unobligated balances. The agency could have carried over balances from the prior year and offset the amount of current-year funds needed for the grant awards, which would have made available a larger amount of current-year funds to address certain States' unmet program needs.

We recommended that HRSA (1) monitor the States' compliance with CARE Act requirements; (2) comply with the current carryover policy; (3) examine the reasons for some States' large unobligated balances; and (4) analyze each State's unobligated balance from the preceding grant year to determine whether the balance should be deobligated or carried over and, if carried over, determine whether the amount should be an addition to the State's full amount of funding approved for the current grant year or, instead, whether the amount should be offset from the State's current-year grant award. HRSA generally disagreed with our findings but provided information on actions it had taken or planned to take to address the first three recommendations. HRSA offered several reasons for not using its offset authority. The Ryan White HIV/AIDS Treatment Modernization Act of 2006, which was enacted after we issued the draft report, may address HRSA's concerns about offsetting future grant awards. (A-06-04-00060)

### **FDA's Oversight of Clinical Trials Through Its Inspection Processes**

We found that data limitations and other factors affect FDA's ability to effectively manage its Bioresearch Monitoring (BiMo) program. The Federal Food, Drug, and Cosmetic Act requires all new drugs and medical devices to undergo trials to demonstrate their safety and efficacy before they are approved for sale. The sponsors, clinical investigators, and institutional review boards (IRB) that conduct and oversee these trials must comply with FDA regulations designed to protect the human subjects participating in them. Three FDA centers monitor and approve medical investigational products for human use. FDA's BiMo Program is a cross-center program that conducts inspections to verify clinical trial data and confirm that human subjects are adequately protected.

FDA's Office of Regulatory Affairs conducts onsite BiMo inspections of sponsors, clinical investigators, and IRBs as assigned by the centers. OIG received a congressional request to evaluate FDA's oversight of clinical trials after a series of news articles highlighted vulnerabilities.

We found that FDA is unable to identify all clinical trials and IRBs and lacks a single database for tracking its own inspections. Furthermore, the three FDA centers and the Office of Regulatory Affairs do not uniformly track or categorize inspections. In addition, FDA guidance and regulations do not reflect current clinical trials practices. Finally, we estimate that FDA inspected about 1 percent of clinical trials for the fiscal year (FY) 2000–2005 period. We recommend that FDA take the following steps to improve its information systems and processes: (1) develop a clinical trial database that includes all clinical trials, (2) create an IRB registry, (3) create a cross-center database that allows complete tracking of BiMo inspections, (4) establish a mechanism to provide feedback to BiMo investigators on their inspection reports and findings, and (5) seek legal authority to provide oversight that reflects current clinical trial practices. In its comments, FDA concurred with four of our five recommendations but did not address our recommendation to establish a mechanism to provide feedback to BiMo investigators on their inspection reports and findings. FDA also emphasized the importance of risk-based approaches to BiMo inspections rather than committing to a specified percentage of clinical trials. (OEI-01-06-00160)

#### **Unobligated Balances of Funds Awarded Under the Bioterrorism Hospital Preparedness Program**

Following previous OIG reviews showing that grantees had unobligated balances of funds granted through HRSA's Bioterrorism Hospital Preparedness program (Bioterrorism Program), we found that the percentage of unobligated funds had decreased from program year 2002 to program year 2004. The Bioterrorism Program provides funding to State, territorial, and municipal governments or health departments to upgrade the preparedness of hospitals and collaborating entities to respond to bioterrorism and other public health emergencies. The Pandemic and All Hazards Preparedness Act (Pub. L. No. 109-417, December 19, 2006) transferred responsibility for the Bioterrorism Program from HRSA to the Assistant Secretary for Preparedness and Response.

Our review of program years 2002 through 2004, with approximately \$1.1 billion in grant funds awarded, determined that unobligated Bioterrorism Program balances declined from 15.7 percent of the awarded funds for program year 2002 to 5.1 percent for program year 2004. We attributed this reduction to HRSA's strengthened oversight, training, onsite monitoring of awardees, and use of available enforcement actions.

We recommended that HRSA continue to use available monitoring tools and enforcement actions to reduce unobligated funds until the Assistant Secretary for Preparedness and Response assumes responsibility for the Bioterrorism Program. HRSA concurred with our recommendation. (A-05-06-00024)

### **Graduate Student Compensation Costs Charged to National Institutes of Health Research Grants**

We found that, between October 2004 and September 2005, graduate student compensation costs charged to NIH research grants to colleges and universities had appropriately limited compensation charges to both the amount paid to a first-year, postdoctoral scientist performing comparable work at the same institution and the National Service Award stipend in effect when NIH awarded the grants. Compensation charges for the 97 grants we sampled met the requirements set forth by the Office of Management and Budget (OMB) Circular A-21 and NIH guidelines. The report, prepared for two members of Congress, contained no recommendations. (A-05-06-00046)

### **Safeguards Over Controlled Substances at Indian Health Service Facilities**

During this semiannual period, we issued four reports identifying weaknesses in IHS facilities' safeguards over controlled (addictive) substances at IHS facilities. IHS maintains pharmacies that dispense controlled substances, the possession and use of which are regulated by the Drug Enforcement Administration (DEA) pursuant to the Controlled Substances Act of 1970. These pharmacies must follow DEA and other requirements to secure, account for, and maintain internal controls over controlled substances. Our reviews, conducted in 2004 and 2005, focused on Schedule II controlled substances, which have the highest potential for abuse among controlled substances with accepted medical uses.

■ **New Mexico** – We found that a hospital located in New Mexico had not instituted all recommended security precautions, internal controls, or accountability controls over Schedule II substances. We recommended that IHS direct the hospital to consider monitoring Schedule II substances with an alarm system after pharmacy hours; divide key duties and responsibilities among pharmacists; ensure that pharmacists account for all on-hand Schedule II substances on monthly inventory reports; and ensure that the disposal of wasted Schedule II substances is appropriately documented. IHS concurred with our recommendations. (A-06-06-00032)

In addition, we found that a health center located in New Mexico had not instituted all recommended security precautions for, or internal controls over, Schedule II substances. We recommended that IHS direct the center to consider monitoring its alarm system after pharmacy hours and establish a control to compensate for a lack of separation of duties related to the receipt of controlled substances. IHS agreed with the recommendations. (A-06-07-00049)

■ **Oklahoma** – We found that a health center located in Oklahoma did not always comply with applicable requirements to secure, or have adequate internal controls over, Schedule II substances. We recommended that IHS direct the center to store Schedule II substances in a locked safe and lock the door to the pharmacy during pharmacy hours, supervise pharmacy visitors at all times, ensure that the pharmacy is reserved only for

official pharmaceutical business, and consider monitoring Schedule II substances with an alarm system after pharmacy hours. IHS concurred with our recommendations. (A-06-06-00034)

In addition, we found that a hospital located in Oklahoma did not have adequate internal controls over its Schedule II substances. We recommended that IHS direct the hospital to establish and enforce written policies and procedures that divide key duties and responsibilities related to Schedule II substances among pharmacists. IHS concurred with our recommendation. (A-06-07-00048)

### **Indian Health Service's Resolution of Audit Recommendations**

We found that, as of December 31, 2005, IHS had not resolved 6,653 audit recommendations, of which 94 percent were past due for resolution. As a result, IHS did not have reasonable assurance that it was exercising proper stewardship over Federal dollars. Audit recommendations stem from OIG's reviews of IHS activities and those of its grantees and contractors and from "single" audits, generally conducted by public accounting firms pursuant to OMB Circular A-133. OMB Circular A-50 requires Federal agencies to resolve audit recommendations within 6 months.

We determined that IHS had not resolved all audit recommendations in a timely manner because it did not follow departmental policies and procedures. Based on the backlog of outstanding audit recommendations, we raised a concern that IHS might not resolve future recommendations in a timely manner. We recommended that IHS resolve the backlog of outstanding audit recommendations and resolve all audit recommendations within 6 months of receiving the audit reports as required. IHS concurred with our recommendations. (A-07-06-03077)

### **Security of Stockpile Sites**

During this semiannual period, we issued reports on the security of the Strategic National Stockpile at selected sites and identified ways to increase the sites' protection against theft, tampering, destruction, or other loss. CDC manages the stockpile to provide ready access to drugs and medical supplies during public emergencies. CDC responded that it was actively addressing the concerns raised. Site reports are considered sensitive and thus are not publicly available.

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

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

### **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 Program Support Center (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, 39 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, a total of 2,099 individuals have taken advantage of the opportunity to enter into settlement agreements or completely repay their debts. That figure includes the 29 individuals who have entered into such settlement agreements or completely repaid their debts during this reporting period. The amount of money being repaid through settlement agreements or through complete repayment is \$151 million. Of that amount, \$3.7 million is attributable to this reporting period.

