

Office of Inspector General

Semiannual Report to Congress

October 1, 2010 - March 31, 2011



Office of Inspector General

Semiannual Report to Congress

" $|\cdot^2 Y^{\cdot} \mu$

ž¤μ«

Message From the Inspector General



This *Semiannual Report to Congress*, submitted pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG), Department of Health & Human Services (HHS), for the 6-month period ending March 31, 2011.

This past six months has been a period of intense activity for our office. We have continued to conduct a wide range of audits, evaluations, investigations, and enforcement and compliance activities to protect the integrity of the Medicare, Medicaid, public health, and human services programs. We have led large-scale health care fraud investigations in collaboration with our Federal, State, and local partners. Finally, our outreach to external stakeholders, including the Congress, has been substantial. This threefold approach to our diverse portfolio—making recommendations for improvement in departmental programs; leveraging critical enforcement resources by working closely with our government partners; and targeting outreach to external stakeholders—continues to be a successful strategy.

Our audit, evaluation, and investigative activity over the past six months addresses important program vulnerabilities such as questionable billing by skilled nursing facilities, improper payments for medical supplies, adverse events in hospitals, rebate concerns in the Medicare Part D program, institutional conflicts of interest by National Institutes of Health (NIH) grantees and alleged fraud by pharmaceutical manufacturers. We continue to diligently monitor the impact of our recommendations. Additionally, public dissemination of our work also heightens our ability to educate a broad range of stakeholders. For instance, our hospital adverse event report was downloaded more than 200,000 times from our Web site.

Our partnership with other law enforcement entities as part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) continues to produce significant results, particularly in its Strike Force actions. This past February, Strike Force teams engaged in an unprecedented health care fraud takedown. Teams across the country arrested more than 100 defendants in 9 cities for their alleged participation in Medicare fraud schemes involving more than \$225 million in false billing. Notably, more than 300 OIG special agents participated in coordination with other Federal and State agencies, including other Offices of Inspector General. During this operation, OIG and the Centers for Medicare & Medicaid Services (CMS) worked to impose payment suspensions that immediately prevented a loss of more than a quarter-million dollars in claims submitted by Strike Force targets.

During this reporting period, OIG witnesses testified at five congressional hearings at which we had the opportunity to talk about our work fighting Medicare fraud, waste, and abuse and our recommendations to strengthen program integrity. We also highlighted our efforts to utilize technology, enhanced data, and other innovative tools to identify and prevent fraud schemes before they become pervasive.

Additionally, our outreach to external stakeholders broadens our mission to educate providers regarding the importance of instituting effective compliance measures within their organizations. We recently issued "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse." This publication assists new physicians and existing health care providers by offering important information about how to avoid violating health care fraud and abuse laws. We are also currently leading a series of Provider Compliance Training sessions around the country. These sessions have been very successful in educating audiences of health care professionals, including small providers, interested in developing or strengthening their compliance programs.

As we tackle an expanding mission to protect HHS's vital health and human service programs, I would like to express my appreciation to Congress and to the Department for their sustained commitment to supporting the important work of our Office.

Daniel R. Levinson

aniel R. Levinson

Inspector General

Highlights

This edition of the Department of Health & Human Services (HHS) Office of Inspector General (OIG) *Semiannual Report to Congress* addresses the first 6-month period of fiscal year (FY) 2011. It describes the results of our reviews and legal and investigative outcomes and presents recommendations that, when implemented, will save taxpayer dollars, put funds to better use, and/or improve HHS programs and operations and quality of care.

Summary of OIG Accomplishments

For the first half of FY 2011, we reported expected recoveries of about \$3.4 billion consisting of \$222.4 million in audit receivables and \$3.2 billion in investigative receivables (which includes \$620 million in non-HHS investigative receivables resulting from our work in areas such as the States' share of Medicaid restitution).

We reported exclusions of 883 individuals and entities from participation in Federal health care programs; 349 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 197 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters.

Here is an outline of activities and findings that are highlighted in this section of the Semiannual Report.

HEAT: Health Care Fraud Prevention & Enforcement Action Team

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and the Department of Justice (DOJ) to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. OIG's participation in Medicare Fraud Strike Force activities is a key component of HEAT.

Medicare Fraud Strike Force

Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud almost as it occurs. The Strike Force began in March 2007 and is operating in nine major cities. Chicago, Illinois and Dallas, Texas were added during this reporting period. During this semiannual reporting period, Strike Force efforts

have resulted in the filing of charges against 213 individuals or entities, 107 convictions, and \$63.9 million in investigative receivables.

In February 2011, Strike Force teams engaged in an unprecedented Federal health care fraud takedown. Teams across the country arrested more than 100 defendants in 9 cities, including doctors, nurses, health care company owners and executives, and others, for their alleged participation in Medicare fraud schemes involving more than \$225 million in false billing. The defendants are accused of various health-care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft. More than 300 special agents from OIG participated in partnership with other Federal and State agencies, including fellow OIGs. The effectiveness of the Strike Force model is enhanced by interagency collaboration. For example, we refer credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so it can suspend payments to the perpetrators of these schemes. During the February Strike Force operations, OIG and CMS worked to impose payment suspensions that immediately prevented a loss of more than a quarter-million dollars in claims submitted by Strike Force targets.

Medicare and Medicaid Prescription Drugs

■ GlaxoSmithKline LLC Pays \$750 Million To Resolve False Claims Violations

GlaxoSmithKline LLC (GSK) agreed to pay \$750 million as part of a global resolution of allegations under the False Claims Act (FCA), including criminal fines for violations of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA). The Government alleged that between January 1, 2001, and April 1, 2005, GSK, via its now closed subsidiary SB Pharmco, manufactured, distributed, and sold certain batches, lots, or portions of lots of drugs consisting of: Paxil CR that contained some split tablets causing consumers to receive either product with no active ingredient and/or with only the active ingredient layer and no controlled release mechanism; Avandamet that contained some tablets with higher or lower amounts of rosigitazone than specified; Kytril that was labeled as sterile but was, in some vials, nonsterile; and Bactroban ointments and creams that, in some packages, contained microorganisms.

Allergan Pays \$600 Million and Enters Global Settlements

Allergan, Inc., and Allergan USA, Inc. (collectively, Allergan), agreed to pay \$600 million and enter a global criminal, civil, and administrative settlement in connection with improper marketing and promotion practices of Botox. Under the civil settlement agreement, Allergan agreed to pay the Federal Government \$225 million to resolve its liability under the FCA. The settlement resolved allegations that Allergan promoted the sale and use of Botox for a variety of conditions that were not approved by the Food and Drug Administration (FDA),

such as headache, pain, spasticity, and overactive bladder, and that Allergan misled physicians about drug safety and efficacy, instructed health care professionals to miscode claims to Federal health care programs, and offered and paid illegal remuneration to health care professionals as inducements. As part of the settlement, Allergan entered into a comprehensive 5-year corporate integrity agreement (CIA) with OIG.

Medicare Part A and Part B Highlights

Patient Safety and Quality

Of the nearly one million Medicare beneficiaries discharged from hospitals in October 2008, an estimated one in seven (13.5 percent) experienced adverse events during their hospital stays.

To establish an estimated adverse incident rate, we included in our review: the National Quality Forum's list of Serious Reportable Events; Medicare hospital-acquired conditions (HAC); and events resulting in prolonged hospital stays, permanent harm, life-sustaining intervention, or death. The incidence rate projects to about 134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during a single month, with such events contributing to the deaths of a projected 15,000 beneficiaries. Physician reviewers determined that 44 percent of events were preventable, most commonly because of medical errors, substandard care, and inadequate patient monitoring and assessment. Our recommendations to CMS included providing incentives for hospitals to reduce the incidence of adverse events through the agency's payment and oversight functions. We also directed recommendations to the Agency for Healthcare Research and Quality (AHRQ). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. OEI-06-09-00090. Full Report

Questionable Billing

From 2006 to 2008, skilled nursing facilities (SNF) increasingly billed for higher-paying resource utilization groups, even though beneficiary characteristics remained largely unchanged.

In that period, Medicare payments to SNFs for ultra-high therapy increased by nearly 90 percent, rising from \$5.7 billion to \$10.7 billion. For billing purposes, SNFs categorize Medicare beneficiaries into resource utilization groups based on their care and resource needs at various points during their stays. Payment rates are generally higher for beneficiaries who are in groups that require physical, speech, or occupational therapy. SNFs further categorize the level of therapy beneficiaries need primarily by the number of minutes that therapy is provided. The resource utilization groups for ultra-high therapy apply to those beneficiaries needing higher levels of therapy. Medicare generally pays the most for ultra-high-level therapy.

This review raised concerns about the potentially inappropriate use of higher-paying resource utilization groups, particularly those for ultra-high therapy. Our recommendations to CMS included strengthening its monitoring of SNFs that are billing for higher-paying resource utilization groups. *Questionable Billing by Skilled Nursing Facilities*. OEI-02-09-00202. Full Report

■ Medicare Claims for Home Blood-Glucose Test Strips and Lancets

We estimated that about \$169.7 million could have been saved in calendar year (CY) 2007 had controls been in place at three Medicare administrative contractors (MAC) to ensure that claims for blood-glucose test strips and/or lancets complied with certain Medicare documentation requirements.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. Additional requirements apply for reimbursements of claims for quantities of test strips and lancets that exceed the utilization guidelines (referred to high-utilization claims). Our recommendations to CMS's administrative contractors included developing cost-effective ways of determining which claims should be further reviewed for compliance.

Following are three reports completed in this semiannual period: (1) Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets-Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B, A-09-08-00044, Report; (2) Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C, A-09-08-00045, Report; and (3) Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D, A-09-08-00046, Report.

Medicare Part C

Impact on the Medicare Program of Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds

The Medicare program loses potential savings associated with the investment income that Medicare Advantage (MA) organizations earn between the time they receive Medicare prepayments and the time the MA organizations pay for medical services.

The Medicare Part A and Part B trust funds (which finance the MA program) could have earned approximately \$450 million of interest income in CY 2007 had prepayments to MA organizations been delayed until after the beginning of the beneficiary's coverage period by the same number of days that we estimated MA organizations held Medicare the funds before using them to pay for services.

Alternatively, we estimated that Medicare could have saved about \$376 million had MA organizations reduced the revenue requirements in bid proposals to account for anticipated investment income. Our recommendations to CMS included pursuing legislation to adjust the timing of Medicare's prepayments to MA organizations. Rollup Review of Impact on Medicare Program for Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007. A-07-10-01080. Full Report

Medicare Part D

Concerns With Rebates in the Medicare Part D Program

Part D sponsors underestimated rebates in 69 percent of their bids for plan year 2008, which led to higher beneficiary premiums and caused beneficiaries and the Government to overpay for the benefit.

Sponsors' bids to participate in Part D include estimates of the cost to provide benefits to beneficiaries. Sponsors also negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the Government and must include an estimate in their bids of the rebates they expect to receive for the plan year. CMS uses bids to calculate beneficiary premiums for each plan. Underestimating rebates increases beneficiary premiums. Recommendations to CMS included taking steps to ensure that sponsors more accurately include their expected rebates in their bids. *Concerns With Rebates in the Medicare Part D Program*. OEI-02-08-00050. Full Report

Medicaid

New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers

New York State improperly claimed an estimated \$207.6 million in Federal Medicaid reimbursement for rehabilitation services submitted by community residence rehabilitation providers during CYs 2004 through 2007.

New York State elected to include coverage of rehabilitation services provided to recipients residing in community residences (group homes and apartments) in its Medicaid program. Of the 100 claims in our random sample, 31 complied with Federal and State requirements, but 69 did not. Our recommendations to the State Medicaid agency included working with the State's Office of Mental Health to implement guidance to physicians regarding State regulations on the authorization of community residence rehabilitation services. *Review of New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers*.

A-02-08-01006. Full Report

■ Inappropriate Claims for Medicaid Personal Care Services

Our 10-State review revealed that Medicaid paid about \$724 million for the 18 percent of personal care services claims that we determined were inappropriate because personal care attendants' qualifications were undocumented.

The qualifications most often undocumented were background checks, age, and education. We estimated that Medicaid paid an additional 2 percent of claims inappropriately because the respondents had no record of providing services to the beneficiaries. Respondents were agencies or individuals that State Medicaid agency officials indicated we should contact to request documentation to support attendants' qualifications. We reviewed claims paid from September 1, 2006, through August 31, 2007. Our recommendations to CMS included working with States to ensure that Medicaid claims for personal care services provided by attendants with undocumented qualifications are not paid. *Inappropriate Claims for Medicaid Personal Care Services*. OEI-07-08-00430. Full Report

Other Health Care Investigations

Durable Medical Equipment Supplier Sentenced

Oliver Nkuku, a manager for K.O. Medical, Inc. (K.O.), and Callistus Edozie, a K.O. delivery employee, were sentenced to 120 months and 41 months of incarceration, respectively, and ordered to pay \$453,112 and \$80,000 in restitution, jointly and severally, for their roles in a durable medical equipment (DME) fraud scheme related to power wheelchairs and other DME that were medically unnecessary and improperly billed as catastrophe-related in connection with Gulf Coast hurricanes.

Physical Therapy Clinic Submitted Multiple False Claims to Medicare

Bernice Brown, owner of Detroit-area physical therapy clinic Wayne County Therapeutic Inc. (WCT), and Daniel Smorynski, WCT vice president, were convicted on charges of health care fraud for their leading roles in a Medicare fraud scheme. Brown and Smorynski were sentenced to 12 years and 7 months and 9 years in prison, respectively, and were ordered to pay \$6.7 million in restitution jointly and severally. From October 2002 to April 2007, WCT caused the submission of multiple claims to the Medicare program for physical therapy, occupational therapy, and psychotherapy services purportedly provided and supervised by WCT staff when, in fact, such services were not professionally provided or supervised.

Public Health Reviews

■ Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations

Four research and development and information technology contracts with the Centers for Disease Control and Prevention (CDC) did not fully comply with one or more appropriations laws and acquisition regulations with respect to competition, funding, and pricing.

Pursuant to a congressional request, we are conducting a series of reviews of CDC's contracting practices. During this semiannual period, we are reporting the results of our reviews of four contractors. Our recommendations included adhering to established procedures and developing and implementing policies and procedures to address compliance with appropriations statutes and acquisition regulations.

Following are the reports that were completed in this semiannual period: Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor B, A-02-09-02005, Report; Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor C, A-02-09-02006, Report; Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor D, A-04-09-01066, Report; and Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor E, A-04-09-06108, Report.

■ Institutional Conflicts of Interest at National Institutes of Health Grantees

The National Institutes of Health (NIH) lacks information on the number of institutional conflicts that exist among its grantee institutions and the impact these conflicts may have on NIH-sponsored research.