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

- **Georgia physician Joyce Rawls** – \$156,000
- **Texas podiatrist Rickey Watson** – \$66,000
- **District of Columbia chiropractor Debra Epard** – \$53,000

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

OIG investigates cases involving the misuse of public health agency funds and threats to public health and safety, such as the improper use of select agents. The following is an example of a case involving improper use of HHS grant funds resolved during this reporting period:

- **Texas** – Iyad El-Hawa and Martha Gonzales were sentenced for fraud related to their scheme to administer fake flu vaccines at several Houston-area locations. El-Hawa owned a home health care business, and Gonzales claimed to be a licensed nurse.

El-Hawa, who pled guilty to health care fraud and misbranding of a drug, was sentenced to 46 months in prison and ordered to pay a \$15,000 fine. For her guilty plea to health care fraud, Gonzales was sentenced to 6 months' home detention and ordered to pay a \$5,000 fine. The investigation revealed that over 1,000 fake flu vaccines had been administered to employees of a refinery during a health fair and that senior citizens had been given the fake vaccines at local nursing homes. El-Hawa and Gonzales actually inoculated individuals with vaccines filled with sterile water with the intent to bill Medicare and private insurers.

## Reports Related to Human Service Programs

### Enrollment Levels in Head Start

Head Start is a nationwide program designed to increase school readiness in children from low-income families. Within ACF, the Office of Head Start administers the program. In FY 2005, ACF provided \$6.8 billion in funding to grantees for approximately 900,000 Head Start enrollees. Head Start regulations require grantees to maintain enrollment at 100 percent of their funded enrollment levels. We evaluated the enrollment levels of Head Start grantees, ACF's program monitoring, and the challenges associated with maintaining enrollment.

In our review of Head Start enrollment in the 2006 program year, we found the following:

- Ninety-one percent of the 200 Head Start grantees sampled had enrollments in excess of 90 percent. Forty percent met the Federal regulatory requirement to be fully enrolled. Sample results translated nationwide to 5 percent of slots that were funded but not filled.
- Fifty-five percent of the grantees sampled reported difficulty maintaining full enrollment, primarily due to difficulty in filling 90 percent of enrollment slots with children from families with low incomes, competition with other childcare programs, and the lack of or obstacles in providing transportation.
- There were inconsistencies in the data grantees reported on actual enrollment levels and the data on funded enrollment maintained by ACF. Only 11 percent of the grantees (200 sampled) reported data to ACF that matched their actual enrollment levels; the majority of those misreporting data overreported enrollment. Twenty-six of the grantees sampled were not able to readily produce accurate attendance counts.
- For grantees without full enrollment, ACF had increased the number of fund-reducing or withholding enforcement actions overall since 2003. However, there were differences across regions due to variations in the levels of underenrollment prompting funding reductions and in the amounts of the reductions. ACF had also increased its use of supplemental monitoring and technical assistance enforcement actions.

We recommended that ACF address grantee challenges to maintain full enrollment, ensure that enrollment data are accurate, and issue guidance concerning the use of funding reductions for grantees not fully enrolled. ACF indicated general support for our recommendations but pointed out problems with implementing our suggestions to address the requirement for grantees to fill 90 percent of slots with children from low-income families. ACF stated that changing income guidelines is outside its purview. It did not agree with our suggestion to amend regulations to increase the allowable percentage of eligible Head Start families that exceed low-income guidelines, stating that this change would allow grantees to enroll higher income children without ensuring participation by the neediest children. We continued to recommend that ACF address grantees' reported challenges to maintaining full enrollment, including challenges related to current income-eligibility guidelines. (OEI-05-06-00250)

### **Aid to Families With Dependent Children Overpayment Recoveries**

Our review of 43 States found that 24 States complied with Federal requirements and reimbursed ACF \$59 million for the Federal share of Aid to Families With Dependent Children (AFDC) overpayment recoveries from July 2002 through June 2006. Although the remaining 19 States and the District of Columbia continued to recover overpayments from former AFDC recipients after the program ended in 1996, these governments did not reimburse ACF \$28.7 million for the Federal share of their recoveries. We determined that 19 States and the District of Columbia did not reimburse ACF as required because they did not follow ACF's program instruction. In addition, ACF did not have monitoring procedures to ensure that the Federal Government received its share of AFDC overpayment recoveries from all States.

We recommended that ACF (1) collect from the 19 States and the District of Columbia the Federal share of AFDC overpayment recoveries totaling \$28.7 million and (2) establish monitoring procedures to ensure that the Federal Government receives its share of future State-recovered AFDC overpayments in a timely manner. ACF agreed with the recommendations. (A-01-06-02510)

### **Costs Claimed for the Statewide Automated Child Welfare Information System in California**

ACF requested that we audit the costs that Sacramento County, California, claimed under Title IV-E of the Social Security Act for the Statewide Automated Child Welfare Information System (SACWIS). SACWIS is a comprehensive case management tool that supports social workers' foster care and adoption assistance case management.

For the period January 1, 1999, through June 30, 2003, the county claimed \$11.2 million as SACWIS-related operating costs. We found that almost \$4 million (\$2 million Federal share) was not allowable under Federal and State regulations, and we could not determine the allowability of the remaining \$7.2 million (\$3.6 million Federal share). We determined that the costs were unallowable because they were not related to the operation of the automated system, did not receive the required approval, or were not adequately documented.

We recommended that California (1) refund the Federal share of the unallowable costs claimed, (2) work with ACF to determine what portion of the \$7.2 million is allowable for reimbursement under Title IV-E and refund the Federal share of any unallowable costs identified, (3) review costs that the county claimed for reimbursement subsequent to the audit period for issues similar to those we identified and refund the Federal share of any unallowable costs identified, and (4) instruct the county to strengthen its internal controls. California partially agreed with our first two recommendations and did not directly comment on our final two recommendations. (A-09-05-00060)

### **Undistributable Child Support Collections in Indiana**

Between October 1998 and December 2005, Indiana did not appropriately recognize or report \$2 million in undistributable child support collections and interest earned on those collections. ACF's Office of Child Support Enforcement (OCSE) oversees the Child Support Enforcement Program, which collects payments from noncustodial parents for distribution to custodial parents. OCSE requires States to offset program costs by recognizing and reporting income from undistributable child support collections and interest earned on the collections.

We recommended that the State report the program income identified in our work, review undistributable child support collections to ensure proper reporting of program income, and implement procedures and training to ensure future identification and reporting of program income. The State agreed with our recommendations. (A-05-06-00038)

## **Child Support Enforcement**

The detection, investigation, and prosecution of noncustodial parents who fail to pay court-ordered child support are priorities for OIG. OIG works closely with OCSE, 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. Since 1995, OIG has opened 3,397 investigations of child support cases nationwide, resulting in 1,323 convictions and court-ordered restitution and settlements of \$71.6 million.

### **Task Forces**

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

To date, the task force units have received more than 12,000 cases from the States. As a result of the work of the task forces, 930 Federal arrests have been made and 880 individuals have been sentenced. The total ordered amount of restitution related to Federal investigations is \$62.3 million.

Investigations to date at the State level have led to 523 arrests and 497 convictions or civil adjudications, resulting in \$37.2 million in restitution ordered.

Overall, more than \$44.9 million of court-ordered restitution has actually been collected and distributed to families.

### **Child Support Investigations**

Nationwide, OIG investigations of child support cases resulted in 47 convictions and court-ordered restitution and settlements of \$2.9 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

■ **Indiana** – James Andrews was sentenced to 24 months' imprisonment and 1 year of probation and was ordered to pay \$218,000 in restitution for failure to pay child support. In 1999, Andrews was ordered to pay \$500 a week to support his six children. The investigation revealed that Andrews, who was formerly a chiropractic doctor, sold two chiropractic clinics and moved to Massachusetts. He later moved to Florida where he was working as a substitute teacher.

■ **Missouri** – Craig McCallum was sentenced to 3 months' imprisonment and 1 year of supervised release and was ordered to pay \$190,000 in restitution for failure to pay child support. The restitution amount includes over \$5,000 that he took from his children's personal bank accounts and includes an amount that he owed for spousal support. The investigation revealed that from 1996 to 2004, McCallum earned a six-figure income yet made only minimal support payments, some of which were as little as \$32 a month. In addition, to avoid paying child and spousal support, McCallum liquidated or concealed assets. In 2006, McCallum was arrested in New Mexico where he was working as a bartender at a golf resort.