Institutional conflicts of interest may arise when institutions' financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of senior officials pose risks of undue influence on decisions involving the institutions' research. No Federal regulations require NIH grantee institutions to identify and report institutional conflicts to NIH. We surveyed 250 grantee institutions and requested information on any institutional financial interests related to NIH grants awarded in FY 2008. Despite the lack of Federal requirements, 70 of 156 responding NIH grantee institutions had written policies and procedures addressing these interests. We also found that although not required for institutional conflicts, 69 of 156 responding NIH grantee institutions had written policies and procedures addressing such conflicts. Fifty-nine of the sixty-nine institutions defined, in writing, what constitutes an institutional conflict. We recommended that NIH promulgate regulations that address institutional financial conflicts of interest. *Institutional Conflicts of Interest at NIH Grantees*. OEI-03-09-00480. Full Report

Education and Outreach Activities

Roadmap for New Physicians

A recent OIG survey indicated that almost half of medical schools and more than two-thirds of institutions offering residency and fellowship programs reported instructing participants about compliance with Medicare and Medicaid fraud and abuse laws. We developed a guide called *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse* (Roadmap). The package includes a slide presentation and speaker notes. You can view the survey and Roadmap on our Web site at http://www.oig.hhs.gov.

The Roadmap summarizes the five main Federal fraud and abuse laws and instructs physicians how to uphold these laws in their relationships with payers such as the Medicare and Medicaid programs, vendors such as drug, biologic, and medical device companies, and fellow providers such as hospitals, nursing homes, and physician colleagues.

Provider Compliance Training Sessions

In 2011, OIG implemented a Provider Compliance Training initiative. The initiative provides free, high-quality compliance training sessions for medical providers and suppliers, compliance professionals, and attorneys at locations throughout the country. We held three training sessions in the past 6 months. Representatives from OIG, DOJ, CMS, and State Medicaid Fraud Control Units (MFCU) educate communities about fraud risks and share compliance best practices to assist providers in strengthening their compliance efforts.

Most-Wanted Fugitives List

For the first time, we published a <u>Most-Wanted Fugitives</u> list on our Web site, and captures were soon reported. The 10 individuals on the original list allegedly defrauded taxpayers of more than \$126.6 million. As of March 31, 2011, four fugitives from our list had been captured and more were added.

Congressional Testimony

During this semiannual period, we testified at five hearings conducted by committees of Congress on aspects of waste, fraud, and abuse in Medicare and Medicaid. The full text of the testimony is available on our Web site at http://www.oig.hhs.gov/testimony.asp.

■ March 17, 2011—House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.

Daniel R. Levinson, Inspector General, testified about our efforts to monitor and make recommendations to reduce improper payments in Medicare and Medicaid, to oversee HHS's measurement of improper payments and to prevent, detect, and recoup wasteful payments. <u>Testimony</u>

■ March 9, 2011—United States Senate Committee on Homeland Security & Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security

Daniel R. Levinson, Inspector General, testified about our efforts and those of our partners to combat waste, fraud, and abuse in Medicare and Medicaid. <u>Testimony</u>

- March 2, 2011 United States Senate Committee on Finance
 - Daniel R. Levinson, Inspector General, testified about preventing health care fraud: new tools and approaches to combat old challenges. <u>Testimony</u>
- March 2, 2011—House of Representatives Committee on Ways and Means, Subcommittee on Oversight

Lewis Morris, Chief Counsel to the Inspector General, testified about improving efforts to combat health care fraud. <u>Testimony</u>

- March 2, 2011—House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight and Investigations
 - Gerald Roy, Deputy Inspector General for Investigations, testified about waste, fraud, and abuse: a continuing threat to Medicare and Medicaid. <u>Testimony</u>
 - Omar Perez, Assistant Special Agent in Charge, OIG Miami Regional Office, testified about waste, fraud, and abuse: a continuing threat to Medicare and Medicaid. <u>Testimony</u>

Outline of Major Parts and Appendixes

Part I: Medicare Reviews

Part II: Medicaid Reviews

Part III: Legal and Investigative Activities Related to

Medicare and Medicaid

Part IV: Public Health, Human Services, and

Departmentwide Issues

Appendix A: Reporting Requirements of the Inspector

General Act of 1978, as Amended

Appendix B: Questioned Costs and Funds

To Be Put to Better Use

Appendix C: Peer Review Results

Appendix D: Summary of Sanction Authorities Appendix E: Acronyms and Abbreviations

Part I: Medicare Reviews

Medicare	e Part A and Part B	1
Hospi	tals	1
	Adverse Events in Hospitals: National Incidence Among Medicare	
_	Beneficiaries	1
	Payments Exceeding Charges for Outpatient Services Processed by Wisconsin Physicians Service Insurance Corporation for Calendar Years 2004 through 2007	2
Nursi	ng Homes	3
	Payments for Ambulatory Surgical Center Services Provided to	
	Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A	2
	Questionable Billing by Skilled Nursing Facilities	
	Nursing Facilities' Employment of Individuals With Criminal	••••
	Convictions	4
Other	Medicare Services	5
	Questionable Billing for Medicare Outpatient Therapy Services	5
	Medicare Market Shares of Mail Order Diabetic Testing Strips	5
	Medicare Claims for Home Blood-Glucose Test Strips and Lancets	6
Part B	Prescription Drugs	7
	Medicare Payments for Newly Available Generic Drugs	7
	Comparison of Average Sales Prices and Average Manufacturer Prices:	
	Impact on Medicare Reimbursement of Part B Prescription Drugs	8
	Questionable Billing for Brand-Name Inhalation Drugs	9
	Payment for Drugs under the Hospital Outpatient Prospective Payment System	9
Medic	are Part A and Part B Administration	10
	Use of Payment Suspensions to Prevent Inappropriate Medicare Payments	10
	Medicare and Medicaid Fraud and Abuse Training in Medical Education	
	Quality Improvement Organizations' Final Responses to Beneficiary	
	Complaints	11

	Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus	
	on Error-Prone Providers	12
	Complaints Received Through the 1-800-HHS-TIPS Hotline	12
	Medicare Contractor Information Security Program Evaluations for	
	Fiscal Year 2008	12
Medicare	e Part C	13
	Impact on Medicare Program of Investment Income That Medicare	
	Advantage Organizations Earned and Retained From Medicare Funds in	
	2007	13
Medicare	e Part D	14
	Medicare Part D Pharmacy Discounts for 2008	14
	Terminated Drugs in the Medicare Part D Program	
	Erectile Dysfunction Drugs in the Medicare Part D Program	15
	Concerns With Rebates in the Medicare Part D Program	16
	Oversight of the Prescriber Identifier Field in Part D Prescription Drug	
	Event Data for Schedule II Drugs	17

Part II: Medicaid Reviews

Medi	caid Services	1
-	New York's Medicaid Rehabilitative Services Claims Submitted by	
	Community Residence Providers	1
	Washington State's Medicaid Claims for Nonqualified Aliens	1
-	Family Planning Services Claimed by Washington State	2
	Inappropriate Claims for Medicaid Personal Care Services	
	Personal Care Services Provided by Tri-State Home Health and	
	Equipment Services, Inc., in the District of Columbia	3
- 1	Federal Reimbursement Claimed by North Carolina for Medicaid	
	Personal Care Services Claims Submitted by Shipman Family Home	
	Care, Inc	4
	Medicaid Personal Care Services Claims Made by Providers in New York	
	State	5
Madi	caid Recovery Act Reviews	=
wieui		9
	Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in Indiana for the Quarter Ending March 31, 2009	5
	Illinois' Prompt Pay Compliance Under the American Recovery and	
_	Reinvestment Act	6
	Medicaid Prompt Pay Requirements in New Hampshire	
	Alabama's Compliance With the Reserve, or Rainy Day, Fund	•••••
	Requirement for the Increased Federal Medical Assistance Percentage	
	Under the American Recovery and Reinvestment Act	7
Medi	caid Administration	8
	Oversight and Evaluation of the Fiscal Year 2008 Payment Error Rate	
	Measurement Program	8
	Indiana's Reporting of Fund Recoveries for Federal and State Medicaid	
	Programs on the Form CMS-64 for Federal Fiscal Years 2000 Through	0
	2008	8
Othe	r Medicaid-Related Reviews	9
	Contract Signatures for the Hurricane Katrina Health-Care-Related	
	Professional Workforce Supply Grant for the Greater New Orleans Area	9

Part III: Legal and Investigative Activities Related to Medicare and Medicaid

Invest	tigative Outcomes	1
Advis	sory Opinions and Other Guidance	1
Educa	tion and Outreach Activities	2
	Roadmap for New Physicians	2
	Provider Compliance Training Sessions	2
-	Most-Wanted Fugitives List	2
HEAT	: Health Care Fraud Prevention & Enforcement Action Team	3
-	Medicare Fraud Strike Force	3
Other	Criminal and Civil Enforcement Activities	4
	Pharmaceutical Manufacturers and Pharmacies	5
	Hospitals	6
	Durable Medical Equipment Suppliers	7
	Practitioner	8
	Physical Therapy Clinic	8
	Laboratory	8
	Home Health Services	9
-	Skilled Nursing Facility	9
Medio	caid Fraud Control Units	9
-	Joint Investigations	10
Provid	der Self-Disclosure Protocol	10
	Self-Disclosure Guidance to Health Care Providers	11
-	Self-Disclosure Cases	11
Office	e of Inspector General Administrative Sanctions	12
	Program Exclusions	
	Corporate Integrity Agreements	
	Civil Monetary Penalties Law	
	Patient Dumping	14

Part IV: Public Health, Human Services, and Departmentwide Issues

Public H	ealth	1
Cente	rs for Disease Control and Prevention	1
	Centers for Disease Control and Prevention's Accountability for Property	
	Centers for Disease Control and Prevention's Compliance With	
	Appropriations Laws and Acquisition Regulations	2
Foods	and Drug Administration	1
roou a		
	FDA's Approval Status of Drugs Paid for by Medicaid	4
Healtl	n Resources and Services Administration	5
	Ryan White Title II Funding in Pennsylvania	5
	Ryan White Title II AIDS Drug Assistance Program Funding in New	
	Jersey	5
Too diam	Haalth Carrie	
indiar	Health Service	0
	Audit of the Indian Health Service's Internal Controls Over Monitoring	
	of Recipients' Compliance With Requirements of the Loan Repayment Program	6
	Audit of the Indian Health Service's Internal Controls Over Monitoring	
_	of Recipients' Compliance With Requirements of Nursing Program	
	Scholarships	7
	•	
Nation	nal Institutes of Health	
	Institutional Conflicts of Interest at NIH Grantees	7
	Appropriations Funding for National Heart, Lung, and Blood Institute	
	Contract HHSN268-2008-00012C With Information Management	
	Services, Inc.	8
Public	-Health-Related Legal Actions and Investigations	9
_ 3.2 110	Health Education Assistance Loan Program	
	HEAT Evolutions	0

Human S	Services	10
Foster	Care	10
	Allegheny County Title IV-E Foster Care Claims From October 1997 Through September 2002	
Head	Start	10
	District of Columbia Department of Parks and Recreation's Compliance	
	With Health and Safety Regulations for Head Start Programs	10
Job an	nd Family Services	12
	Ohio Department of Job and Family Services Claims for Costs Reported	
	by the Hamilton County Department of Job and Family Services	12
Child-	-Support Enforcement	12
	Child-Support Task Forces	12
-	Child-Support Investigations	
Departm	entwide Issues	13
	Departmental Financial Statement Audit	13
	Non-Federal Audits	
	Contract Audits	
	Grantee Fraud and Misconduct	
	Recovery Act Retaliation Complaint Investigation	
	Legislative and Regulatory Reviews	
	Zegishtive and negatitiony neviews	••••••

Part I: Medicare Reviews

Part I:

Medicare Reviews

Part I:

Medicare Reviews

The Office of Inspector General (OIG) relies on the Department of Health & Human Services (HHS) management, other policymakers in the executive branch, States, and Congress to implement the recommendations that arise from our reviews. Many of our recommendations are directly implemented by organizations within HHS, and some are acted on by States that collaborate with HHS to administer, operate, and/or oversee joint programs, such as Medicaid and Head Start program grants. Congress often incorporates our recommendations into legislative actions, resulting in substantial improvements in HHS programs and operations and in funds being made available for better use.

Medicare Part A and Part B

Hospitals

Medicare > Part A and Part B > Hospitals > Adverse Events

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries

Of the nearly 1 million Medicare beneficiaries who were discharged from hospitals in October 2008, an estimated one in seven (13.5 percent) experienced adverse events during their hospital stays.

To establish an estimated adverse events incident rate, we included in our review:

- the National Quality Forum's Serious Reportable Events;
- Medicare hospital-acquired conditions (HAC); and
- events resulting in prolonged hospital stays, permanent harm, life-sustaining intervention, or death.

The incidence rate projects to about 134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during a single month, with such events contributing to the deaths of a projected 15,000 beneficiaries. Physician reviewers determined that 44 percent of events were preventable, most commonly because of medical errors, substandard care, and inadequate patient monitoring and assessment.

We recommended that Administration for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) broaden patient safety

efforts to include all types of adverse events and enhance efforts to identify events. We also recommended that CMS provide more incentives for hospitals to reduce adverse events through its payment and oversight functions, including strengthening the Medicare HAC policy and holding hospitals accountable for adopting evidence-based practices. AHRQ and CMS concurred with our recommendations. *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. OEI-06-09-00090. Full Report

Medicare > Part A and Part B > Hospitals > Hospital-Based Outpatient Services

■ Payments Exceeding Charges for Outpatient Services Processed by Wisconsin Physicians Service Insurance Corporation for Calendar Years 2004 through 2007

Wisconsin Physicians Service Insurance Corporation (WPS), a Medicare contractor, made incorrect Medicare payments to hospitals in excess of their charges for outpatient services for calendar years (CY) 2004 through 2007. The incorrect payments included overpayments totaling \$9.2 million, which hospitals had not refunded by the start of our audit.

Medicare pays hospitals for outpatient services using the hospital outpatient prospective payment system. In this method of reimbursement, the Medicare payment is not based on the amount that the hospital charges. Consequently, the billed charges (the prices that a hospital sets for its services) do not affect the current Medicare payment amounts. Billed charges generally exceed the amount that Medicare pays the hospital. Therefore, a Medicare payment that significantly exceeds the billed charges is at high risk of overpayment. The incorrect payments involved excessive units of service, Healthcare Common Procedure Coding System (HCPCS) codes that did not reflect the procedures performed, unallowable services, and lack of supporting documentation.

We recommended that WPS recover the \$9.2 million in identified overpayments and use the results of this audit in its hospital education activities. WPS described actions that it had taken or planned to take to address our recommendations. *Review of Payments Exceeding Charges for Outpatient Services Processed by Wisconsin Physicians Service Insurance Corporation for Calendar Years* 2004 Through 2007. A-07-10-04167. Full Report

Part I: Medicare Reviews

Nursing Homes

Medicare > Part A and Part B > Nursing Homes > Part B Payments During Part A Stays

■ Payments for Ambulatory Surgical Center Services Provided to Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A

Medicare contractors made at least an estimated \$6.6 million in overpayments to ambulatory surgical centers (ASC) for services provided to beneficiaries during Part A skilled nursing facility (SNF) stays in CYs 2006 through 2008.

All 100 services that we reviewed, totaling \$103,000, were already included in the SNFs' Part A payments but were nevertheless billed to Medicare Part B. As a result, Medicare paid twice for these services.