■ **Georgia** – Richard Stillmank was sentenced to 5 years' probation and ordered to pay \$52,000 in restitution for failure to pay child support. In 1992, Stillmank received a passport and moved with his second wife to Bulgaria, where he owned a toy train company that manufactured toy train parts. The investigation revealed that Stillmank's passport expired in 2002. In July 2006, Stillmank went to the U.S. Embassy in Bulgaria to obtain a passport to return to the United States. In August 2006, he was arrested upon his arrival at an Illinois airport.

■ **South Dakota** – Pursuant to his guilty plea, Joseph Tippmann was sentenced to time served of 8 days for failure to pay child support. Prior to sentencing, he paid his full arrearage amount of \$18,000. In 1990, Tippmann was ordered to pay \$205 a month for his child who is now 18 years old. Since 2001, only three involuntary payments totaling less than \$2,000 were received. An investigation revealed that Tippmann, living in Colorado, was a self-employed sculptor who displayed his pieces priced from \$18,000 to \$56,000 on an Internet Web site.

## **Misuse of ACF Grant Funds**

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

■ **Missouri** – Pursuant to their guilty pleas, Angela Allen and Pamela Harden were each sentenced to 1 day in jail and ordered to pay \$92,000 in joint and several restitution. The two women defrauded the State’s Independent Living Program (ILP), a federally funded program administered through the State’s Department of Social Services intended to provide independent living skills training and support for foster and former foster youth. The women created shell companies purportedly to provide ILP services. Investigations revealed that during a 2-year period, fraudulent invoices were submitted resulting in the companies being paid for services that were never performed.

## **Reports Related to Departmentwide Issues**

### **Departmental Processes for Awarding Hurricane Contracts**

During this semiannual period, we issued 30 reports addressing the Department’s processes for awarding contracts in response to Hurricanes Katrina and Rita. For 27 of these procurements, which provided almost \$50 million, we determined that the Department entered into the respective contracts in compliance with applicable requirements, including the Federal Acquisition Regulation, the Health and Human Services Acquisition Regulation, and a waiver issued by the Department’s Office of Acquisition Management and Policy to temporarily suspend competitive procurement requirements with respect to urgently needed items and services. Most of these procurements—17 of the 27—were made by PSC, which provides administrative services throughout the Department; the others were made by SAMHSA (4), FDA (3), HRSA (2), and NIH (1). The contracts covered a broad range of items and services, such as medical supplies and services, travel for personnel and evacuees, lodging for displaced Federal Government employees, mental health services and training, and various types of equipment.

For the remaining three contracts, PSC did not document the results of its determinations that no other contract types were suitable. PSC agreed with the recommendation in each of these reports to execute a written determination when awarding time-and-materials contracts. (Multiple Reports)

### **Hurricane-Related Costs Billed to a Contract**

Our audit found that a transportation company billed to HHS costs that did not fully comply with the contract terms. In October 2005, PSC entered into a \$21 million cost-plus-fixed-fee contract with the company to arrange for the transportation of returning evacuees requiring medical care following Hurricanes Katrina and Rita.

We determined that of the \$5.8 million in costs that the company billed to the Department between October 2005 and April 2006, charges totaling \$2 million did not fully comply with the contract terms. For example, the company did not always arrange for the most

economical transportation or arrange the transportation mode selected by the discharge planners and documented on the patient medial record necessity forms.

We recommended that the company work with HHS to determine the allowability of the costs billed without having determined the most economical transportation, ensure that future transports are arranged in the most economical fashion, refund the excess costs resulting from arranging transports at a higher level of care than was medically necessary, and ensure that future transports are arranged using the transportation modes indicated on the medical necessity forms. The company disagreed with our findings and recommendations. (A-06-07-00009)

### **Emergency Response to Hurricane Katrina: Use of the Government Purchase Card**

Our review of HHS's Hurricane Katrina purchase card transactions found that 15 percent did not meet selected purchasing requirements. These transactions lacked proof that approving officials had reviewed the procurements, were made by unauthorized personnel, or did not have the required documentation.

Between August 28 and December 14, 2005, HHS used purchase cards for 1,139 transactions totaling more than \$2.1 million to procure supplies and services supporting Hurricane Katrina rescue and relief operations. Purchase cards were designed to save the Government money by avoiding costly paperwork and to expedite the purchasing process.

We also found that cardholders had questions and concerns regarding some purchases, with over half of cardholders expressing the need for additional written guidance regarding emergency purchasing procedures; there were some inaccuracies related to Hurricane Katrina purchase data.

We recommended that the Assistant Secretary for Administration and Management (ASAM) provide additional written guidance on emergency purchasing procedures, require training on emergency purchasing procedures, and develop a tracking system for monitoring Government purchase card transactions during emergency situations. ASAM agreed with the recommendations and stated that it had established a course of action to strengthen the purchase card program, including additional written guidance for and training in emergency purchasing procedures and a tracking system for monitoring purchases during emergency situations. (OEI-07-06-00150)

### **Non-Federal Audits**

OMB Circular A-133 establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under this circular, covered entities must conduct annual organizationwide "single audits" of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entity's management of Federal funds. In FY 2007, OIG's National External Audit Review Center reviewed 1,395 reports that covered \$1.59 trillion

in audited costs. Federal dollars covered by these audits totaled \$468 billion, about \$219 billion of which was HHS money.

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

OIG maintains a quality control review process to assess the quality of the non-Federal reports received and the audit work that supports selected reports. The non-Federal audit reports reviewed and issued during this reporting period are categorized in the box below.

<b>Reports issued:</b>	
<b>Without changes or with minor changes</b>	1,173
<b>With major changes</b>	145
<b>With significant inadequacies</b>	77
<b>Total</b>	<u>1,395</u>

The 1,395 reports included 6,142 recommendations for improving management operations. In addition, these audit reports provided information for 124 special memoranda that identified concerns for increased monitoring by management.

## Resolving Recommendations

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

**Table 1: Reports With Questioned Costs\***

<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>	267	\$1,525,118,000	\$119,646,000
Issued during the reporting period	67	\$289,461,000	\$113,117,000
<b>Total Section 1</b>	334	\$1,814,579,000	\$232,763,000
<b>Section 2</b>			
For which a management decision was made during the reporting period <sup>2,3</sup>			
Disallowed costs	179	\$470,276,000	\$3,350,000
Costs not disallowed	8	\$ 72,937,000	\$546,000
<b>Total Section 2</b>	187	\$543,213,000	\$3,896,000
<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>	147	\$1,271,366,000	\$228,867,000
<b>Section 4</b>			
For which no management decision was made within 6 months of issuance <sup>4</sup>	100	\$1,052,370,000	\$105,237,000

\*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>	45	\$1,252,792,000
Issued during the reporting period	6	\$83,265,000
<b>Total Section 1</b>	51	\$1,336,057,000
<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	16	\$721,534,000
Based on proposed legislative action		
Value of recommendations not agreed to by management	2	\$25,758,000
<b>Total Section 2</b>	18	\$747,292,000
<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>	33	\$588,765,000

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

## Legislative and Regulatory Review and Development

### Regulatory Review Functions

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

During this reporting period, OIG was involved in the review and clearance of the implementing regulations and other policy guidance from the various provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Deficit Reduction Act of 2005.

### Regulatory Development

OIG is responsible for the development and publication of a variety of sanction regulations addressing civil money penalty and program exclusion authorities administered by the IG, as well as regulations promulgating safe harbors related to the anti-kickback statute. During this semiannual reporting period, we continued to develop final rulemaking addressing a new safe harbor for Federally Qualified Health Centers, as well as new proposed rulemaking addressing the reorganization and revisions to 42 CFR part 1003, which sets forth OIG's regulatory authorities for imposing civil monetary penalties and assessments. We are also in the process of updating the regulations at 42 CFR part 1001, regarding mandatory and permissive exclusions.

In addition, OIG periodically publishes *Federal Register* notices that, among other things, offer guidance to alert program beneficiaries, health care providers, and other entities about potential problems or areas of special interest. During this semiannual period, we developed a *Federal Register* notice, announcing the availability of a Proactive Disclosure Service (PDS) Prototype for customers of the Healthcare Integrity and Protection Data Bank (June 11, 2007; 72 FR 32126). The PDS was developed in conjunction with National Practitioner Data Bank efforts to be more responsive to customers' interest in real-time monitoring of practitioners and credentials.

## 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 examples:

- **Maryland** – McClellan Walther, a former NIH senior researcher, was sentenced to 4 years in prison followed by supervised release for life, fined \$12,500 and ordered to register as a sex offender for possession of child pornography. The investigation revealed that Walther used his NIH e-mail account to order child pornography videos. In a search

of Walther's home, child pornography videos, as well as a home computer containing over 600 child pornographic images, were discovered.