We recommended that the CMS instruct its Medicare contractors to: (1) recover the \$103,000 in overpayments for the 100 incorrectly billed services that we identified; (2) review the 20,806 services that we did not review and recover overpayments estimated to total at least \$6.5 million; and (3) provide guidance to ASCs on consolidated billing requirements and the need for timely and accurate communication between ASCs and SNFs about beneficiaries' Medicare Part A status. We also recommended that CMS establish an edit in the Common Working File (CWF) to prevent Part B payments for ASC services that are subject to consolidated billing. Payments for Ambulatory Surgical Center Services Provided to Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A in Calendar Years 2006 through 2008. A-01-09-00521. Full Report

Medicare > Part A and Part B > Nursing Homes > SNF Payment Rules

Questionable Billing by Skilled Nursing Facilities

From 2006 to 2008, SNFs increasingly billed for higher-paying resource utilization groups, even though beneficiary characteristics remained largely unchanged.

In that period, Medicare payments to SNFs for ultra-high therapy increased by nearly 90 percent, rising from \$5.7 billion to \$10.7 billion. For billing purposes, SNFs categorize Medicare beneficiaries into resource utilization groups (RUG) based on their care and resource needs at various points during their stays. Payment rates are generally higher for beneficiaries who are in groups that require physical, speech, or occupational therapy. The RUGs for ultra-high therapy apply to those beneficiaries needing higher levels of therapy. Medicare generally pays the most for ultra-high level therapy. This review raised concerns about the potentially inappropriate use of higher-paying RUGs, particularly those for ultra-high therapy.

We recommended that CMS: (1) monitor overall payments to SNFs and adjust rates, if necessary; (2) change the current method for determining how much therapy is needed to ensure appropriate payments; (3) strengthen monitoring of SNFs that are billing for higher-paying RUGs; and (4) follow up on the SNFs identified as having questionable billing. CMS concurred with three of the four recommendations. It did not concur with the recommendation to change the method for determining how much therapy is needed but stated that it is committed to pursuing improvements to the SNF payment system. We remain concerned that the payment system continues to provide incentives to SNFs to bill for more therapy than is needed, and we strongly encourage CMS to pursue the options we recommended to reduce this vulnerability. *Questionable Billing by Skilled Nursing Facilities*. OEI-02-09-00202. <u>Full Report</u>

Medicare > Part A and Part B > Nursing Homes > Background Checks of Employees

Nursing Facilities' Employment of Individuals With Criminal Convictions

Almost all (92 percent) of nursing facilities in our review employed at least one individual with at least one criminal conviction.

We analyzed criminal history records maintained by the Federal Bureau of Investigation (FBI) and found that overall, 5 percent of nursing facility employees had at least one criminal conviction. Forty-four percent of employees with criminal convictions committed crimes against property such as burglary, shoplifting, and writing bad checks. Most convictions occurred prior to employment. We found that the FBI's records do not contain information on whether the victim of a crime was a nursing facility resident and therefore cannot be used by themselves to determine whether a conviction disqualifies an individual from nursing facility employment. We also found that most States required, and/or nursing facilities reported conducting, some type of background check.

The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires the Secretary of HHS to carry out a nationwide program for States to conduct national and statewide criminal background checks for direct patient access employees of nursing facilities and other providers. States may participate in the national background check program by entering into agreements with the Secretary.

In light of the background check program that the Affordable Care Act created, we recommended that CMS develop background check procedures, including (1) clearly defining the employee classifications that are direct patient access employees and (2) working with participating States to develop a list of convictions that disqualify an individual from nursing facility employment under the Federal regulation and timeframes in which each conviction bars the individual from employment. CMS agreed with our recommendation. *Nursing Facilities' Employment of Individuals With Criminal Convictions*. OEI-07-09-00110. Full Report

Other Medicare Services

Medicare > Part A and Part B > Outpatient Therapy Services

Questionable Billing for Medicare Outpatient Therapy Services

Medicare's per-beneficiary spending on outpatient therapy services in Florida's Miami-Dade County was three times the national average in 2009.

We identified 20 high-utilization counties that had, in 2009, (1) the highest average Medicare payment per beneficiary and (2) more than \$1 million in total Medicare payments for outpatient therapy. We analyzed Miami-Dade County separately from the other 19 counties because it had the highest average Medicare payments per beneficiary among the high-utilization counties and the highest total Medicare payments for outpatient therapy in 2009. Medicare's per-beneficiary spending on outpatient therapy services to the 19 other high-utilization counties as a group was 72 percent greater than the national average. We found that for five of six questionable billing characteristics that may indicate fraud, Miami-Dade's levels were at least three times the national levels. The other 19 counties also exhibited questionable billing. As a group, the other 19 counties had at least twice the national levels for five of the six questionable billing characteristics.

We recommend that CMS (1) target outpatient therapy claims in high-utilization areas for further review, (2) target outpatient therapy claims with questionable billing characteristics for further review, (3) review geographic areas and providers with questionable billing and take appropriate action based on results, and (4) revise the current therapy cap exception process. CMS concurred with the recommendations. *Questionable Billing for Medicare Outpatient Therapy Services*. OEI-04-09-00540. Full Report

Medicare > Part A and Part B > Medical Equipment and Supplies > Diabetic Testing Strips

■ Medicare Market Shares of Mail Order Diabetic Testing Strips

We found that suppliers submitted claims for at least 75 types of mail order diabetic testing strips during the 3-month period ending December 2009. We projected that 2 types accounted for approximately 26 percent of the Medicare mail order market share, 7 types accounted for approximately 50 percent, and 19 types accounted for approximately 81 percent.

Section 154(d)(3)(B) of the Medicare Improvements for Patients and Providers Act (MIPPA) requires OIG to complete this review to determine market shares of diabetic testing strips. MIPPA requires that future rounds of Competitive Bidding Program contracts for mail order diabetic testing strips be awarded to suppliers who provide at least 50 percent, by volume, of all types of mail order diabetic testing strips (the MIPPA 50-percent requirement). Our findings may help in determining

whether future rounds of suppliers' mail order diabetic test strip bids comply with the MIPPA 50-percent requirement. Our report provided the data requested by MIPPA but did not make recommendations. *Medicare Market Shares of Mail Order Diabetic Testing Strips*. OEI-04-10-00130. Full Report

Medicare > Part A and Part B > Medical Equipment and Supplies > Blood-Glucose Test Strips and Lancets

■ Medicare Claims for Home Blood-Glucose Test Strips and Lancets

We estimated that about \$169.7 million could have been saved for CY 2007 had controls been in place at four Medicare administrative contractors to ensure that claims for blood-glucose test strips and/or lancets complied with certain Medicare documentation requirements.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. Additional requirements apply for reimbursements of claims for quantities of test strips and lancets that exceed the utilization guidelines (referred to as high-utilization claims).

To help achieve potential savings for the Medicare program in the future, we recommended that the contractors (1) implement system edits to identify high-utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements; (2) implement system edits to identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary; and (3) enforce Medicare documentation requirements for claims for test strips and/or lancets by identifying durable medical equipment (DME) suppliers with a high volume of high utilization claims, performing prepayment reviews of those suppliers, and referring them to the OIG or CMS for further review or investigation when necessary. Following are the contractor names and audit report titles and numbers for our reviews.

- National Government Services, Inc. Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B. A-09-08-00044. Full Report
- CIGNA Government Services, LLC and Palmetto Government Benefits Administrators, LLC. Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C. A-09-08-00045. Full Report
- Noridian Administrative Services, LLC. Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D. A-09-08-00046. Full Report

Part B Prescription Drugs

Medicare > Part A and Part B > Part B Prescription Drugs > Payment Calculations

■ Medicare Payments for Newly Available Generic Drugs

Medicare and its beneficiaries could have saved an estimated \$111 million had payment amounts reflected actual sales prices during the initial period in which 16 generic drugs became available.

The potential savings account for 25 percent of total expenditures for the drugs during the same period. We found that during the period of initial generic availability, generic versions of these drugs were being administered or dispensed to beneficiaries, but Medicare was still paying brand prices. Manufacturers are required to submit average sales price (ASP) data to CMS within 30 days after the close of each quarter, and those data are used to calculate the payment amounts for the following quarter. As a result, there is a two-quarter lag between the point at which drug sales occur and when the payment amounts reflect those sales. This lag is especially problematic when newly available generic drugs enter the market because their ASPs are often substantially lower than their brand counterparts; however, payment amounts remain at the higher brand level for two quarters or more. According to the Food and Drug Administration (FDA), 26 of the 48 brand-only drugs with the highest Part B expenditures in 2008 could have first generic versions approved in the next several years, meaning that the vulnerability posed by the two-quarter lag likely will continue to grow.

We recommended that CMS work with Congress to require manufacturers of first generics to submit monthly ASP data during the period of initial generic availability. This could substantially reduce the two-quarter lag and make Medicare payment amounts more reflective of market prices. If CMS finds this to be an effective means for alleviating the financial impact of the two-quarter lag, it could consider requiring monthly ASP submissions for all Part B-covered drugs. CMS did not concur with our recommendation, citing potential problems with manufacturer price submissions and increased administrative burdens under a proposed monthly ASP reporting requirement. We maintain that the savings from a reduced reimbursement lag may outweigh any issues involved with implementing a monthly ASP reporting system. *Medicare Payments for Newly Available Generic Drugs*. OEI-03-09-00510. Full Report

■ Comparison of Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement of Part B Prescription Drugs

The Social Security Act, § 1847A(d), requires OIG to compare ASPs to average manufacturers prices (AMP) and notify the Secretary of HHS if the ASP for a particular drug exceeds the drug's AMP by a threshold of 5 percent. If the 5-percent threshold is met, pursuant to section 1847A(d)(3)(A), the Secretary may disregard the ASP for the drug when setting reimbursement and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. Although CMS has yet to make any changes to Part B drug reimbursement as a result of the reviews, the agency published a proposed rule at 75 Fed. Reg. 40040, 40259 (July 13, 2010) that specified circumstances under which AMP-based price substitutions would occur. However, the agency opted not to finalize the price substitution policy from the proposed rule. Some of OIG's previous reports comparing ASPs and AMPs have contained recommendations, which we continue to support. We did not make additional recommendations in the reports below.

- First-Quarter 2010: Impact on Third Quarter 2010. We identified 38 HCPCS codes with ASP that exceeded AMP by at least 5 percent in the first quarter of 2010. Of these, 13 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If reimbursement amounts for all 13 codes with complete AMP data had been based on 103 percent of the AMPs during the third quarter of 2010, we estimate that Medicare expenditures would have been reduced by about \$988,000 in that quarter alone. If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 10 of the 13 drugs with complete AMP data would have been reduced, resulting in estimated savings of \$840,000 in the third quarter of 2010. We could not compare ASPs and AMPs for 68 HCPCS codes because AMP data were not submitted for any of the national drug codes (NDC) that CMS used to calculate reimbursement. Manufacturers for 23 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010. OEI-03-10-00440. Full Report
- Second-Quarter 2010: Impact on Fourth Quarter 2010. We identified 25 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the second quarter of 2010. Of these, 10 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If reimbursement amounts for all 10 codes with complete AMP data had been based on 103 percent of the AMPs during the fourth quarter of 2010, we estimate that Medicare

expenditures would have been reduced by \$713,000 in that quarter alone. We could not compare ASPs and AMPs for 54 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for 16 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. *Comparison of Second-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010.* OEI-03-11-00030. Full Report

Medicare > Part A and Part B > Part B Prescription Drugs > Inhalation Drugs

Questionable Billing for Brand-Name Inhalation Drugs

Medicare payments to South Florida suppliers for the inhalation drug budesonide were reduced by almost half after Medicare implemented a utilization edit for the drug in September 2008. However, the decreases were offset by payments for the inhalation drug arformoterol (for which there was no edit), which then more than doubled within 6 months. Medicare paid South Florida suppliers for up to 10 times more units of arformoterol than were distributed for sale in the geographic area.

The substantial difference between the sales data provided by arformoterol's manufacturer and the claims data for South Florida suppliers suggests that these suppliers were billing for drugs that may not have been actually purchased.

We recommended that CMS (1) require DME contractors to implement utilization edits in high-fraud areas as soon as Medicare begins paying for a brand-name drug, (2) monitor utilization changes among brand-name inhalation drugs, (3) strengthen initial claim review processes to focus on prevention of improper payments, and (4) perform site visits and request documentation to support budesonide and arformoterol billings from the South Florida suppliers that we will refer for further review. CMS concurred with our recommendations; however, the concurrence with our first recommendation included the caveat that certain procedures, such as developing and issuing a local coverage determination, would need to be followed before implementing edits. *Questionable Billing for Brand-Name Inhalation Drugs in South Florida*. OEI-03-09-00530. Full Report

Medicare > Part A and Part B > Part B Prescription Drugs > Hospital-Based Outpatient Prescription Drugs

Payment for Drugs under the Hospital Outpatient Prospective Payment System

We found that Medicare payments were 31 percent higher than acquisition costs among responding hospitals that participate in the Public Health Service Act section

340B drug pricing program (340B Program) and 1 percent higher than acquisition costs among responding non-340B hospitals for selected separately payable drugs.

The 340B Program, which is overseen by the Health Resources and Services Administration (HRSA), was created to assist entities that provide services to disproportionately low-income, uninsured, and underinsured populations and allow them to purchase drugs at reduced prices. Under the 340B Program, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for certain sales to certain covered entities.

The hospital Outpatient Prospective Payment System (OPPS) was implemented to pay hospitals for Part B outpatient services including, but not limited to, certain Part B-covered drugs. The OPPS payment for drugs is generally divided into two categories: separately payable drugs and packaged drugs. For more than half of the selected drugs, Medicare payments exceeded non-340B hospital acquisition costs. For the remaining drugs, Medicare payments were below average non-340B acquisition costs by between 0.6 and 11 percent. This report did not contain recommendations. *Payment for Drugs Under the Hospital Outpatient Prospective Payment System*. OEI-03-09-00420. Full Report

Medicare Part A and Part B Administration

Medicare > Part A and Part B > Administration > Program Integrity > Payment Suspensions

■ Use of Payment Suspensions to Prevent Inappropriate Medicare Payments

We found that CMS used payment suspensions in 2007 and 2008 almost exclusively as a tool to fight fraud, though the sanction is available in overpayment circumstances short of fraud, and that CMS's guidance on payment suspensions to its contractors has incomplete or inconsistent requirements. In particular, guidance lacks specificity in terms of the types of information that its contractors should submit with a request for a suspension, as well as in describing the circumstances in which an extension is permitted.