■ **South Dakota** – Clinton Swallow, a former IHS employee, was ordered to pay \$1,700 in restitution and fines for his guilty plea to theft or embezzlement in connection with health care. While working as a maintenance worker at the Pine Ridge Indian Hospital, Swallow illegally took possession of Government property, including tools, a snow blower, a refrigerator, ladders, and other items. Many of the stolen items were recovered at Swallow's residence.

# Appendixes



## Appendix A: Savings Achieved Through Implementation of Recommendations in Audits and Evaluations for Fiscal Year 2007

The Congressional Budget Office (CBO) estimates annual Federal savings expected to result from the enactment of legislation as part of the process of informing Congress of the potential impact of legislation under consideration. After laws involving HHS programs have been enacted, OIG analyzes them to identify provisions that were recommended in OIG-issued reports. A similar process occurs with respect to administrative changes recommended by OIG and implemented by HHS management. In the latter cases, the savings estimated to accrue are developed by the relevant HHS operating or staff division or by OIG.

Savings of this kind depend greatly on the contributions of others, such as other HHS divisions and the Department of Justice. The savings stated in this appendix represent funds that will be available for better use as a result of documented 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.

Total estimated savings from implemented recommendations and other actions to put funds to better use was \$39,016.7 million (\$39 billion) for the fiscal year (FY) that ended September 30, 2007.

OIG Recommendation	Implementing Action	Savings (millions)
<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>		
<p><b>Medicare Home Health Payments:</b>            CMS should restructure the payment system for home health care to eliminate inappropriate incentives that unnecessarily increase cost and utilization; prevent unscrupulous providers from gaining entry into the program; and improve program controls, such as eligibility determinations and approval of plans of care and services.            (OEI-04-93-00260; OEI-09-96-00110; A-04-96-02121)</p>	<p>Chapter 1 of Subtitle G of the Balanced Budget Act of 1997 (BBA) (as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1998), which pertains to home health benefits, addresses OIG's concerns regarding the need to restructure and control the payment system for these services. For example, it mandates that a prospective payment system (PPS) be developed and that the total payments in FY 2000 be equal to the amount that would have been paid under the prior system if cost limits were reduced by 15 percent. It also eliminates periodic interim payments to home health agencies (HHA).</p>	\$8,070

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
<p><b>State-Enhanced Payments Under Medicaid Upper Payment Limit Requirements:</b>            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)</p>	<p>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.</p>	<p>\$6,300</p>
<p><b>Medicare Part A Payments for Skilled Nursing Facilities:</b>            Services should be bundled into Medicare and Medicaid's payments to nursing homes; Part B payments for services normally included in the extended care benefit should continue to be examined for appropriateness; and legislation should prohibit entities other than skilled nursing facilities (SNF) from seeking payment on behalf of persons in Part A-covered SNF stays for enteral nutrition, incontinence care, and surgical dressings and limit Medicare coverage of these services to Part A. In 1997 congressional testimony, OIG supported establishing a PPS and consolidated billing. (OEI-03-94-00790; OEI-06-92-00863; OEI-06-92-00864; A-17-95-00096; A-14-98-00350)</p>	<p>Section 4432 of the BBA (as amended by the Balanced Budget Refinement Act of 1999, or BBRA) established a prospective payment for SNF care. Covered services include Part A SNF benefits and all services for which payment may be made under Part B (except physician and certain other professional services) during the period when the beneficiary is provided covered SNF care.</p>	<p>\$5,480</p>
<p><b>Medicare Indirect Medical Education:</b>            CMS should base the indirect medical education adjustment factor on the level supported by CMS's empirical data. (A-07-88-00111)</p>	<p>Section 4621 of the BBA (as amended by the BBRA) reduced the indirect teaching adjustment factor from 7.7 percent in FY 1997 to 7 percent in FY 1998, 6.5 percent in FY 1999, 6 percent in FY 2000, and 5.5 percent in FY 2001 and thereafter.</p>	<p>\$2,920</p>
<p><b>Medicaid Enhanced Payments to Local Providers:</b>            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>\$2,800</p>
<p><b>Medicare Secondary Payer Extensions:</b>            CMS should establish a centralized database of information about private insurance coverage of Medicare beneficiaries. CMS should also extend the Medicare secondary payer (MSP) provision to include end stage renal disease (ESRD) beneficiaries as long as they have employer-based coverage available. (OEI-07-90-00760; OEI-03-90-00763; A-10-86-62016; A-09-89-00100; A-09-91-00103; A-14-94-00391; A-14-94-00392)</p>	<p>The database capacity was achieved through the authorization of a data exchange between the Social Security Administration and CMS and between the Internal Revenue Service and CMS. Section 4631 of the BBA permanently extended current MSP policies for beneficiaries who are disabled and have ESRD. For ESRD beneficiaries, the statute also increased the time period Medicare is secondary payer from 18 to 30 months.</p>	<p>\$2,580</p>

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
<p><b>Medicare Outlier Payments:</b> 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 timelag between the payment of outliers and the actual closing of a specific hospital's cost report, particularly with regard to the hospitals that the fiscal intermediary identifies 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 timelag 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>Capital-Related Costs of Hospital Services:</b> CMS should extend congressionally mandated reductions in capital-related hospital costs. OIG believes that CMS should seek legislative authority to continue mandated reductions in capital payments; excess capacity was not considered in the capital cost policy. (A-09-91-00070; A-07-95-01127)</p>	<p>Section 4402 of the BBA provided for rebasing of capital payment rates for an additional reduction in the rate of 2.1 percent.</p>	<p>\$1,200</p>
<p><b>Medicare Payments for Oxygen:</b> CMS should reduce Medicare payments for oxygen concentrators and ensure that beneficiaries receive necessary care and support in connection with their oxygen therapy. (OEI-03-91-00710; OEI-03-91-00711)</p>	<p>Section 4552(a) of the BBA reduced Medicare reimbursement for oxygen by 25 percent until 1999 and by 30 percent for each subsequent year.</p>	<p>\$1,100</p>
<p><b>Payment Reform for Part B Drugs and Biologicals:</b> 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, unless they meet certain exceptions. CBO specifically attributed the FY 2004 savings to sections 304 and 305. Since 2004, most drug prices have been based on the average sales price or competitive acquisition instead of AWP.</p>	<p>\$1,100</p>

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
<p><b>Medicare Laboratory Reimbursements:</b>            In 1989, OIG recommended that CMS take advantage of economies of scale present in the laboratory industry by considering competitive bidding or making reductions to the fee schedule amounts. In 1990, OIG recommended that CMS 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. In a 1996 followup, OIG found that Medicare continued to pay more to clinical laboratories than to physicians for the same tests. Although the Omnibus Budget Reconciliation Act (OBRA) of 1993 reduced the fee schedule to 76 percent of the average in 1996, OIG recommended that CMS periodically evaluate the national fee schedule to ensure that it is in line with the prices that physicians pay for the same clinical laboratory services. (OEI-02-89-01910; A-09-89-00031; A-09-93-00056)</p>	<p>Section 4553 of the BBA provided for reducing fee schedule payments by lowering the cap to 74 percent of the median for payment amounts, with no inflation update for 1998 through 2002. The MMA mandated that the annual adjustment to the clinical laboratory fee schedule for 2007 through 2008 be 0 percent.</p>	<p>\$1,000</p>
<p><b>Medicare Secondary Payer:</b>            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 MSP provisions. This builds on other program improvements related to OIG's work that were implemented by the BBA, OBRA 1993, OBRA 1990, and OBRA 1989.</p>	<p>\$800</p>
<p><b>Graduate Medical Education Payments:</b>            CMS should reevaluate Medicare's policy of paying graduate medical education (GME) costs for all physician specialties and consider backing legislation to reduce Medicare's investment in GME for a more accurate and representative sharing of GME costs. (A-06-92-00020)</p>	<p>Sections 4623 and 4626 of the BBA provided for limits in the number of residents counted for purposes of Medicare GME payments and offered payments for voluntary reductions in the number of residents to limit Medicare's share of GME costs.</p>	<p>\$760</p>
<p><b>Payments for Durable Medical Equipment:</b>            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>	<p>\$700</p>