After we collected data for this evaluation, the Affordable Care Act established new provisions for payment suspensions. The Affordable Care Act states that a provider's payments may be suspended based on a credible allegation of fraud, unless there is good cause not to suspend such payments. The statute also requires CMS to consult with OIG in determining whether a credible allegation of fraud exists. On September 23, 2010, CMS issued proposed regulations at 75 Fed. Reg. 58204, 58239 (Sept. 23, 2010) for these provisions. In finalizing the regulations and developing related guidance, CMS could also address the inconsistencies that this report identified. The report did not contain recommendations. *The Use of Payment Suspensions To Prevent Inappropriate Medicare Payments*. OEI-01-09-00180. Full Report

Medicare > Part A and Part B > Administration > Program Integrity

■ Medicare and Medicaid Fraud and Abuse Training in Medical Education

Despite lack of a Federal requirement, 44 percent of medical schools and 68 percent of institutions offering residency and fellowship programs reported providing instruction to students and participants on compliance with Medicare and Medicaid fraud and abuse laws in 2010.

Almost all the medical schools and institutions offering residency and fellowship programs that we reviewed expressed interest in receiving OIG-provided instructional materials relating to Medicare and Medicaid fraud and abuse. Most respondents expressed interest specifically in more information about the civil False Claims Act (FCA), the anti-kickback statute, and the physician self-referral statute.

Accordingly, OIG decided to (1) prepare educational materials appropriate for medical schools and institutions offering residency and fellowship programs, (2) distribute the materials to those medical schools and institutions that sponsor residency and fellowship programs, and (3) seek feedback from the medical schools and institutions offering residency and fellowship programs on ways to improve the materials. *Medicare and Medicaid Fraud and Abuse Training in Medical Education*. OEI-01-10-00140. Full Report

Medicare > Part A and Part B > Administration > Quality Improvement Organizations

Quality Improvement Organizations' Final Responses to Beneficiary Complaints

Our review covering August 1, 2008, through December 31, 2009, showed that most Quality Improvement Organizations' (QIO) responses to beneficiary complaints are meeting applicable standards and CMS's additional criteria that apply when the involved practitioners provide consent for disclosure.

CMS contracts with QIOs, which, among other responsibilities, review written complaints from Medicare beneficiaries about the quality of care the beneficiaries received and, at the conclusion of such reviews, send to the beneficiaries final responses summarizing the findings of the reviews. We found that of the 120 QIO final responses to Medicare beneficiaries' complaints that we reviewed in detail, 116 met requirements. However, we found that QIOs do not obtain consent for disclosure from almost half of the practitioners involved. Medicare regulations allow practitioners to refuse to give consent to the QIOs' release of information in final reports that identify them. We made no recommendations based on this review. *Quality Improvement Organizations' Final Responses to Beneficiary Complaints*. OEI-01-09-00620. Full Report

Medicare > Part A and Part B > Administration > Program Inegrity > Error-Prone Providers

■ Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus on Error-Prone Providers

Although Medicare payment contractors developed corrective actions based on available error rate data, they typically did not focus on error-prone providers for review and corrective action.

Using the reported error rate data from the Hospital Payment Monitoring Program and the Comprehensive Error Rate Testing (CERT) program for fiscal years (FY) 2005 through 2008, we identified 740 error-prone providers. These providers accounted for a significant portion of the total dollars in error in the sampled years. Focusing on error-prone providers for corrective action and repayment of improper payments could improve the effectiveness of CMS's efforts to reduce improper payments.

We recommended that CMS (1) use available error rate data to identify error-prone providers, (2) require error-prone providers to identify the root causes of claim errors and to develop and implement corrective action plans, (3) monitor provider-specific corrective action plans, and (4) share error rate data with its contractors to assist in identifying improper payments. CMS concurred with our recommendations. *Centers for Medicare & Medicaid Services' Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus on Error-Prone Providers*. A-05-08-00080. Full Report

Medicare > Part A and Part B > Administration > Program Integrity > Hotline

Complaints Received Through the 1-800-HHS-TIPS Hotline

Our review revealed that as of March 2010, CMS had resolved or closed administratively 88 percent of the complaints it received during the first 6 months of 2008 from the 1-800-HHS-TIPS hotline. CMS and contractor staff reported the need for written guidance for processing hotline complaints.

We recommended that CMS (1) issue written guidance to its own staff and contractor staff for processing hotline complaints and (2) upgrade its information system for processing complaints. CMS concurred with our recommendations. CMS's Processing of Complaints Received Through the 1-800-HHS-TIPS Hotline. OEI-07-09-00020. Full Report

Medicare > Part A and Part B > Administration > Program Integrity > Information Security

Medicare Contractor Information Security Program Evaluations for Fiscal Year 2008

We found that the PricewaterhouseCoopers LLP (PwC) information security program evaluations for FY 2008 were adequate in scope and sufficiency. However,

we could not determine the scope and sufficiency of work performed by JANUS Associates, Inc. (JANUS) because of several issues with its working papers.

Pursuant to the Social Security Act, § 1874A(e)(2)(C)(ii), we assessed the scope and sufficiency of Medicare contractor information security program evaluations and data center technical assessments. OIG is required to report to Congress annually on the results of these contractor-conducted evaluations.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added information security requirements for Medicare contractors to the Social Security Act. Each Medicare contractor must have its information security program evaluated annually by an independent entity. To comply with this provision, CMS contracted with PwC to evaluate information security programs at the contractors using a set of agreed-upon procedures. The Social Security Act also requires evaluations of the information security controls for a subset of systems. To satisfy this requirement, CMS developed an information security assessment methodology and contracted with JANUS to perform technical assessments at Medicare datacenters using the methodology.

We recommended that CMS review all contractor documentation related to future data center technical assessments and ensure that the work performed complies with CMS contractual requirements. At a minimum, this should include a review of test plans to ensure that the contractor has completed all required testing procedures and a review of contractor working papers to verify that reported gaps have been adequately supported, identified, and included in the technical assessment reports. CMS concurred with our recommendation and stated that it would take the appropriate actions to address the identified issues. *Review of Medicare Contractor Information Security Program Evaluations for Fiscal Year 2008*. A-18-09-30200. Full Report

Medicare Part C

Medicare > Part C > Prepayments to MA Organizations

■ Impact on Medicare Program of Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007

The Medicare program loses potential savings associated with investment income that Medicare Advantage (MA) organizations earn between the time that they receive Medicare prepayments and the time that the MA organizations pay for medical services.

We estimated that in CY 2007 MA organizations held Medicare funds for about 46 days before paying for medical services. The Medicare Part A and Part B trust

funds (which finance the MA program) could have earned approximately \$450 million of interest income in CY 2007 had prepayments to MA organizations been delayed until after the beginning of the beneficiary's coverage period by the same number of days that we estimated MA organizations held the Medicare funds.

Alternatively, we estimated that Medicare could have saved about \$376 million that 457 MA organizations earned in CY 2007 had Federal requirements been established to require MA organizations to reduce their revenue requirements in bid proposals to account for anticipated investment income. In contrast to the Federal requirements that govern the MA program, the Federal Employees Health Benefits (FEHB) program limits the ability of companies to retain as additional revenue the investment income earned from Federal funds.

We recommended that CMS evaluate the audit results and either (1) pursue legislation to adjust the timing of Medicare's prepayments to MA organizations to account for the time that these organizations invest Medicare funds before paying providers for medical services, or (2) develop and implement regulations that require MA organizations to reduce their revenue requirements in bid proposals to account for anticipated investment income. CMS did not concur with our recommendations because of concern that the implementation of either option would cause most MA organizations to increase their bid proposals to recoup the investment income that they would lose, which would result in a decrease in most or all of the estimated cost savings. CMS noted that it could be asked to pay interest on the additional payments that CMS frequently makes to MA organizations after the completion of the risk adjustment reconciliation each year. *Rollup Review of Impact on Medicare Program for Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007*. A-07-10-01080. Full Report

Medicare Part D

Medicare > Part D > Pharmacy Discounts

■ Medicare Part D Pharmacy Discounts for 2008

For five of the six sponsors we reviewed, pharmacy discounts negotiated by pharmacy benefit managers on behalf of Part D sponsors were not always passed on to beneficiaries and to the Government. These discounts directly affect the amount that beneficiaries and the Government pay for drugs.

This report, which does not make recommendations, provides information about how third-party pharmacy benefit managers negotiate with pharmacies on behalf of Part D sponsors for discounts on Part D drug prices.

The Part D sponsors we reviewed relied on pharmacy benefit managers to negotiate the discounts. Pharmacies generally accepted the lower prices negotiated by pharmacy benefit managers because participating in sponsors' networks increased

the number of beneficiaries who used their pharmacies. For brand-name drugs, the pharmacy discounts were based on average wholesale prices and varied by the length of supply, pharmacy type, and geographic location, whereas discounts for generic drugs were based on prices established by the pharmacy benefit managers. *Medicare Part D Pharmacy Discounts for 2008.* OEI-02-10-00120. Full Report

Medicare > Part D > Terminated Drugs

■ Terminated Drugs in the Medicare Part D Program

Of the approximately \$115 billion in gross drug costs included in Medicare Part D sponsors' prescription drug event (PDE) data for CYs 2006 and 2007, CMS accepted PDE data totaling \$112.1 million associated with 2,967 terminated drugs.

Terminated drugs are discontinued drugs that have passed their shelf life or drugs that have been pulled from the market for health or safety reasons. Such medications could be weak, ineffective, or detrimental to beneficiaries' health. However, Federal regulations do not specifically prohibit coverage of terminated drugs under the Part D program. After the close of the coverage year, CMS is responsible for reconciling prospective payments made to Part D sponsors with actual costs. This reconciliation is based on final PDE data.

We recommended that CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs and, in the interim, publish a list of these drugs on its Web site. CMS did not concur and questioned our reliance on the termination dates reported by drug manufacturers for use in the Medicaid program. CMS also disagreed that terminated drugs were actually dispensed to Medicare beneficiaries. *Review of Terminated Drugs in the Medicare Part D Program*. A-07-09-03130. Full Report

Medicare > Part D > Drug Categories

■ Erectile Dysfunction Drugs in the Medicare Part D Program

Of approximately \$133 billion in gross drug costs included in private prescription drug plans' and MA plans' (collectively known as sponsors) PDE data for CYs 2007 and 2008, CMS improperly accepted PDE data totaling \$3.1 million in gross Medicare Part D drug costs for erectile dysfunction (ED) drugs approved only for the treatment of sexual or erectile dysfunction.

Pursuant to the Social Security Act, § 1860D-2(e)(2)(A), effective January 1, 2007, Part D should not have covered these drugs. According to CMS officials, the software edit in place in CMS's Medicare Drug Data Processing System during our audit period did not prevent CMS from accepting PDE data for some ED drugs in CY 2007 and most of CY 2008 because the Part D program used an incomplete list of excluded drugs as the basis for the edit. Although the officials indicated that CMS

had updated its list of ED drugs in CY 2008, CMS accepted PDE data for some ED drugs during our entire audit period.

We recommended that CMS (1) determine whether it can impose financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction and (2) strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by collaborating with FDA to create and maintain a comprehensive list of ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction, regularly disseminating this list to all sponsors, and periodically updating the edit used to reject PDE data for ED drugs used for the treatment of sexual or erectile dysfunction. CMS partly agreed and partly disagreed with our recommendations. *Review of Erectile Dysfunction Drugs in the Medicare Part D Program.* A-07-10-03143. Full Report

Medicare > Part D > Rebates

■ Concerns With Rebates in the Medicare Part D Program

Part D sponsors underestimated rebates in 69 percent of their bids for plan year 2008, which led to higher beneficiary premiums and caused both beneficiaries and the Government to overpay for the benefit.

Part D is Medicare's optional prescription drug program. Private insurance companies, known as sponsors, provide drug coverage to beneficiaries who choose to enroll. Sponsors' bids to participate in Part D include estimates of the cost to provide the benefit to each beneficiary. CMS uses bids to calculate beneficiary premiums for each plan. Sponsors also negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the Government. Sponsors must include an estimate in their bids of the rebates they expect to receive for the plan year. Underestimating rebates increases beneficiary premiums. Sponsors may pass rebates on to beneficiaries at the point of sale to reduce beneficiaries' drug costs and copayments, but they commonly did not. Our review revealed that Medicare Part D sponsors reported receiving \$6.5 billion in drug manufacturer rebates in 2008.

Our review also revealed that some sponsors reported large differences in rebates across their plans and received manufacturer rebates when they encouraged beneficiaries to use certain drugs. Some sponsors had complex contractual relationships with their third-party pharmacy benefit managers that sometimes lacked transparency, and some reported that their pharmacy benefit managers collected fees from drug manufacturers that were not always passed on to the Part D program.

We recommended that CMS: (1) take steps to ensure that sponsors more accurately include their expected rebates in their bids, (2) require sponsors to use methods CMS

deems reasonable to allocate rebates across plans, (3) ensure that sponsors have sufficient audit rights and access to rebate information, and (4) ensure that sponsors appropriately report the fees that pharmacy benefit managers collect from manufacturers. CMS concurred with our first recommendation and partially concurred with our fourth recommendation. *Concerns With Rebates in the Medicare Part D Program.* OEI-02-08-00050. Full Report

Medicare > Part D > Prescription Drug Event Data

Oversight of the Prescriber Identifier Field in Part D Prescription Drug Event Data for Schedule II Drugs

Our audit of PDE records for drugs classified as Schedule II pursuant to the Controlled Substances Act revealed approximately 228,000 PDE records with invalid prescriber identifiers, accounting for about \$20.6 million in gross drug costs for CY 2007.

Without valid identifiers from sponsors, CMS and its Part D contractors might not be able to monitor excessive prescribing patterns, determine whether a prescription was written by an excluded or deceased provider, or identify those physicians who illegally prescribe Schedule II drugs. Schedule II drugs have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused. With limited guidance and edits in place for the prescriber identifier field, CMS and Medicare Part D sponsors did not identify the invalid prescriber identifiers that we found. In addition, because of invalid prescriber identifiers, we were unable to identify top prescribers for oxycodone, Ritalin, and methadone, which are three Schedule II drugs that are frequently involved in health care investigations.

We recommended that CMS (1) issue specific guidance requiring sponsors to include a valid Drug Enforcement Administration (DEA) number on standard and nonstandard format PDE records involving Schedule II drugs and (2) implement an edit to reject PDE records for Schedule II drugs when the prescriber identifier field contains an invalid prescriber identifier number. CMS did not concur. It believes that the DEA number is not suitable as a single identifier because only a fraction of PDE volume involves Schedule II drugs. *Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs*. A-14-09-00302. Full Report

Part II: Medicaid Reviews

Part II:

Medicaid Reviews

Part II: Medicaid Reviews

Part II:

Medicaid Reviews

Medicaid Services

Medicaid Services > Community Rehabilitation Providers > Federal Share > New York

New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers

New York State improperly claimed an estimated \$207.6 million in Federal Medicaid reimbursement for rehabilitation services submitted by community residence rehabilitation providers during calendar years (CY) 2004 through 2007.

New York State elected to include coverage of rehabilitation services provided to recipients residing in community residences (group homes and apartments) in its Medicaid program. Of the 100 claims in our random sample, 31 complied with Federal and State requirements, but 69 did not. The deficient claims lacked one or more elements such as the required physicians' authorizations or reauthorizations for rehabilitation services, a service of at least 15 minutes, and/or a service plan reviewed and signed by a qualified mental health staff member.

We recommended that the State (1) refund \$207.6 million to the Federal Government and (2) work with the State's Office of Mental Health to implement guidance to physicians regarding State regulations on the authorization of community residence rehabilitation services. The State disagreed with our first recommendation and agreed with our second recommendation. *Review of New York's Medicaid Rehabilitative Services Claims Submitted by Community Residence Providers*. A-02-08-01006. Full Report

Medicaid Services > Nursing Homes > Federal Share > Washington State

Washington State's Medicaid Claims for Nonqualified Aliens

Washington State claimed an estimated \$1.5 million (\$760,000 Federal share) for nursing home services provided to nonqualified alien beneficiaries without prior approval from a State medical consultant or to beneficiaries who were misclassified and not eligible for the Alien Emergency Medical (AEM) program.

The State also claimed \$6,000 (\$3,000 Federal share) for various medical services provided to treat conditions that were not authorized. Finally, the State claimed \$1.5 million (\$744,000 Federal share) for prescription drugs and \$369,000 (\$185,000 Federal share) for dental services that the State agency could not determine were

related to treating emergency medical conditions. Federal Medicaid funding is available to States for medical services provided to nonqualified aliens only when those services are necessary to treat an emergency medical condition. A nonqualified alien is an individual who is not a citizen or national of the United States and is not in a satisfactory immigration status.

We recommended that the State (1) refund \$763,000 to the Federal Government for nursing home and medical services that were improperly claimed, (2) work with the Centers for Medicare & Medicaid Services (CMS) to determine what portion of the \$1.9 million (\$929,000 Federal share) claimed for prescription drugs and dental services was related to emergency medical conditions and refund any improperly claimed amounts, (3) ensure that only nursing home claims that receive prior approval from a State medical consultant and that are eligible for the AEM program are claimed for reimbursement, (4) ensure that the Medicaid cards issued to nonqualified aliens limit services to those necessary to treat conditions defined as emergency medical conditions, and (5) ensure that the Medicaid Management Information System (MMIS) edits limit claims for services provided to nonqualified aliens to emergency medical conditions or to services approved by a State medical consultant. The State concurred with our recommendations. *Review of Washington State's Medicaid Claims for Nonqualified Aliens*. A-09-09-00039. Full Report

Medicaid Services > Family Planning > Federal Share > Washington State

Family Planning Services Claimed by Washington State

From October 1, 2005, through September 30, 2008, Washington State improperly claimed about \$18.7 million Federal share of medical services and supplies at the 90-percent enhanced rate for family planning that should have been claimed at the regular rate.

Contrary to State requirements, the claims for services did not contain approved primary diagnosis codes, and the claims for supplies did not contain approved therapeutic classification codes. By calculating the difference between what the State agency claimed and what it should have claimed, we determined that the Federal Government overpaid the State agency almost \$8.5 million in Federal share. This overpayment occurred because the State agency's MMIS controls did not properly distinguish claims eligible for reimbursement at the 90-percent rate from claims eligible for reimbursement at the regular Federal medical assistance percentage (FMAP) rate. The Federal share of the Medicaid program is determined by the FMAP, which was 50 percent during our audit period; family planning claims were reimbursed at 90 percent.

We recommended that the State (1) refund \$8.5 million to the Federal Government and (2) identify and refund any overpayments for family planning claims before October 1, 2005, that did not contain approved primary diagnosis or therapeutic classification codes identifying the claims as eligible for reimbursement at the

90-percent rate. The State concurred with our findings and our first recommendation. Regarding our second recommendation, the State said that because it had implemented a new MMIS in May 2010, it was unable to review medical claims submitted before December 2005 or pharmacy claims submitted before April 2006. A-09-09-00049. *Review of Family Planning Services Claimed by Washington State During the Period October 1, 2005, Through September 30, 2008*. Full Report

Medicaid Services > Personal Care > Federal Share > 10-State Review

Inappropriate Claims for Medicaid Personal Care Services

Our 10-State review revealed that Medicaid paid about \$724 million for personal care services claims that we determined were inappropriate because personal care attendants' qualifications were undocumented. These claims represented 18 percent of our universe.

The qualifications most often undocumented were background checks, age, and education. We estimated that Medicaid paid an additional 2 percent of claims inappropriately because the respondents had no record of providing services to the beneficiaries. Respondents were agencies or individuals that State Medicaid agency officials indicated we should contact to request documentation to support attendants' qualifications. We reviewed claims paid from September 1, 2006, through August 31, 2007. We recommended that CMS work with States to ensure that Medicaid claims for personal care services provided by attendants with undocumented qualifications are not paid and take action regarding the inappropriately paid claims identified in our review. CMS concurred with both recommendations. *Inappropriate Claims for Medicaid Personal Care Services*. OEI-07-08-00430. Full Report

Medicaid Services > Personal Care > Federal Share > District of Columbia

Personal Care Services Provided by Tri-State Home Health and Equipment Services, Inc., in the District of Columbia

From July 1, 2006, through September 30, 2007, the District of Columbia (the District) paid Tri-State Home Health and Equipment Services, Inc. (Tri-State), an estimated \$1.6 million (\$1.1 million Federal share) for personal care services that were not provided or that did not comply with the Medicaid plan or waiver requirements for allowable hours of service.

The District's Medicaid plan authorizes personal care services, which provide assistance with activities of daily living, including bathing, grooming, and eating, for up to 8 hours per day and 1,040 hours during any 12-month period. The District also provides personal care services through a section 1915(c) waiver that allows up to 16 hours of services per day.

We set aside for CMS's adjudication another \$1.2 million (\$808,000 Federal share) paid on behalf of 44 beneficiaries for whom Tri-State claimed hours of service under the waiver. Tri-State documented that it had submitted requests for waiver services for these beneficiaries but did not have evidence that it had received preauthorization for services under the waiver. We also determined that the District did not ensure that all of Tri-State's personal care aides met the District's qualification requirements.

We recommended that the District (1) refund the \$1.1 million Federal share for claims in excess of State plan limits paid without documentation of the required authorization, (2) refund \$5,000 for claims paid for services that were not provided, (3) work with CMS to determine the allowability of \$808,000 paid for waiver claims for which preauthorization of services was not adequately supported, (4) implement prepayment controls to monitor personal care service claims for compliance with Federal and District requirements, and (5) provide more effective monitoring of personal care aides' compliance with qualification requirements. The District concurred with our recommendations and described the actions that it had taken, or planned to take, to address them. Review of Personal Care Services Provided by Tri-State Home Health and Equipment Services, Inc., in the District of Columbia. A-03-08-00207. Full Report

Medicaid Services > Personal Care > Federal Share > North Carolina

Federal Reimbursement Claimed by North Carolina for Medicaid Personal Care Services Claims Submitted by Shipman Family Home Care, Inc.

North Carolina improperly claimed an estimated \$1.3 million Federal share for unallowable personal care services during the period July 1, 2005, through June 30, 2007.

Of the 100 sampled claim line items in our random sample, 44 complied with Federal and State requirements, but 56 did not. Of the 56 items that were not compliant, 24 contained more than 1 deficiency. These deficiencies occurred because the State's Division of Medical Assistance did not have sufficient resources to adequately monitor Shipman Family Home Care, Inc.'s (Shipman) personal care services program for compliance with certain Federal and State requirements. Personal care services are generally furnished to individuals in their homes and not residing in hospitals, nursing facilities, or institutions.

We recommended that the State (1) refund the improperly claimed \$1.3 million Federal share to the Federal Government and (2) continue its efforts to implement additional procedures and controls for monitoring the providers of personal care services for compliance with Federal and State requirements. Shipman acknowledged that some of its claims were noncompliant but believed that these claims were anomalous and not representative of its general compliance efforts.

The State concurred with all of our findings and found the recommendations to be both reasonable and appropriate. *Review of Federal Reimbursement Claimed by North Carolina for Medicaid Personal Care Services Claims Submitted by Shipman Family Home Care, Inc.* A-04-09-04041. <u>Full Report</u>

Medicaid Services > Personal Care > Federal Share > New York

Medicaid Personal Care Services Claims Made by Providers in New York State

New York State improperly claimed an estimated \$100.3 million in Federal Medicaid reimbursement for personal care services claims submitted by providers during CYs 2004 through 2006.

Of the 100 claims in our sample, 61 complied but 31 did not comply with Federal and State requirements pertaining to nursing assessments, physicians' orders, nursing supervision, in-service training of personal care aides, or documentation of the time spent providing services. In addition, for the eight remaining claims in our sample, we estimated that the State claimed \$15.3 million for Consumer Directed Personal Assistance Program (CDPAP) claims that may not have complied with State requirements for physicians' orders and nursing assessments. Personal care services are generally furnished to individuals in their homes. Examples of personal care services include cleaning, shopping, grooming, and bathing.

We recommended that the State: (1) refund the improperly claimed \$100.3 million Federal share to the Federal Government; (2) improve its monitoring of the personal care services program to ensure compliance with Federal and State requirements; (3) work with CMS to resolve the eight CDPAP claims and, if applicable, refund the estimated \$15.3 million in unallowable payments; and (4) promulgate specific regulations related to claims submitted under the CDPAP. The State disagreed with our first recommendation and agreed with our remaining recommendations.

Review of Medicaid Personal Care Services Claims Made by Providers in New York State.

A-02-08-01005. Full Report

Medicaid Recovery Act Reviews

Medicaid > Recovery Act Funds > Increased Federal Share > Indiana

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in Indiana for the Quarter Ending March 31, 2009

Indiana's claim for Federal reimbursement of Medicaid expenditures on the Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) for the quarter ended March 31, 2009, was adequately supported by actual recorded expenditures.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) provided fiscal relief to States to protect and maintain State Medicaid programs during an economic downturn. For the recession adjustment period (October 1, 2008, through December 31, 2010), the Recovery Act provided an estimated \$87 billion in additional Medicaid funding based on temporary increases in FMAPs. CMS reimburses States based on the FMAP for the majority of Medicaid expenditures claimed. For the quarter ended March 31, 2009, Indiana's regular FMAP for Medicaid expenditures was 64.26 percent, and the temporarily increased FMAP was 73.23 percent. The report contained no recommendations. Review of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in Indiana for the Quarter Ending March 31, 2009. A-05-09-00091. Full Report

Medicaid > Recovery Act Funds > Increased Federal Share > Illinois

Illinois' Prompt Pay Compliance Under the American Recovery and Reinvestment Act

Illinois did not always comply with prompt-pay requirements for receiving the increased FMAP under the Recovery Act.

As a result, it improperly received approximately \$2.6 million in increased FMAP from February 18, 2009, through September 30, 2009. The State agency's initial prompt-pay calculations included several inaccuracies related to the 30/90-day prompt-pay requirements and the inclusion or exclusion of certain claims in the daily prompt-pay compliance calculation. The State agency also failed to adjust the Form CMS-64 for the quarter ended June 30, 2009, for expenditures not eligible for increased FMAP.

We recommended that the State (1) refund \$2.6 million to the Federal Government for unallowable increased FMAP and (2) ensure that calculations are performed in accordance with prompt-pay requirements. The State agreed that it had applied an incorrect prompt-pay standard and incorrectly excluded or included certain prompt-pay claims. To cover all corrections, State officials said they made an adjustment of \$2.5 million and reported it on the December 2009 Form CMS-64. *Review of Illinois' Prompt Pay Compliance Under the American Recovery and Reinvestment Act of 2009 From January 1, 2009, Through September 30, 2009*. A-05-09-00083. Full Report

Medicaid > Recovery Act > Increased Federal Share > New Hampshire

Medicaid Prompt Pay Requirements in New Hampshire

We could not determine whether New Hampshire fully complied with prompt-pay requirements for receiving the increased Federal medical assistance percentage under the Recovery Act.

The State agency's policies and procedures did not ensure that it always recorded a claim's receipt date as the actual day that it received the claim. As a result, we could not rely on the State agency's receipt dates to verify that it met requirements. Federal regulations require State Medicaid agencies to pay 90 percent of all clean claims from practitioners within 30 days of receipt. A clean claim is one that can be processed without obtaining additional information from the provider or a third party.

We recommended that the State agency implement policies and procedures to ensure that it records a claim's receipt date as the actual day that it receives the clean Medicaid claim. Specifically, we recommend that the State agency record the receipt date as the day that it receives a claim (1) by mail for paper claims or (2) at the Translator for electronic claims. *Review of American Recovery and Reinvestment Act of 2009 Medicaid Prompt Pay Requirements in New Hampshire*. A-01-10-00009. Full Report

Medicaid > Recovery Act > Increased Federal Share > Alabama

Alabama's Compliance With the Reserve, or Rainy Day, Fund Requirement for the Increased Federal Medical Assistance Percentage Under the American Recovery and Reinvestment Act

Alabama complied with the Recovery Act reserve fund requirement for receiving increased FMAP.

For the recession adjustment period (October 1, 2008, through December 31, 2010), the Recovery Act provided an estimated \$87 billion in additional Medicaid funding based on temporary increases in States' FMAPs. However, pursuant to section 5001(f)(3) of the Recovery Act, a State was not eligible for the increased FMAP if any amounts attributable (directly or indirectly) to such an increase were deposited or credited into any reserve, or rainy day, fund. Alabama did not use additional Medicaid funding to supplement any such account. Therefore, we have no recommendations.

As an additional matter, the State drew down about \$2.4 million in Federal Recovery Act funds that exceeded the amount of the Recovery Act expenditures reported on its Form CMS-64 reports for the audit period. The State agency did not provide an explanation for the excessive drawdown of Recovery Act funds, and we were unable to determine whether the excessive drawdowns were used for allowable Recovery Act purposes. Review of Alabama's Compliance With the Reserve or Rainy Day Fund Requirement for the Increased Federal Medical Assistance Percentage Under the American Recovery and Reinvestment Act. A-04-10-03058. Full Report

Part II: Medicaid Reviews

Medicaid Administration

Medicaid Administration > Payment Error Rate Measurement Program

Oversight and Evaluation of the Fiscal Year 2008 Payment Error Rate Measurement Program

CMS could not be assured that the Payment Error Rate Measurement (PERM) program produced a reasonable estimate of improper payments.

One State in our review did not maintain hospital information on a claim-by-claim basis, and we were not able to reconcile the State universes from four other States to their Forms CMS-64. The States' Medicaid fee-for-service and managed care universes for the fiscal year (FY) 2008 PERM program were or may have been incomplete or inaccurate. Federal law requires the head of a Federal agency with any program or activity that may be susceptible to significant improper payments to report to Congress the agency's estimates of the improper payments. In addition, for any program or activity with estimated improper payments exceeding \$10 million, the agency must report to Congress the actions to reduce those payments. CMS developed the PERM program to comply with Federal requirements for measuring improper Medicaid and Children's Health Insurance Program (CHIP) payments.