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
<p><b>Clinical Diagnostic Laboratory Tests:</b>            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 action in the BBA, OBRA 1993, OBRA 1990, and legislation in 1984 that was also responsive to OIG's recommendations to curb excessive clinical laboratory test reimbursements by Medicare.</p>	<p>\$600</p>
<p><b>Payments for Durable Medical Equipment:</b>            Excessive Medicare Part B payments for enteral and parenteral nutrition, equipment, and supplies should be reduced, or competitive acquisition strategies should be employed. (OEI-03-94-00021; OEI-06-92-00866; OEI-03-96-00230; OEI-06-92-00861)</p>	<p>Section 4551(b) of the BBA froze Medicare payments for enteral and parenteral nutrition and supplies for 1998 through 2002 and simplified the process used to reduce inherently unreasonable prices by 15 percent.</p>	<p>\$500</p>
<p><b>Medicare Home Health Payments:</b>            The 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 3 quarters of 2004 equal to the market basket increase minus 0.8 percent.</p>	<p>\$500</p>
<p><b>Payment for Services Furnished in Ambulatory Surgical Centers:</b>            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.</p>	<p>\$200</p>
<p><b>Medicare Payments to Hospitals for Bad Debt:</b>            CMS should seek legislative authority to modify the bad debt payment policy. (A-14-90-00039)</p>	<p>Section 4451 of the BBA reduced bad debt payments to providers by 25 percent in FY 1998, 40 percent in FY 1999, and 45 percent in later years. The Benefits Improvement and Protection Act of 2000 reduced bad debt payments further to 30 percent.</p>	<p>\$170</p>
<p><b>Hospice Certification:</b>            CMS should restructure hospice benefit policies to curb inappropriate growth in the program, particularly with regard to the fourth benefit period. (OEI-05-95-00250; A-05-96-00023)</p>	<p>Sections 4441- 4449 of the BBA contained provisions to control hospice payments and practices, such as replacing the current unlimited fourth benefit period with an unlimited number of 60-day benefit periods (each requiring recertification).</p>	<p>\$90</p>

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
<p><b>Rural Health Clinics:</b> The oversight and functioning of the current cost reimbursement system should be improved by implementing caps on provider-based rural health clinics and allowing States to do so or finding other ways to make reimbursement between provider-based and independent clinics more equitable.</p> <p>In addition, the certification process should be modified to increase State involvement in the placement of the clinics. Recertification should be required within a specific time limit (for example, 5 years), applying new criteria to document the need and impact on access. (OEI-05-94-00040)</p>	<p>Section 4205 of the BBA extended the per-visit payment limits to provider-based clinics and mandated that the shortage area requirements designation be reviewed triennially.</p>	<p>\$90</p>
<p><b>Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations:</b> 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.</p> <p>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)</p>	<p>CMS issued Medicaid Drug Rebate Program Release #47 in July 2000 to make it clear that manufacturers should not exclude other prices from best prices, as required by section 1927 of the Social Security Act.</p>	<p>\$81</p>
<p><b>Fraud and Abuse Provisions of the Balanced Budget Act:</b> CMS should require DME suppliers and HHAs to provide Social Security numbers and employee identification numbers; refuse to enter into a provider agreement with any HHA whose owners or principals have prior criminal records or are the relatives of owners of providers that have defrauded Medicare, apply “inherent reasonableness” provisions when assessing the appropriateness of Medicare payments, and authorize competitive bidding as a means of providing Medicare services.</p> <p>Moreover, CMS should clarify which general, administrative, and fringe benefit costs at hospitals and HHAs are related to patient care.</p>	<p>A number of provisions in Subtitle D of the BBA corresponded to and were supported by OIG work. For example, the BBA authorized the HHS Secretary to collect Social Security numbers and employer identification numbers from entities under Medicare, Medicaid, and Title V; authorized the Secretary to refuse to enter into contracts with physicians or suppliers that have been convicted of felonies; authorized the exclusion of entities owned or controlled by the families or household members of excluded individuals; authorized CMS to make inherent reasonableness adjustments of up to 15 percent to all Part B services except physician services;</p>	<p>\$80</p>

<b>OIG Recommendation</b>	<b>Implementing Action</b>	<b>Savings (millions)</b>
Specifically, CMS should distinguish between employee benefits and/or prerequisites to entertainment and patient care; and specify that the cost of entertainment, goods, or services for personal use, and alcohol, all fines, penalties and associated interest, dues, and membership costs associated with civic and community organizations are not allowable. (OEI-04-96-00240; OEI-09-96-00110; OEI-09-96-00110; OEI-03-94-00392; OEI-03-94-00021; OEI-06-92-00866; OEI-03-96-00230; A-03-92-00017; A-04-93-02067)	authorized up to five demonstration projects to be completed by December 31, 2002 (one was required to be oxygen and oxygen equipment), which can have multiple sites, to allow competitive bidding; and prohibited “reasonable cost” payments for items such as entertainment, gifts and donations, education expenses, and personal use of automobiles.	
<b>Hospital Sales:</b> CMS should eliminate the requirement that Medicare adjust for gains and losses when hospitals undergo changes of ownership. (OEI-03-96-00170)	Section 4404 of the BBA eliminated the requirement that Medicare make adjustments by making the Medicare capital asset sales price equal to the net book value.	\$70
<b>Payments for Ambulance Services:</b> CMS should seek legislative authority to develop a fee schedule for ambulance transportation and examine the inherent reasonableness of current allowable charges. (OEI-05-95-00300)	Section 4531 of the BBA made interim reductions in ambulance payments by limiting the allowed rate of increase and mandated the establishment of a fee schedule by January 1, 2000. The fee schedule was to be set so that aggregate payments would be reduced by 1 percent.	\$20
<b>Administration for Children and Families</b>		
<b>Availability of Health Insurance for Title IV-D Children:</b> 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 the State Children’s Health Insurance Program to enhance Medicaid coverage provided to children and to allow States to create insurance options for families who exceed Medicaid resource and income limits. Under Connecticut law, applicants include noncustodial parents ordered to provide health insurance.	\$5.7



## Appendix B: Notes to Tables 1 and 2

### Notes to Table 1

<sup>1</sup>The opening balance was adjusted upward \$1.4 million.

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

Central Identification Number (CIN): A-02-03-01019 UPPER PAYMENT LIMIT CALCULATIONS – NEW JERSEY – Additional unallowable costs of \$8.06 million were recovered.

CIN: A-04-05-81819 STATE OF KENTUCKY – Estimated disallowance of \$5 million reported in a prior semiannual period was resolved in a subsequent OIG audit.

CIN: A-09-03-00053 AUDIT OF ORGAN ACQUISITION COSTS AT CPMC – Based on a subsequent review, CMS determined that \$2.3 million previously disallowed costs were allowable.

CIN: A-04-03-06003 MEDICAID ACCOUNTS RECIEVABLE OVERPAYMENTS IN FLORIDA – Based on a subsequent review, CMS determined that \$1.5 million previously disallowed costs were allowable.

Not detailed are revisions to previously disallowed management decisions totaling \$3.4 million.

<sup>3</sup>Included are management decisions to disallow \$216.9 million that was identified in nonfederal audit reports.

<sup>4</sup>Because of administrative delays, many of which are beyond management control, resolution of the following 100 audits were not completed within 6 months of issuance; however, based upon discussions with management, resolution is expected before the end of the next semiannual reporting period:

CIN: A-02-03-01029	REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - NEW YORK CITY DEPT. OF EDUCATION, OCT 2006, \$259,433,325
CIN: A-05-01-00099	U OF I HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$140,281,912
CIN: A-04-03-02027	REVIEW OF MEDICIAD UPPER PAYMENT LIMIT CALCULATIONS IN ALABAMA, DEC 2005, \$73,432,381
CIN: A-04-04-03000	COMPLIANCE WITH MEDICARE'S POSTACUTE CARE TRANSFER POLICY - FY 01 & 02, APR 2005, \$72,369,964
CIN: A-03-03-00002	NATIONWIDE REVIEW OF IDTF SERVICES AND PROVIDERS, JUN 2006, \$71,664,839
CIN: A-02-04-01021	REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - REST OF STATE (ROS), OCT 2006, \$60,188,395
CIN: A-01-04-00527	REVIEW OF HOME HEALTH AGENCIES' BILLING FOR SERVICES PRECEDED BY A HOSPITAL DISCHARGE, MAR 2006, \$48,135,395
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 - CONNECTICUT, MAY 2003, \$32,780,146
CIN: A-01-04-00513	REVIEW OF MEDICARE PART B PAYMENTS FOR AMBULANCE SERVICES RENDERED TO BENEFICIARIES DURING AN INPATIENT STAY, MAR 2006, \$21,705,010

CIN: A-01-04-00528 REVIEW OF MEDICARE PART B PAYMENTS FOR RADIOLOGY SERVICES RENDERED DURING AN INPATIENT STAY, AUG 2006, \$20,011,162

CIN: A-09-01-00098 AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950

CIN: A-01-04-00006 REVIEW OF TARGETED CASE MANAGEMENT SERVICES RENDERED BY THE MASSACHUSETTS DEPARTMENT OF SOCIAL SERVICES DURING FEDERAL FISCAL YEARS 2002 AND 2003, MAY 2006, \$13,460,989