We recommended that CMS (1) require the one State that was found not to be maintaining hospital payment information on a claim-by-claim basis to begin doing so for use in future PERM reviews and (2) continue to work with all States, CMS Regional Offices, and statistical contractors on reconciling the PERM universes to State financial reports. CMS agreed with our recommendations and discussed the corrective actions it had taken or plans to take in response. *Oversight and Evaluation of the Fiscal Year 2008 Payment Error Rate Measurement Program.* A-06-09-00037. Full Report

Medicaid Administration > Federal Share of Overpayments and Interest

■ Indiana's Reporting of Fund Recoveries for Federal and State Medicaid Programs on the Form CMS-64 for Federal Fiscal Years 2000 Through 2008

For Federal FYs 2000 through 2008, we estimated that Indiana did not report Medicaid overpayments totaling \$61.6 million (\$38.9 million Federal share) in accordance with Federal requirements.

Also, the State did not report interest it collected on 24 overpayments totaling \$62,000 (\$39,000 Federal share) in accordance with Federal requirements. Federal law requires States to refund the Federal share of Medicaid overpayments. In addition, Federal regulations require States to refund interest earned on overpayments before requesting additional Federal funds.

We recommended that Indiana (1) include unreported Medicaid overpayments of \$61.6 million on the Form CMS-64 and refund the \$38.9 million Federal share to the Federal Government, (2) include unreported interest it collected on Medicaid recoveries totaling \$62,000 on the Form CMS-64 and refund the \$39,000 Federal share to the Federal Government, and (3) develop and implement internal controls to correctly report and refund the Federal share of identified Medicaid overpayments and interest collected on the overpayments on the Form CMS 64. In written comments related to the first recommendation to refund the Federal share of unreported overpayments, the State provided additional documentation and indicated that most of the overpayments exceeding \$1 million that we initially identified in our draft report were repaid, reported, or resolved. As a result of the additional documentation, we revised our findings as reflected above. In response to the second recommendation related to interest earned on overpayment amounts, the State said it "routinely uses interest assessment" as a form of settlement with providers. The State's policies on interest are not in accordance with Federal regulations. The State agreed with our third recommendation about implementing internal controls. Review of Indiana's Reporting Fund Recoveries for Federal and State Medicaid Programs on the Form CMS-64 for Federal Fiscal Years 2000 Through 2008. A-05-09-00021. Full Report

Other Medicaid-Related Reviews

Other Medicaid-Related Reviews > Hurricane Katrina Grants

Contract Signatures for the Hurricane Katrina Health-Care-Related
 Professional Workforce Supply Grant for the Greater New Orleans Area

From March 2007 through January 2009, Louisiana's Bureau of Primary Care and Rural Health (the Bureau) paid \$330,000 in grant funds to seven practitioners who may not have agreed to comply with the grant's terms and conditions.

We found that seven contracts did not contain authentic signatures. These errors occurred because the Bureau did not have adequate policies and procedures to ensure that employees processing the contracts were obtaining authentic signatures on the agreements from both parties before payments were made. CMS had awarded the Bureau a Professional Workforce Supply Grant (the grant) to restore access to health care in communities affected by Hurricane Katrina. Practitioners were required to submit applications for funding and sign contracts.

We recommended that the Bureau (1) obtain authentic signatures for the seven contracts that were not re-signed or refund the \$330,000 of grant funds to CMS, and (2) ensure that all of the contracts that were not part of our review contain authentic signatures. The Bureau said that some of the original contracts might not be on file. The Bureau also said that it had reviewed the remaining contracts but provided no

Part II: Medicaid Reviews

supporting documentation. Nothing in the Bureau's comments caused us to revise our recommendations. *Review of Contract Signatures for the Hurricane Katrina Health-Care-Related Professional Workforce Supply Grant for the Greater New Orleans Area*. A-06-09-00053. <u>Full Report</u>

Part III:

Legal and Investigative Activities Related to Medicare and Medicaid

Part III:

Legal and Investigative Activities Related to Medicare and Medicaid

Investigative Outcomes

During this semiannual reporting period, the Government's enforcement efforts resulted in 294 criminal actions and 196 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$2.6 billion in Department of Health and Human Services (HHS) and \$618 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare; Medicaid; and other Federal, State, and private health care programs.

Advisory Opinions and Other Guidance

As part of the Office of Inspector General's (OIG) continuing efforts to promote the highest level of ethical and lawful conduct by the health care industry, we issue advisory opinions and other guidance to educate industry and other stakeholders on how to avoid fraud, waste, and abuse.

In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (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 on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. From October 1, 2010, through March 31, 2011, OIG received 22 advisory opinion requests and issued 7 advisory opinions. Advisory opinions are available on our Web site.

OIG also publishes on its Web site <u>compliance program guidance</u>, <u>fraud alerts</u>, <u>special advisory bulletins</u>, and <u>other guidance</u>. On October 20, 2010, OIG published <u>guidance</u> that sets forth nonbinding factors OIG will consider in deciding whether to impose permissive exclusion in accordance with the Social Security Act, § 1128(b)(15)(A)(ii), which authorizes us to exclude an officer or managing employee of an entity that has been excluded from Federal health care programs or has been convicted of certain offenses.

Education and Outreach Activities

Roadmap for New Physicians

A recent OIG review indicated that almost half of medical schools and more than two-thirds of institutions offering residency and fellowship programs reported instructing participants about compliance with Medicare and Medicaid fraud and abuse laws. Because nearly all were interested in having OIG provide instructional materials, we developed a guide called *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse* (Roadmap). The package also includes a slide presentation and speaker notes.

The Roadmap summarizes the five main Federal fraud and abuse laws (the False Claims Act (FCA), the anti-kickback statute, the physician self-referral law (Stark Law), OIG's exclusion authorities, and civil monetary penalties authorities). It instructs physicians how to uphold these laws in their relationships with payers such as the Medicare and Medicaid programs; vendors such as drug, biologic, and medical device companies; and other providers such as hospitals, nursing homes, and physician colleagues. You can view the survey and Roadmap on our Web site at http://www.oig.hhs.gov.

Provider Compliance Training Sessions

Our Provider Compliance Training initiative provides free, high-quality compliance training sessions for medical providers and suppliers, compliance professionals, and attorneys in various locations throughout the country. Representatives from OIG, DOJ, HHS's Centers for Medicare & Medicaid Services (CMS), and State Medicaid Fraud Control Units (MFCU) educate communities about fraud risks and share compliance best practices to assist providers in strengthening their compliance efforts. The training helps providers to:

- understand laws and compliance program basics;
- know where to go when a compliance issue arises; and
- understand the consequences of health care fraud and abuse.

During the reporting period, we conducted sessions in Houston, Kansas City, and Tampa and have sessions planned in three other cities. Because all sessions filled quickly, we scheduled a Webcast of our Washington, DC, training in May 2011.

■ Most-Wanted Fugitives List

For the first time, we published a <u>Most-Wanted Fugitives</u> list on our Web site, and captures were soon reported. The 10 individuals on the original list allegedly defrauded taxpayers of more than \$126.6 million. As of March 31, 2011, four had been captured and more were added.

HEAT: Health Care Fraud Prevention & Enforcement Action Team

In 2009, HHS and DOJ announced the Health Care Fraud Prevention and Enforcement Action Team (HEAT), whose mission is to prevent, deter, and aggressively prosecute health care fraud, waste, and abuse. OIG's participation in Medicare Fraud Strike Force activities is a key example of OIG's contribution to the mission of HEAT.

Medicare Fraud Strike Force

The Medicare Fraud Strike Force is a partnership between DOJ, U.S. Attorneys' Offices, OIG, the Federal Bureau of Investigation (FBI), and State and local law enforcement agencies. The Strike Force, a key component of HEAT, has a proven record of successfully analyzing data to quickly identify and prosecute fraud almost as quickly as it occurs. The Strike Force began in March 2007 and is now operating in nine major cities: Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas. During this semiannual reporting period, Strike Force efforts have resulted in the filing of charges against 213 individuals or entities, 107 convictions, and \$63.9 million in investigative receivables.

In February 2011, Strike Force teams engaged in an unprecedented Federal health care fraud takedown. Teams across the country arrested more than 100 defendants in 9 cities, including doctors, nurses, health care company owners and executives, and others, for their alleged participation in Medicare fraud schemes involving more than \$225 million in false billing. The defendants are accused of various health-care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft. More than 300 special agents from OIG participated in partnership with other Federal and State agencies, including fellow OIGs. The effectiveness of the Strike Force model is enhanced by interagency collaboration. For example, we refer credible allegations of fraud to CMS so it can suspend payments to the perpetrators of these schemes. During the February Strike Force operations, OIG and CMS worked to impose payment suspensions that immediately prevented a loss of more than a quarter-million dollars in claims submitted by Strike Force targets.

Examples of Strike Force cases follow.

■ Florida — Yudel Cayro, owner and operator of Courtesy Medical Group Inc. (CMG), a medical clinic in Miami, was sentenced to 60 months of incarceration and ordered to pay \$9.8 million for his role in a Medicare fraud scheme. Another owner and operator of CMG, co-defendant Arturo Fonseca, was sentenced to 60 months of incarceration. CMG allegedly provided unnecessary prescriptions, plans of care and medical certifications to Miami-area home health agencies in return for kickbacks and bribes. CMG falsified patient files to make it appear as if Medicare beneficiaries qualified for daily skilled nursing visits to administer diabetic insulin injections. In fact, the beneficiaries did not need or qualify for

- these services and in some cases, did not receive the services. CMG issued approximately 344 unnecessary prescriptions.
- Michigan—Christopher Collins, a licensed Registered Nurse, was sentenced to 63 months of incarceration and ordered to pay \$6.6 million jointly and severally in restitution with other defendants for health care fraud conspiracy. Collins, a co-owner of All American Home Care (All American), conspired with the owner, and several other co-conspirators to pay kickbacks to Medicare beneficiaries, who, in turn, served as purported patients at All American and Patient Choice Home Health Care. These Medicare beneficiaries received cash and other methods of payment in exchange for signing documents making it appear that they had received the treatments being billed to Medicare when, in fact, the treatments were medically unnecessary or were not provided.
- Florida—Flor Crisologo, owner and operator of J & F Community Medical Center Inc. (J & F), was sentenced to 120 months of incarceration and ordered to pay \$8 million in restitution for conspiracy to commit health care fraud. Crisologo, in collaboration with a physician and other individuals, allegedly utilized J & F to submit false and fraudulent claims to Medicare for human immunodeficiency virus (HIV) injection and infusion services. Crisologo and her conspirators paid Medicare beneficiaries kickbacks to induce them to claim that they received legitimate services at J & F when, in fact, the HIV infusion services were not provided or were not medically necessary.

Other Criminal and Civil Enforcement Activities

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 FCA. A description of these enforcement authorities can be found in Appendix D.

The successful resolution of false claims often involves the combined investigative efforts and resources of OIG, FBI, MFCUs, and other law enforcement agencies.

DOJ and OIG launched a program in which OIG attorneys serve as Special Assistant United States Attorneys. OIG attorneys are detailed full time to DOJ's Criminal Division, Fraud Section, for temporary assignments, such as with the Medicare Fraud Strike Force described above; others prosecute matters on a case-by-case basis. Both arrangements offer excellent litigation training for OIG attorneys and enhance collaboration between the departments in fighting fraud. Under this program, OIG attorneys have successfully litigated important criminal cases relating to durable medical equipment (DME), infusion therapy, physical therapy, and other types of Medicare and Medicaid fraud.

Pharmaceutical Manufacturers and Pharmacies

- Massachusetts—As part of a global resolution of allegations under the FCA, GlaxoSmithKline LLC (GSK) agreed to pay \$750 million, including criminal fines for violations of the Federal Food, Drug, and Cosmetic Act (FDCA). The Government alleged that between January 1, 2001, and April 1, 2005, GSK, via its now closed subsidiary SB Pharmco, manufactured, distributed, and sold defective and contaminated drugs. The drugs consisted of (1) Paxil CR that contained some split tablets causing consumers to receive either product with no active ingredient and/or with only the active ingredient layer and no controlled release mechanism; (2) Avandamet that contained some tablets with higher or lower amounts of rosigitazone than specified; (3) Kytril that was labeled as sterile but was, in some vials, nonsterile; and (4) Bactroban ointments and creams that, in some packages, contained microorganisms. The Government contends that this improper conduct resulted in the submission of false claims to the Federal health care programs. As a result of this investigation, SB Pharmco agreed to plead to a felony violation of the FDCA for violating current good manufacturing practice requirements and introducing adulterated drugs into interstate commerce.
- Georgia Allergan, Inc. and Allergan USA, Inc. (collectively, Allergan) agreed to pay \$600 million and enter a global criminal, civil, and administrative settlement in connection with the improper marketing and promotion of Botox. Under the civil settlement agreement, Allergan agreed to pay the Federal Government \$225 million to resolve its FCA. Botox is a neurotoxin and a biologic that was approved by the Food and Drug Administration (FDA) for several uses, including blepharospasm (uncontrollable closing of the eyelids); cervical dystonia (muscle spasm and pain in the neck and shoulder); and temporary improvement in the appearance of moderate to severe glabellar lines (facial age wrinkles) in adults up to age 65. The settlement resolves allegations that Allergan promoted the sale and use of Botox for a variety of conditions, such as headache, pain, spasticity, and overactive bladder, which were not approved by the FDA and were not covered by the State Medicaid programs.

The settlement further resolves allegations that Allergan: (1) misled physicians about the safety and efficacy of unapproved uses of Botox; (2) instructed health care professionals to miscode claims for the treatment of headache and pain using inapplicable diagnosis codes to ensure payment by various Federal health care programs; and (3) offered and paid illegal remuneration to health care professionals that was intended to induce them to promote and prescribe Botox. As part of the settlement, Allergen entered into a comprehensive 5-year corporate integrity agreement with OIG, which included several provisions intended to increase transparency about Allergen's promotional practices, and which required Allergan to establish internal monitoring programs to review promotional activities.

- Wisconsin & Louisiana Kos Pharmaceuticals (Kos) entered into an approximately \$41 million global criminal, civil, and administrative settlement agreement. Under the civil settlement agreement, Kos agreed to pay the Federal Government \$38.1 million to resolve FCA allegations in connection with improper marketing and promotion practices associated with the drugs Niaspan and Advicor. The Government contends that Kos intentionally marketed Advicor for therapy that did not comport with the uses indicated in its label during the relevant time period. Kos also agreed to enter into a Deferred Prosecution Agreement to resolve criminal liability in connection with the company's violation of the anti-kickback statute. Kos allegedly paid substantial inducements to encourage physicians to prescribe Advicor and Niaspan to patients. The payments took several forms, including honoraria for false speaker programs, grants for sham studies, and payments for participating in phony preceptorship programs. In addition, the company paid managed care organizations who directed their affiliate physicians to switch patients to Advicor and Niaspan.
- New Jersey—CVS Pharmacy, LLC agreed to pay \$969,230 to resolve its liability under the FCA. From September 20, 2005, through July 31, 2009, three CVS Pharmacy stores, two in New York and one in New Jersey, allegedly submitted or caused to be submitted to the TRICARE and Medicare programs claims for prescription drugs that were dispensed by an excluded pharmacist. The pharmacist filled the prescriptions and entered data into a system that was then used to bill Medicare. The pharmacist was excluded in 2004 from participating in Federal health care programs based on his conviction for attempted criminal sale of a controlled substance in New York.