CIN: A-01-02-00509 REVIEW OF MEDICARE ADMINISTRATIVE COSTS - PART A & B – UNITED HEALTHCARE INSURANCE COMPANY, MAR 2005, \$12,991,420

CIN: A-04-04-00008 PPS PAYMENTS TO REHABILITATIVE HOSPITALS FOR TRANSFERS, SEP 2006, \$11,967,555

CIN: A-06-03-00027 REVIEW OF HUMANA’S BIPA MODIFICATIONS, JUL 2005, \$10,500,000

CIN: A-03-06-00563 MARYLAND TITLE IV-E ADMIN AND TRAINING COST, FEB 2007, \$8,317,637

CIN: A-06-02-00034 REV OF COST REPORTS & MEDICARE FEE-FOR-SERVICE PYMTS @ SCOTT & WHITE, MAY 2003, \$8,229,574

CIN: A-01-04-00525 REVIEW OF INTERRUPTED STAYS AT INPATIENT REHABILITATION FACILITIES, DEC 2005, \$5,868,697

CIN: A-09-05-00060 REVIEW OF CALIFORNIA’S STATEWIDE AUTOMATED CHILD WELFARE INFORMATION SYSTEM, SACRAMENTO COUNTY, MAR 2007, \$5,590,709

CIN: A-06-02-00060 REVIEW PACIFICARE OK BIPA MODIFICATIONS TO CY 2001 ACRP, JUN 2004, \$5,204,042

CIN: A-05-03-00096 REVIEW OF ADMINISTRATIVE COSTS FOR ADMINASTAR FEDERAL, AUG 2004, \$5,000,598

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

CIN: A-02-03-01020 REVIEW OF ADMINISTRATIVE COSTS CLAIMED BY EMPIRE MEDICARE SERVICES, MAR 2006, \$4,686,611

CIN: A-09-03-00051 REVIEW OF BLUE SHIELD CALIFORNIA BIPA MODIFICATIONS TO CY 2001 ACRP, OCT 2004, \$4,555,992

CIN: A-07-05-01016 MEDICARE FEE-FOR-SERVICE PROGRAM FOR BENEFICIARIES ENROLLED IN AN MCO, NOV 2006, \$4,553,997

CIN: A-05-01-00102 MT. SINAI HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$4,516,112

CIN: A-02-00-01047 DEMO BSWNY - FINANCIAL, MAR 2002, \$4,505,051

CIN: A-01-06-02506 REVIEW OF CONNECTICUT’S IV-E ADOPTION ASSISTANCE COSTS, FEB 2007, \$4,300,000

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

CIN: A-07-06-00210 REVIEW OF PRB COSTS CLAIMED BY BLUE CROSS BLUE SHIELD OF RHODE ISLAND, OCT 2006, \$3,558,976

CIN: A-06-04-00076 MEDICAL REVIEW OF SYNERGY’S PHP CLAIMS, MAR 2006, \$3,098,296

CIN: A-01-04-00004 REVIEW OF MAINE’S MEDICAID RETROACTIVE CLAIMS FOR SCHOOL-BASED HEALTH SERVICES – JANUARY 2001 THROUGH JUNE 2003, JAN 2005, \$3,044,211

CIN: A-03-03-00220 DELAWARE MEDICAID MANAGED CARE FAMILY PLANNING FACTOR VALIDATION AUDIT, JAN 2006, \$2,916,288

CIN: A-04-04-00013 INPATIENT REHAB. FACILITY PATIENT TRANSFERS TO HOME HEALTH AGENCIES, NOV 2006, \$2,331,042

CIN: A-07-05-04048 MEDICAID DRUG REBATE FOLLOW-UP - COLORADO, NOV 2005, \$1,925,367

CIN: A-05-06-00047 ESRD #11 PRE-AWARD AUDIT, MAY 2006, \$1,420,997  
 CIN: A-07-02-03021 ANTHEM BCBS OF CT - PENSION SEGMENT CLOSING, FEB 2004,  
 \$1,351,284  
 CIN: A-01-06-02500 REVIEW OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN  
 MASSACHUSETTS FROM OCTOBER 1, 1998, THROUGH  
 SEPTEMBER 30, 2005, DEC 2006, \$1,300,000  
 CIN: A-06-06-00045 AUDIT OF NEW MEXICO TITLE IV-E CONTRACTED  
 ADMINISTRATIVE & UNIVERSITY TRAINING COSTS,  
 FEB 2007, \$1,235,888  
 CIN: A-01-06-02502 CONNECTICUT REVIEW OF UNDISTRIBUTABLE CHILD SUPPORT  
 COLLECTIONS, JAN 2007, \$1,066,738  
 CIN: A-04-01-05004 REVIEW MEDICARE CLAIMS FOR DEPORTED BENEFICIARIES,  
 MAR 2002, \$836,711  
 CIN: A-01-06-02504 REVIEW OF AFDC OVERPAYMENT COLLECTIONS IN MAINE,  
 DEC 2006, \$669,522  
 CIN: A-06-05-00062 MEDICARE PRESCRIPTION DRUG DISCOUNT CARD PROGRAM,  
 JUL 2006, \$652,135  
 CIN: A-07-06-01020 REVIEW OF NON-RISK MANAGED CARE CONTRACT  
 ADMINISTRATIVE FEES IN UTAH, MAR 2007, \$625,489  
 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 INDIANA-UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS,  
 MAR 2007, \$461,430  
 CIN: A-07-05-03069 MISSOURI UNDISTRIBUTABLE CHILD SUPPORT PAYMENTS,  
 JUL 2006, \$457,128  
 CIN: A-03-04-00205 MEDICAID PROVIDER OVERPAYMENTS--DELAWARE, OCT 2004,  
 \$437,592  
 CIN: A-01-04-00506 REVIEW OF DISPROPORTIONATE SHARE HOSPITAL PAYMENTS  
 CLAIMED BY SAINT MARY'S HOSPITAL FOR FISCAL YEAR  
 ENDING DECEMBER 31, 2002, MAY 2004, \$433,502  
 CIN: A-04-04-02010 REVIEW OF COMPREHENSIVE OUTPATIENT REHABILITATION  
 THERAPY SERVICES PROVIDED BY ABSOLUTE THERAPY  
 INC., NOV 2006, \$414,712  
 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-05-06-00048 EVALUATION OF ESRD NO. 9 PRE-AWARD AUDIT, MAY 2006,  
 \$289,883  
 CIN: A-09-04-00068 REVIEW OF CALIFORNIA'S STATE AUTOMATED CHILD WELFARE  
 INFORMATION SYSTEM (SACWIS) AT SANTA CLARA  
 COUNTY, APR 2006, \$286,464  
 CIN: A-05-05-00033 MICHIGAN-UNDISTRIBUTED CHILD SUPPORT COLLECTIONS,  
 AUG 2006, \$257,859  
 CIN: A-03-04-00353 ACCOUNTABILITY OVER CDC BT FUNDS, JUN 2005, \$238,537  
 CIN: A-05-01-00094 PAYMENTS TO KAISER OF OAKLAND FOR INSTITUTIONAL  
 BENEFICIARIES, OCT 2002, \$229,656

CIN: A-05-06-00049 EVALUATION OF ESRD NO. 10 PRE-AWARD AUDIT, MAY 2006, \$210,049

CIN: A-02-01-01019 DEMO BSWNY - CASH MANAGEMENT, OCT 2002, \$208,271

CIN: A-01-05-00509 REVIEW OF MEDICARE CONTRACT TERMINATION/SEVERANCE COSTS CLAIMED BY BLUE CROSS & BLUE SHIELD OF RHODE ISLAND (RIBCBS), SEP 2005, \$205,384

CIN: A-05-06-00052 REVIEW OF SAMHSA GRANT, SEP 2006, \$203,112

CIN: A-01-04-01501 NORTHEASTERN UNIVERSITY DHHS GRANT COSTS GRANT #S 9274, 4000 AND 4111, JAN 2005, \$194,890

CIN: A-06-05-00066 MEDICARE PRESCRIPTION DRUG CARD PROGRAM, SEP 2006, \$168,782

CIN: A-07-06-00216 PENSION COSTS CLAIMED AT BLUE CROSS BLUE SHIELD OF ARIZONA, AUG 2006, \$142,343

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-01-03-00010 MEDICAID SCHOOL-BASED HEALTH SERVICES ADMINISTRATIVE CLAIMING REVIEW - RHODE ISLAND, JUN 2004, \$123,010

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-05-01-00079 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-05-01-00089 ADDITIONAL BENEFITS REVIEW OF MANAGED CARE ORGANIZATION, OCT 2002, \$77,000

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

CIN: A-05-01-00086 PAYMENTS TO HMO OF NE PA FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$62,432

CIN: A-03-02-00373 REVIEW OF US HELPING US, DEC 2003, \$45,558

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

CIN: A-02-06-02010 ACF REQUEST FOR LIMITED REVIEW OF HEAD START GRANTEE – CONCERNED PARENTS, SEP 2006, \$32,490

CIN: A-08-03-73541 SOUTH DAKOTA FOUNDATION FOR MEDICAL CARE, JAN 2003, \$28,573

CIN: A-07-02-00150	PAYMENTS TO COVENTRY--PITTSBURG FOR INSTITUTIONAL BENEFICIARIES, JUN 2003, \$26,000
CIN: A-05-01-00078	PAYMENTS TO HEALTH NET-TUCSON, ARIZONA- FOR INSTITUTIONAL BENEFICIARIES, APR 2002, \$21,233
CIN: A-08-04-76779	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003, \$18,925
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR INSTITUTIONALIZED BENEFICIARIES, MAY 2002, \$18,842
CIN: A-05-01-00095	PAYMENTS TO HUMANA OF ARIZONA FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$18,645
CIN: A-07-03-00151	REVIEW OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, JUN 2003, \$18,400
CIN: A-01-02-01504	REVIEW OF CDC'S HIV PROGRAMS AT FENWAY COMMUNITY HEALTH CENTER, JUN 2003, \$18,028
CIN: A-07-04-01011	PAYMENTS FOR UNITED HEALTHCARE FOR INSTITUTIONAL BENEFICIARIES, MAR 2005, \$13,128
CIN: A-05-01-00070	PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$11,089
CIN: A-09-05-00058	WEDGE: HAWAII MEDICAID NURSING FACILITIES EXPENDITURES, FEB 2006, \$9,562
CIN: A-06-06-00014	MEDICARE PRESCRIPTION DRUG CARD PROGRAM: ACCLAIM, SEP 2006, \$8,800
CIN: A-03-03-00393	AUDIT OF CDC HIV/AIDS GRANT TO SEXUAL MINORITY YOUTH ASSISTANCE LEAGUE, OCT 2003, \$1,155

**Total CINs:** 100

**Total Amount:** \$1,052,370,139

## Notes to Table 2

<sup>1</sup>The opening balance was adjusted upward by \$74.8 million.

<sup>2</sup>Management decision has not been made within 6 months on 29 reports.

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

CIN: A-09-04-00038	WEDGE: LA COUNTY 1115 WAVIER, OCT 2006, \$285,200,000
CIN: A-05-05-00053	REVIEW OF LAYERED GPOs -- ROLL-UP, JUN 2006, \$59,000,000
CIN: A-07-04-04031	MEDICAID HOSPITAL OUTLIER PAYMENTS IN ILLINOIS, MAY 2005, \$56,449,668
CIN: A-04-01-02006	MEDICAID DISPROPORTIONATE SHARE PAYMENTS IN ALABAMA, JUN 2004, \$45,763,327
CIN: A-01-02-00503	FURTHER EXPANSION OF THE DRG PAYMENT WINDOW, AUG 2003, \$37,000,000
CIN: A-05-02-00078	ROLLUP OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, FEB 2004, \$12,764,202
CIN: A-05-04-00073	ROLL-UP OF ADDITIONAL GPOs, MAY 2005, \$6,600,000
CIN: A-05-02-00077	MICHIGAN MEDICAID/SCHIP REVIEW, NOV 2003, \$5,908,350
CIN: A-03-02-00203	VIRGINIA - SCHIP/TITLE IV - D SURVEY, JUL 2004, \$5,402,491
CIN: A-05-05-00033	MICHIGAN - 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-01-05-02502	REVIEW OF CONNECTICUT'S TRAINING AND IV-E ADOPTION ASSISTANCE COSTS, JUL 2006, \$2,400,000
CIN: A-05-02-00075	INDIANA MEDICAID/SCHIP REVIEW, NOV 2003, \$1,885,708
CIN: A-05-06-00038	INDIANA - UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, MAR 2007, \$871,677
CIN: A-05-02-00082	BID PROPOSAL FOR 1-800 MEDICARE HOTLINE ADMINISTRATION, AUG 2002, \$609,950
CIN: A-05-03-00021	CIMRO PRO PRE-AWARD AUDIT FOR NEBRASKA, NOV 2002, \$504,650
CIN: A-05-06-00020	MEDICAID PAYMENTS FOR SERVICES TO BENEFICIARIES WITH CONCURRENT ELIGIBILITY IN MICHIGAN AND OHIO - MICHIGAN REPORT, AUG 2006, \$467,317
CIN: A-04-06-07004	ESRD BID PROPOSAL BY NETWORK ORGANIZATION NO. 8, MAY 2006, \$415,630
CIN: A-07-04-01008	FAMILY PLANNING - FEE-FOR-SERVICE - COLORADO, JAN 2005, \$269,024
CIN: A-04-06-07003	ESRD BID PROPOSAL BY NETWORK ORGANIZATION NO. 7, MAY 2006, \$235,966
CIN: A-01-05-00512	REVIEW OF 2004 ACRP MODIFICATION SUBMITTED AS A RESULT OF MMA FOR THE FALLON COMMUNITY HEALTH PLAN, JAN 2006, \$154,970
CIN: A-05-02-00023	SCHOOL-BASED MEDICAID ADMIN & SERVICE COSTS - WISCONSIN, MAR 2003, \$144,909
CIN: A-05-03-00059	ESRD #9 PRE-AWARD AUDIT (RFP-CMS-03-001/JAC), MAY 2003, \$139,816
CIN: A-04-03-08013	ESRD NETWORK COST PROPOSAL, MAY 2003, \$116,085
CIN: A-05-03-00060	ESRD #10 PREAWARD AUDIT (RFP-CMS-03-001/JAC), MAY 2003, \$114,289
CIN: A-05-01-00070	PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$98,698
CIN: A-04-06-07005	ESRD BID PROPOSAL FOR NETWORK ORGANIZATION NO. 17, MAY 2006, \$43,435
CIN: A-05-06-00023	MINNESOTA - UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, SEP 2006, \$28,240
CIN: A-05-04-00051	ALLOWABILITY OF CDC BIOTERRORISM COSTS - OHIO DEPARTMENT OF HEALTH, FEB 2005, \$4,154

**Total CINS:** 29

**Total Amount:** \$530,989,689

## 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. Where there are no data to report under a particular requirement, the word “None” appears.

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

Section of the Act	Requirement	Location
Section 4(a)(2)	Review of legislation and regulations	p. 51
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. 27
(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. 49
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	p. 50
(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 IG 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 of 1996 (HIPAA, Pub. L. No. 104–191), the Inspector General (IG) is required to solicit proposals annually via *Federal Register* 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 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 2006 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
New safe harbors for various types of patient assistance programs (PAP) for financially needy beneficiaries, including charity models, pharmaceutical company models, Part B wraparound assistance, medication therapy management programs, and others.	OIG is considering these suggestions. OIG has issued guidance on this topic through a Special Advisory Bulletin (70 FR 20623) and numerous advisory opinions.
Modification of the safe harbor for electronic health records (EHR) arrangements to (i) exclude commercial laboratories and laboratory operators from the category of protected EHR software donors and (ii) to provide that donors cannot tie the donation of qualifying software to the acceptance and use of donor-specific interfaces, upgrades, or modifications.	These suggestions require further study. With respect to the first suggestion, in the preamble to the final rule, OIG expressed concern about potential abuses by laboratories and indicated that we would revisit the determination to protect laboratory donors if abuses occurred. With respect to the second suggestion, we note 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 group purchasing organization (GPO) safe harbor to clarify the scope and nature of protected payments.	This suggestion requires further study.
Modification of GPO safe harbor to (i) establish a presumption that vendor fees are for the benefit of the GPO and need not satisfy additional discount safe harbor standards and (ii) protect arrangements whereby vendors make case-by-case determinations regarding whether administrative fees represent indirect discounts to GPO members.	OIG is not adopting these suggestions. The arrangements described pose a risk of abuse under the anti-kickback statute and should be evaluated on a case-by-case basis, such as under the advisory opinion procedures.