Hospitals

- Indiana—St. John's Health System (St. John's) agreed to pay the United States \$318,364 to resolve its liability under the FCA for submitting fraudulent claims to Medicare and Medicaid for psychotherapy services. The settlement resolves allegations that, from January 1, 2005 through December 31, 2008, St. John's billed for multiple units of psychotherapy services under the code for group medical psychotherapy. The Government contends that the services that were provided, however, were not psychotherapy sessions, but group counseling meetings, including Alcoholics Anonymous meetings provided by unqualified professionals. The settlement also resolved allegations that St. John's billed for services provided by lower-level practitioners without using modifiers to indicate who provided the services, resulting in a 25% higher payment under Medicare and Medicaid.
- California—Christus Health and seven of its hospitals (collectively, Christus) agreed to pay \$970,987 to resolve their civil liability for allegedly violating the FCA, the civil monetary penalties law, and certain common law causes of action.

Christus is a health system that operates hospitals throughout the southwestern United States. At the advice of a consulting firm, Healthcare Financial Advisers (HFA), Christus allegedly filed inflated cost reports. HFA allegedly prepared and Christus filed cost reports that sought reimbursement for various categories of items of unallowable costs, while simultaneously preparing a second set of cost reports, which more accurately represented the amount of reimbursement to which the hospitals were entitled. In addition to the settlement amount, Christus also refunded to Medicare a \$649,210 overpayment which it received as a result of improperly seeking reimbursement for unallowable costs on past cost reports.

Durable Medical Equipment Suppliers

- Texas Dr. Howard Grant, Obisike Nwankwo, John Lachman, Michael Obasi, Basil Kalu, and Darnell Willis were sentenced to 41 months, 21 months, 26 months, 46 months, 70 months, and 41 months of incarceration, respectively, for their roles in a DME fraud scheme at Onward Medical Supplies (Onward). Two others, Ju Qian and Clinton Lee Jr., were sentenced to 10 months of community and home confinement and 3 years of probation, respectively. Restitution was ordered jointly and severally among the defendants in excess of \$1.3 million. Evidence presented at trial showed that from 2003 to 2009, Onward billed Medicare for fraudulent DME, including power wheelchairs and orthotic devices. Under the scheme, Grant ratified prescriptions for medically unnecessary DME, Lachman created fraudulent patient files and paid kickbacks to recruiters, and Nwankwo delivered DME, such as power wheelchairs and orthotics, to beneficiaries who had no medical need for the equipment. The owner of Onward, Doris Vinitski, and other remaining defendants have pleaded guilty for their participation in various parts of the fraud scheme. Judicial proceedings continue for those individuals. This Medicare Fraud Strike Force investigation was a joint investigation between the Texas MFCU, OIG, and FBI.
- Texas—Oliver Nkuku, a manager for K.O. Medical, Inc. (K.O.), and Callistus Edozie, a K.O. delivery person, were sentenced to 120 months and 41 months of incarceration, respectively, and ordered to pay \$453,112 and \$80,000 in restitution, jointly and severally, for their roles in a DME fraud scheme. In 2007, Nkuku, submitted fraudulent claims to Medicare on behalf of K.O. for power wheelchairs and other DME that were medically unnecessary, and Edozie delivered medically unnecessary DME. The DME was billed as catastropherelated in connection with Hurricanes Katrina, Rita, Ike, and Gustav, even though the Medicare beneficiaries had either never owned power wheelchairs at the time of these catastrophes, or had owned wheelchairs that were not subjected to damage during the hurricanes.

Practitioner

Puerto Rico — Edgar Herran Garcia (Herran) was sentenced by the District of Puerto Rico to 18 months of incarceration, and ordered to pay a \$10,000 fine and \$3,544 in restitution after he pleaded guilty to four counts of misbranding of a drug with the intent to defraud. Herran, a former licensed nurse, allegedly presented himself as a physician in Puerto Rico, despite never having a license to practice medicine in that territory. Nonetheless, Herran purported to specialize in wound care and treated several Medicare beneficiaries who suffered from skin ulcers. Herran regularly provided patients with prescriptions for medications to treat skin ulcers. These pharmacy claims were paid by health care benefit programs, including Medicare Advantage Plans. When writing the fraudulent prescriptions, Herran used his expired U.S. Virgin Islands nursing license number, which matched that of a legitimate Puerto Rican physician with no knowledge or involvement in the scheme. This case involved OIG and FDA's Office of Criminal Investigations.

Physical Therapy Clinic

Michigan — Bernice Brown, owner of Detroit-area physical therapy clinic Wayne County Therapeutic Inc. (WCT), and Daniel Smorynski, WCT vice president, were convicted on charges of health care fraud for their leading roles in a Medicare fraud scheme. Brown and Smorynski were sentenced to 12 years and 7 months and 9 years in prison, respectively, and were ordered to pay \$6.7 million in restitution jointly and severally. From October 2002 to April 2007, WCT submitted multiple claims to the Medicare program for physical therapy, occupational therapy, and psychotherapy services purportedly provided and supervised by WCT staff when, in fact, such services were not professionally provided or supervised. As part of the scheme, Brown purchased fake physical and occupational therapy files from third-party contractors who used cash kickbacks to induce Medicare beneficiaries to provide their Medicare numbers and sign false documentation making it appear as if they received therapy. Brown instructed her staff to create false documents to add to the fictitious medical files to make it appear that WCT therapists, who were licensed in the State and enrolled with Medicare, had performed the services. In addition, Brown and Smorynski directed WCT staff to call their clients. These phone calls were billed to Medicare as 45 to 50 minute in-person psychotherapy visits.

Laboratory

Oregon—Northwest Mobile Services, LLC and Northwest Mobile Imaging (collectively, Northwest Mobile) agreed to pay \$950,000 to settle allegations of utilizing unlicensed/unqualified x-ray technicians to provide x-ray services. Between January 2003 and July 2007, Northwest Mobile allegedly caused claims to be submitted to the Medicare program for services provided by x-ray technicians that did not meet formal education requirements for x-ray technicians.

■ Home Health Services

Medicine (Statewide), were each sentenced to 120 months of incarceration and ordered to pay \$18 million in restitution, jointly and severally, for making false statements relating to a health care matter, theft of Government funds, and conspiracy to commit money laundering. Between 2001 and 2004, Statewide submitted false claims for in-home physical therapy and physical medicine services to Medicare and Medicaid programs falsely purporting that the services had been rendered by a physician or a qualified employee under the physician's direct supervision when, in fact, they were not. Statewide also inflated the time billed by claiming that beneficiaries received as many as 10 hours of therapy per session.

Skilled Nursing Facility

• Maine—Judith Schickle pleaded guilty to one count of health care fraud and three counts of embezzlement from a health care benefit program. She was sentenced to 5 years of probation and ordered to pay \$79,767 in restitution. Between 2000 and 2005, Schickle received \$79,000 in wages and benefits to which she was not entitled. During the course of her employment, as a full-time bookkeeper at the Varney Crossing Nursing Home, Schickle provided herself with multiple unauthorized pay increases. Consequently, her hourly rate of pay increased from \$11.25 in 2000 to more than \$22.00 per hour by 2004. In addition, Schickle was paid for hours of leave and earned benefit time that greatly exceeded the amount of earned benefit time and other leave hours that she had accrued. Schickle reported the unauthorized earned benefit time under departments in which she did not work, including the nursing and housekeeping departments, which resulted in the submission of false cost reports by ManorCare and improper reimbursement to the Varney Crossing Nursing Home.

Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. In fiscal year (FY) 2010, HHS awarded \$193.6 million in Federal grant funds to 50 State MFCUs (including Washington, DC), which employed a total of 1,827 individuals.

Collectively, in FY 2010, MFCUs reported 13,210 investigations, of which 9,710 were related to Medicaid fraud and 3,500 were related to patient abuse and neglect, including patient funds cases. The cases resulted in 1,603 individuals being indicted or criminally charged, including 1,048 for fraud and 555 for patient abuse and neglect, including theft

from the personal funds accounts of nursing home patients. In total, 1,324 convictions were reported in FY 2010, of which 836 were related to Medicaid fraud and 488 were related to patient abuse and neglect, including patients' funds cases. Examples of joint investigations follow.

Joint Investigations

- Michigan Specialized Pharmacy Services (Specialized) agreed to pay \$11.6 million and enter into a settlement agreement with the State of Michigan Attorney General's Office to settle liability under the FCA. The settlement resolves allegations that from 2002 to 2009, Specialized charged Medicaid a greater amount for prescription medications than it did private insurance companies by providing nursing homes the services of their consultant pharmacists at a rate well below market price. Under Michigan law, a pharmacy cannot bill Medicaid more than it customarily accepts from a private health insurer for prescription medications. This case was jointly investigated with the FBI and the Michigan MFCU.
- Texas—Muhammad Usman, owner of Royal Ambulance Service, Inc. (Royal Ambulance) and First Choice EMS, Inc. (First Choice), was sentenced to 15 years of incarceration and ordered to pay \$1.3 million in restitution after being convicted of 12 counts of health care fraud, conspiracy to commit health care fraud, and money laundering. Royal Ambulance and First Choice provided medically unnecessary transports of Medicare and Medicaid beneficiaries to and from dialysis treatments. This case was investigated jointly with the Internal Revenue Service (IRS), FBI, the Texas MFCU, and the Office of Personnel Management (OPM).
- Indiana—Ali Abdelaziz Ahmed, owner of United Transportation (United), pleaded guilty to health care fraud and was ordered to pay restitution in the amount of \$42,668. United and Ahmed had been under investigation, along with numerous other subjects, for upcoding ambulatory transportation services as wheelchair van transports. This upcoding scheme paid the provider twice the amount it should have received as reimbursement for the services provided. This case was jointly investigated with the Indiana MFCU.

Provider Self-Disclosure Protocol

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abusive practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. In doing so, the

self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in overpayments). After making an initial disclosure, the provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action.

Self-Disclosure Guidance to Health Care Providers

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

See also: Open Letters at http://www.oig.hhs.gov/fraud/openletters.asp

Self-Disclosure Cases

During this reporting period, self-disclosure cases resulted in \$11.2 million in HHS receivables. Examples of self-disclosure cases follow.

- California Santa Clara Valley Medical Center (SCVMC), agreed to pay \$4.3 million to resolve its liability under the FCA in connection with improper billing for 1-day hospital admissions that did not meet medical necessity criteria for inpatient services. SCVMC is an acute-care hospital owned and operated by the County of Santa Clara, California. SCVMC disclosed that it had billed Medicare and Medi-Cal for 1-day inpatient hospital stays which, instead, should have been billed as outpatient observation services.
- \$1.2 million to resolve its liability under the civil monetary penalties law and the Stark Law. On January 23, 2009, St. Elizabeth disclosed an improper billing arrangement for provider-based services involving a rural vascular outreach program that had occurred at one of the St. Luke Hospitals prior to its merger with St. Elizabeth. St. Elizabeth also disclosed several improper financial relationships between St. Luke and a referring physician involving the provision of free and below-fair-market-value space and support services without written agreements, which created potential liability under the Stark Law and the anti-kickback statute.
- North Dakota—Mercy Medical Center (Mercy) agreed to pay \$88,331 to resolve its liability under the civil monetary penalties law. Mercy disclosed that it employed a staffer who was excluded from the Medicare program. The staffer was hired by Mercy in January 2008 to work as a Licensed Practical Nurse in the

Kidney Dialysis Unit (KDU), where the staffer remained until September 2009. St. Alexius Medical Center, which leased space from Mercy and used Mercy staff to operate the KDU, submitted multiple claims to Medicare for work that had been completed by the excluded staffer.

Office of Inspector General Administrative Sanctions

During this reporting period, OIG imposed 902 administrative sanctions. OIG has the authority to impose administrative sanctions for fraud or abuse or other activities that pose a risk to Federal health care programs and their beneficiaries (see Appendix D for an explanation of OIG's sanction authorities). These sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of civil monetary penalties for submitting false or fraudulent claims to a Federal health care program or for violating the anti-kickback statute, the Stark Law, or the Emergency Medical Treatment and Active Labor Act (EMTALA or patient dumping statute). Examples of administrative sanctions follow.

Program Exclusions

During this semiannual reporting period, OIG excluded 883 individuals and entities from 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. See on the Web: http://exclusions.oig.hhs.gov/. Examples of exclusions follow.

- **District of Columbia**—The U.S. District Court for the District of Columbia affirmed OIG's determination to exclude former Purdue Frederick Co. executives Michael Freidman, Paul Goldenheim, M.D., and Howard Udell from participation in Federal health care programs for 15 years. The exclusions were based on the executives' convictions for their failure as responsible corporate officers to prevent or correct the fraudulent misbranding and distribution of OxyContin. Michael Freidman is the former Chief Operating Officer and Chief Executive Officer, Paul Goldenheim is the former Chief Scientific Officer, and Howard Udell is the former General Counsel at Purdue Frederick.
- **Kentucky**—Tammy Brewer, an emergency medical technician, was excluded for a minimum of 25 years based on her conviction for manslaughter. While under the influence of Methadone, Brewer was driving an ambulance and swerved off the road striking a utility pole and chain link fence. The collision caused blunt force trauma to the patient that she was transporting, which caused the patient's death. Brewer was sentenced to 10 years of incarceration. The Kentucky Board of Emergency Medical Services revoked her license to practice as an emergency medical technician.
- Pennsylvania John Kristofic, a physician, was excluded for a minimum of 20 years based on his health care fraud conviction. Over a 5-year period,

Kristofic submitted false and fraudulent claims to Medicare, TRICARE, the Federal Employee Health Benefit (FEHB) program, and private insurers for treatment and services which were not rendered because Kristofic was not in the office or the patients were being treated by other physicians on the dates claimed. Kristofic was sentenced to 1 year and 1 day of incarceration and ordered to pay \$1 million in restitution.

- Mississippi—Melinda Busby, a registered nurse, was excluded for a minimum of 14 years based on her felony conviction related to the unlawful distribution of controlled substances. Over a 2-year period, Busby conspired to possess and distribute in excess of 50 grams of a substance containing a detectable amount of methamphetamine, which is a Schedule II controlled substance. Busby was sentenced to 121 months of incarceration and surrendered her license to practice as a registered nurse to the Mississippi State Board of Nursing.
- California Anthony Tun Lee, a medical doctor, was excluded for a minimum of 13 years based on his felony conviction for sexually assaulting a patient under his care. Lee subjected a 16-year-old patient to inappropriate touching during her examination, and represented that this touching served a professional purpose. Lee was sentenced to 3 years of incarceration. In addition, the Pennsylvania State Board of Medicine and the New York State Board of Professional Medical Conduct accepted the surrender of his medical licenses in those States.

Corporate Integrity Agreements

OIG assists 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 corporate integrity agreements with OIG to avoid exclusions from Medicare, Medicaid, and other Federal health care programs. Such agreements are monitored by OIG and require the providers to enhance existing compliance programs or establish new ones. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct.