<b>Proposal</b>	<b>OIG Response</b>
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 considering these suggestions.
Modification of an existing safe harbor to prohibit surgeons from hiring in-house anesthesiologists and certified registered nurse anesthetists (CRNA).	OIG is not adopting this suggestion. It is unclear which safe harbor the commenter wants modified, although we interpret the comment to seek modification of the safe harbor for investments in group practices. We are not persuaded that the modification is necessary or feasible. Safe harbor compliance is voluntary; therefore, no added safe harbor condition would prohibit surgeons from employing anesthesiologists or CRNAs. Further, modifying the safe harbor to exclude certain groups based on their specific physician composition would introduce additional complexity into the regulatory scheme without significant additional protection against abuse.
A new safe harbor for arrangements that offer complimentary local transportation to beneficiaries to enable them to obtain in-person medical necessity determinations for power mobility devices (PMD), as required under 42 C.F.R. 410.38(c)(2)(i).	OIG continues to consider generally the issue of complimentary local transportation for beneficiaries. However, the described arrangements pose a risk of abuse under the anti-kickback statute and should be evaluated on a case-by-case basis, such as under the advisory opinion procedures.

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

<b>Proposal</b>	<b>OIG Response</b>
Modification of the existing GPO safe harbor to clarify: (i) the application of the safe harbor to pharmacy benefit managers, (ii) the application of the "wholly owned" standard, and (iii) the treatment of administrative fees distributed by a GPO to its members.	OIG is considering these suggestions.
Modification of the discount safe harbor with respect to Medicare Part D plans to (i) incorporate documentation and disclosure standards for manufacturers, Part D plans, and certain other business relationships; and (ii) clarify its application to the additional entities with which manufacturers may contract under the MMA (e.g., pharmacy benefits managers, retail pharmacies, and Part D drug plan sponsors).	OIG is considering these suggestions as we gain experience with the Part D program.
New safe harbor for implementation of a "communitywide" health information network.	OIG is considering this suggestion as we gain experience with the new safe harbor for EHR arrangements. OIG previously solicited comments regarding this suggestion (70 FR 59015).

<b>Proposal</b>	<b>OIG Response</b>
Modification of the existing safe harbor for obstetrical malpractice insurance subsidies to include (i) additional types of physicians and (ii) subsidies for which there is documented need and the amounts are limited in scope and duration.	This suggestion requires further study.
New safe harbor for manufacturer donations to PAPs (see similar suggestions above).	OIG is considering this suggestion.
New safe harbor for certain practices related to “economic credentialing” of physicians by hospitals.	OIG is not adopting this suggestion. This issue was addressed in the OIG Supplemental Compliance Guidance for Hospitals issued in 2005. Comments previously received in response to a solicitation for public comments on this subject variously suggested issuance of different types of guidance; some comments requested that OIG take no action. OIG continues to consider generally the issues raised by “economic credentialing.”
A new Medicare SELECT safe harbor to cover (i) coinsurance waivers for inpatient services negotiated between a hospital and an Employee Retirement Income Security Act employee welfare benefit plan that covers retirees and (ii) Part B waivers for employer group plans.	These suggestions require further study.
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 considering this suggestion.
Modification of the existing shared risk exception to cover (i) second-tier contractors of Federally-qualified health centers (FQHC) and (ii) the TRICARE program.	OIG is considering this suggestion.
New safe harbor for certain fee-for-service arrangements between FQHCs and other providers, practitioners, and suppliers.	OIG published a final safe harbor addressing this suggestion. See 72 FR 56632 (Oct. 4, 2007).
Modification of the discount safe harbor to 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.	OIG is considering this suggestion.
Modification of the discount safe harbor to (i) clarify its application to discounts applied to a manufacturer’s full product line, (ii) modify the reporting and disclosure requirements, and (iii) standardize the requirements for offerors and sellers.	OIG is considering generally the issues raised by these suggestions.
Modification of existing safe harbors to conform them to the final regulations under the physician self-referral statute published by the Centers for Medicare & Medicaid Services (CMS) and new safe harbors analogous to new self-referral exceptions created by the CMS regulations.	OIG is considering making some conforming changes with respect to the group practice investments safe harbor. With respect to other safe harbors, 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 address protection of startup multispecialty ASCs that otherwise comply with the current safe harbor conditions.	OIG is considering this suggestion.

<b>Proposal</b>	<b>OIG Response</b>
Modification of the safe harbor for ASCs jointly owned by hospitals and physicians to add conditions under which hospitals would not be in positions to make or influence referrals.	OIG is considering this suggestion.
Modification of the ASC safe harbor to specify whether an ASC can require investors to comply with safe harbor conditions.	OIG is considering this suggestion.
Modification of the ASC safe harbor to clarify (i) the use of “pass-through” entities to hold ownership interests and (ii) the treatment of physician investors who invest at different times.	OIG is considering this suggestion.
New safe harbor for rural health networks operating pursuant to the Medicare Rural Hospital Flexibility Program.	This suggestion requires further study.
New safe harbor for arrangements that comply with section 513 of the IRS Code pertaining to the provision of certain supporting goods and services by tax-exempt hospitals to other tax-exempt hospitals.	This suggestion requires further study.

## Appendix E: Summary of Sanction Authorities

The Inspector General Act of 1978 (Pub. 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. 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 HHS administrative law judge and appeals to the HHS Departmental Appeals Board and Federal district and appellate courts) regarding whether the basis for the exclusion exists and the length of the exclusion is reasonable.

### Patient Dumping

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

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

OIG is authorized to collect civil monetary penalties 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 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).

Individuals and entities that engage in unlawful referral or kickback schemes may be subject to criminal penalties under the general criminal anti-kickback statute, civil monetary penalties under OIG’s CMPL authority (section 1128A(a)(7) of the 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 suit 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
AFDC	Aid to Families With Dependent Children
AMP	average manufacturer price
AoA	Administration on Aging
ASAM	Assistant Secretary for Administration and Management
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
BiMo	Bioresearch Monitoring Program
CARE	Comprehensive AIDS Resources Emergency Act
CBO	Congressional Budget Office
CCC	Comprehensive Cancer Centers, Inc.
CDC	Centers for Disease Control and Prevention
CFO	Chief Financial Officers Act of 1990
CFR	Code of Federal Regulations
CIA	corporate integrity agreement
CMHC	community mental health center
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
CRNA	certified registered nurse anesthetist
CSE	child support enforcement
CY	calendar year
DEA	Drug Enforcement Administration
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DMERC	durable medical equipment regional carrier
DOJ	Department of Justice
DRA	Deficit Reduction Act of 2005
DSH	disproportionate share hospital
EHR	electronic health record
EMS	emergency medical services
EMTALA	Emergency Medical Treatment and Active Labor Act
ERC	Ethics Resource Center
ESRD	end stage renal disease
FBI	Federal Bureau of Investigation
FCA	False Claims Act
FDA	Food and Drug Administration

FISMA	Federal Information Security Management Act
FQHC	federally qualified health center
FR	Federal Register
FUL	Federal upper limit
FY	fiscal year
GAO	Government Accountability Office
GME	graduate medical education
GMRA	Government Management Reform Act of 1994
GPO	group purchasing organization
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
HIE	health information exchange
HIPAA	Health Insurance Portability and Accountability Act
HIT	health information technology
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
ID	identification number
IG	Inspector General
IHS	Indian Health Service
ILP	Independent Living Program
IRB	institutional review board
IRF	inpatient rehabilitation facility
IT	information technology
IVIG	intravenous immune globulin
LCD	local coverage determination
MFCU	Medicaid Fraud Control Unit
MITA	Medicaid Information Technology Architecture
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMIS	Medicaid Management Information System
MPFS	Medicare Physician Fee Schedule
MRO	Medicaid Rehabilitation Option
MSP	Medicare Secondary Payer
NDC	National Drug Codes
NIH	National Institutes of Health
OAS	Office of Audit Services
OBRA	Omnibus Budget Reconciliation Act of 1990, 1993
OCIG	Office of Counsel to the Inspector General
OCSE	Office of Child Support Enforcement
OEI	Office of Evaluation and Inspections
OI	Office of Investigations

OIG	Office of Inspector General
OMB	Office of Management and Budget
PAP	patient assistance program
PBM	Pharmacy Benefit Manager
PCIE	President's Council on Integrity and Efficiency
PDIG	Principal Deputy Inspector General
PDP	prescription drug plan
PDS	Proactive Disclosure Service
PECOS	Provider Enrollment, Chain and Ownership System
PMD	power mobility device
PPS	prospective payment system
PSC	Program Safeguard Contractor/Program Support Center
Pub. L.	Public Law
QIO	Quality Improvement Organization
RSP	retail sales price
SACWIS	Statewide Automated Child Welfare Information System
SAMHSA	Substance Abuse and Mental Health Administration
SCHIP	State Children's Health Insurance Program
SNF	skilled nursing facility
UPL	upper payment limit
U.S.C.	United States Code
WAMP	widely available market price

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