■ Civil Monetary Penalties Law

The civil monetary penalties law authorizes OIG to impose administrative penalties and assessments against a person who, among other things, submits or causes to be submitted claims to a Federal health care program that the person knows or should know are false or fraudulent. During this reporting period, OIG concluded cases involving more than \$4.5 million in penalties and assessments.

North Carolina — Long Term Care, Inc. (LTC), a durable medical supplier, agreed to pay \$170,000 to resolve its liability under the civil monetary penalties law. LTC employed an excluded individual over a period of 4 years. LTC hired the excluded individual through a contract arrangement with a professional

employment organization that provided human resources and staffing support to LTC.

■ Florida — Orthopedic surgeon Steven J. Lancaster agreed to pay \$101,000 to resolve his civil monetary penalty liability for allegedly soliciting kickbacks from a medical device manufacturer. The Government contends that Lancaster offered to leverage his product usage and ability to influence purchasing decisions through his position as Chief of Orthopedics at Baptist Medical Center Beaches Hospital in exchange for a personal services contract worth a guaranteed \$40,000.

Patient Dumping

Some of the civil monetary penalty cases that OIG resolved between October 1, 2010, and March 31, 2011, were pursued under EMTALA, a statute designed to ensure patient access to appropriate emergency medical services.

- Alabama Mobile Infirmary paid \$45,000 to resolve allegations that it improperly refused to accept a patient transferred from another hospital. The patient came to the transferring hospital's emergency room complaining of severe abdominal pain and required immediate specialized surgical intervention not available at the hospital. Mobile Infirmary allegedly refused to accept the transfer even though it had the capacity and specialized capabilities to treat the patient's condition. Ultimately, the patient was transferred to a hospital 60 miles away. The patient's condition deteriorated en route and he had to be transported by Life Flight helicopter to the receiving hospital, where he later died.
- Texas Houston Northwest Medical Center (Houston Northwest) paid \$40,000 to resolve allegations that it failed to provide an appropriate medical screening examination or stabilizing treatment and inappropriately transferred a pregnant woman who came to Houston Northwest while having contractions. Houston Northwest transferred the patient by ambulance to a hospital nearly 2 hours away; however she went into active labor en route and was diverted to a closer hospital.
- Georgia North Fulton Regional Hospital (North Fulton), a hospital located in Roswell, Georgia, agreed to pay \$40,000 to resolve allegations that it failed to provide a medical screening examination for a pregnant patient. The patient, who was 30 weeks pregnant, reported to the hospital's emergency department upon the advice of her physician after she experienced labor pains. North Fulton is a part of the Tenet Healthcare Corporation, which disclosed the conduct to the OIG under its corporate integrity agreement.
- **Florida**—Port St. Lucie Hospital (Port St. Lucie) paid \$19,000 to resolve allegations that it refused to accept a patient from a transferring hospital. Port

St. Lucie is an inpatient mental health facility. A nurse at Port St. Lucie allegedly refused to accept the transfer of a patient with acute psychosis because the nurse believed the patient was uninsured.

Part IV:

Public Health, Human Services, and Departmentwide Issues

Part IV:

Public Health

Centers for Disease Control and Prevention

Public Health > CDC > Property Management

Centers for Disease Control and Prevention's Accountability for Property

In response to a congressional request, we audited the Center for Disease Control and Prevention's (CDC) Property Management System (property system) and found that it was neither accurate nor complete. Based on our sample results, we estimated that CDC had lost or misplaced approximately \$8.2 million worth of Government property as of September 30, 2007.

CDC did not add all newly acquired items to the property system or correctly record the value of the items in the system. We estimated that the property system was understated by approximately \$1.5 million for purchases made during fiscal year (FY) 2007. These inaccuracies occurred because CDC did not always adjust the property system to reflect the results of an annual physical inventory and did not barcode all newly acquired property for entry in the property system. CDC had not fully implemented the Office of Inspector General's (OIG) recommendations in a 1995 report to strengthen management controls over property.

As a result of our current review, we recommended that CDC improve its controls over property by (1) adjusting the property system based on annual physical inventory results and removing from the system any lost or missing property, including the estimated \$8.2 million worth that we identified; (2) ensuring that all newly acquired items, including at least \$1.5 million worth of items acquired in FY 2007, are barcoded and correctly added to the property system; and (3) reconciling the general ledger to the property system to identify discrepancies and resolve them. CDC concurred with our recommendations. *Review of the Centers for Disease Control and Prevention's Accountability for Property*. A-04-07-01054. Full Report

Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations

Four research and development and information technology contracts with CDC did not fully comply with one or more appropriations laws and acquisition regulations with respect to competition, funding, and pricing.

Pursuant to a congressional request, we are conducting a series of reviews of CDC's contracting practices. During this semiannual period we reviewed companies referred to as Contractors B, C, D, and E. Our recommendations included adhering to established procedures and developing and implementing policies and procedures to address compliance with appropriations statutes and acquisition regulations. Summaries of reports completed in this semiannual period follow.

- Contractor B Audit. In 2002, a CDC research and development contract awarded to "Contractor B" did not fully comply with appropriations laws and acquisition regulations with respect to pricing. Specifically, CDC did not perform cost analyses for four contract modifications that exceeded \$650,000 each and totaled \$10.9 million. The failure to perform cost analyses occurred because CDC did not adhere to its policies and procedures for determining the reasonableness of contract modifications. By failing to perform cost analyses, CDC violated the Federal Acquisition Regulation (FAR). As a result, CDC did not ensure that it obtained vaccine safety research studies at fair and reasonable prices. The contract complied with appropriations laws and acquisition regulations with respect to competition, inherently governmental functions, personal services, subcontracting, additional performance activities, and contract funding. We recommended that CDC adhere to its procedures for performing cost analyses on contract modifications exceeding \$650,000 each. CDC concurred with the recommendation. Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor B. A-02-09-02005. Full Report
- Contractor C Audit. In 2002, a research and development contract awarded to a company referred to as "Contractor C" did not fully comply with appropriations laws and acquisition regulations with respect to competition. Specifically, CDC awarded task orders to Contractor C that significantly exceeded the estimated contract cost without recompeting the contract. CDC's cumulative award of \$13.4 million exceeded the estimated contract cost by \$12.1 million because CDC failed to adhere to its procedures for periodically monitoring cumulative contract costs. By failing to do so, CDC violated the FAR requirement for full and open competition. As a result, CDC did not ensure that it obtained information related to the prevention of infectious diseases in the most economical and efficient manner. The contract complied with appropriations laws and acquisition regulations with respect to inherently governmental functions, personal services,

- pricing, and contract funding. We recommended that CDC adhere to its procedures for periodically monitoring cumulative contract costs. CDC concurred with our finding and recommendation and described the corrective actions that it was taking. Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor C. A-02-09-02006. Full Report
- Contractor D Audit. In 2003, a CDC information technology service contract and six sampled task orders awarded to a company referred to as "Contractor D" did not fully comply with appropriations laws and acquisition regulations with respect to contract funding and pricing. Specifically, for three of the six task orders, CDC used annual appropriations to pay for expenses incurred after the appropriations' 1-year period of availability had expired. Additionally, CDC did not sufficiently document price or cost analyses under all six task orders. As a result, CDC violated the bona fide needs statute by expending \$1.6 million of annual appropriations beyond their period of availability and did not ensure that the pricing of task orders and modifications totaling \$73 million was fair and reasonable. The contract and sampled task orders complied with acquisition regulations with respect to competition, inherently governmental functions, and personal services. We recommended that CDC (1) determine whether the \$1.6 million expended outside the 1-year period of availability violated the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and, if so, report the violation as required; (2) develop and implement policies and procedures to address compliance with appropriations statutes and acquisition regulations on obligating and expending funds; and (3) implement and monitor the effectiveness of policies and procedures for documenting determinations of fair and reasonable pricing. In response, CDC described its corrective actions to address each of our recommendations. Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations — Contractor D. A-04-09-01066. Full Report
- Contractor E Audit. A 2003 CDC information technology service contract and six sampled task orders awarded to a company referred to as "Contractor E" did not fully comply with appropriations laws and acquisition regulations with respect to contract funding and pricing. For two of the six task orders, CDC used annual appropriations to pay for expenses incurred after the appropriations' 1-year period of availability had expired. Additionally, CDC did not sufficiently document price or cost analyses under all six task orders. As a result, CDC violated the bona fide needs statute by expending \$231,000 of annual appropriations beyond their period of availability and did not ensure that the pricing of task orders and modifications totaling \$21.5 million was fair and reasonable. The contract and sampled task orders complied with acquisition regulations with respect to competition, inherently governmental functions, and personal services. We recommended that CDC (1) determine whether the

\$231,000 expended outside the 1-year period of availability violated the Anti-Deficiency Act and, if so, report the violation as required; (2) develop and implement policies and procedures to address compliance with appropriations statutes and acquisition regulations on obligating and expending funds; and (3) implement and monitor the effectiveness of policies and procedures for documenting determinations of fair and reasonable pricing. In response, CDC described its corrective actions to address each of our recommendations. *Review of the Centers for Disease Control and Prevention's Compliance With Appropriations Laws and Acquisition Regulations—Contractor E.* A-04-09-06108. <u>Full Report</u>

Food and Drug Administration

Public Health > FDA > National Drug Code Directory

FDA's Approval Status of Drugs Paid for by Medicaid

This report highlights the fact that the National Drug Code (NDC) Directory cannot reliably be used to verify the approval and listing status of drugs paid for under Medicaid. Previous OIG reports also found problems with the accuracy and completeness of FDA's NDC Directory.

Sixty-two percent of drugs paid for by Medicaid in 2008 had an approved application number in the NDC Directory. The remaining 38 percent either did not have an approved application number listed or were not in the NDC Directory.

In 2008, there was congressional concern that Medicaid pays for drugs that are not approved by the Food and Drug Administration (FDA). Without accurate approval and listing information, it was impossible to determine whether some drugs were paid for appropriately.

Generally, covered outpatient drugs must be approved by FDA to qualify for Federal payments under Medicaid. Data contained in the NDC Directory were inaccurate and incomplete, thereby preventing us from determining whether FDA approved these drugs. As a result, Medicaid could potentially pay for drugs that are not approved.

We recommended that FDA improve the completeness and accuracy of the NDC Directory by taking the following steps: (1) conduct frequent reviews of its NDC Directory to ensure its completeness and accuracy and (2) work with Congress and the Center for Medicare & Medicaid Services (CMS) to seek a legislative or regulatory change that compels manufacturers to list all approved products with FDA before they become eligible for Medicaid payment. FDA generally agreed with our recommendation to improve the completeness and accuracy of the NDC Directory and stated that it is working on several strategies for evaluating and correcting drug-listing data. CMS deferred to FDA regarding the response to our

recommendations. FDA's Approval Status of Drugs Paid for by Medicaid. OEI-03-08-00500. Full Report

Health Resources and Services Administration

Public Health > HRSA > Grants Management > CARE Act Grants

Ryan White Title II Funding in Pennsylvania

Pennsylvania did not always comply with Federal requirements in administering funds provided for treatment of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) under Title II of the Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) of 1990.

From April 1, 2004, through March 31, 2007, Pennsylvania claimed at least \$3.2 million (\$2.2 million Federal share) that did not comply with the Title II requirements that funds be used only for eligible clients and only for drugs that are not eligible for coverage by other Federal, State, or private health insurance plans. Title II grants fund the purchase of medications through the AIDS Drug Assistance Program (ADAP) and other health care and support services for people who have HIV/AIDS and who have no health insurance or are underinsured. At the Federal level, the Health Resources and Services Administration (HRSA) oversees the CARE Act.

We recommended that Pennsylvania (1) refund \$2.2 million to the Federal Government, (2) review clients identified by this review as ineligible or having other health insurance to determine whether additional Title II payments made outside the audit period were improper, (3) review and validate information provided by clients on their ADAP applications before admitting clients to the program, and (4) ensure that the ADAP is considered the payer of last resort for clients who are enrolled in both the ADAP and the State's Pharmaceutical Assistance Contract for the Elderly program. The State generally agreed with our findings and outlined its actions to address our recommendations. *Review of Ryan White Title II Funding in Pennsylvania*. A-03-08-00552. Full Report

Public Health > HRSA > CARE Act Administration

Ryan White Title II AIDS Drug Assistance Program Funding in New Jersey

From April 1, 2003, through June 30, 2004, New Jersey improperly billed about \$2.5 million to Title II of the CARE Act for ADAP clients who were covered by the Medicaid program.

Title II grant funds may not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance, including Medicaid. Title II grants fund the purchase of medications through the ADAP and other health care and

support services for people who HIV/AIDS and who have no health insurance or are underinsured. We recommended that the health department refund \$2,498,819 to the Federal Government. In its response to our report, New Jersey did not directly address the recommendation. We maintain that the amount we identified should be refunded. *Review of Ryan White Title II AIDS Drug Assistance Program Funding in New Jersey*. A-02-08-02007. Full Report

Indian Health Service

Public Health > IHS > Loan Repayment Program

Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' Compliance With Requirements of the Loan Repayment Program

The Indian Health Service (IHS) did not have adequate internal controls to monitor recipients' compliance with certain requirements of the Loan Repayment Program related to Government and commercial loans obtained for education in health professions.

IHS did not always follow its policies and procedures to verify that recipients were employed at IHS-approved sites before awarding loan repayment funds and to ensure that recipients fulfilled their required-service obligations. As a result, IHS could not ensure that all recipients were in compliance with loan repayment requirements. Under the program, IHS is authorized to pay directly to the recipient of a loan repayment award the principal, interest, and related expenses associated with Government and commercial loans obtained for education in health professions. Recipients must sign contracts with IHS in which they agree to fulfill a service obligation at an IHS-approved site in return for funds to pay health profession education loans.

We recommended that IHS follow its policies and procedures to verify that recipients are employed before awarding loan repayment funds and that recipients fulfill their service obligations. IHS concurred with our recommendation and described actions that it planned to take to address the recommendation. *Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' Compliance With Requirements of the Loan Repayment Program.* A-09-10-01005. <u>Full Report</u>

Public Health > IHS > Nursing Program Scholarships

Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' Compliance With Requirements of Nursing Program Scholarships

IHS did not have any internal controls to monitor recipients' fulfillment of education requirements and service obligations for Nursing Program scholarships. As a result, IHS could not provide assurance that recipients fulfilled education requirements and service obligations.

Under the Nursing Program, IHS provides grants to colleges, universities, and other programs to develop and maintain nursing education programs and recruit individuals to provide nursing services to Indians. Each recipient of a Nursing Program scholarship must maintain full-time enrollment until completion of the program, maintain an acceptable level of academic standing, and fulfill a minimum service obligation. We recommended that IHS develop and implement internal controls for monitoring recipients' fulfillment of education requirements and service obligations for Nursing Program scholarships. IHS concurred with our recommendation and described actions that it was taking to address the recommendation. *Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' Compliance With Requirements of Nursing Program Scholarships*. A-09-10-01006. Full Report

National Institutes of Health

Public Health > NIH > Grants Management

■ Institutional Conflicts of Interest at NIH Grantees

The National Institutes of Health (NIH) lacks information on the number of institutional conflicts that exist among its grantee institutions and therefore cannot evaluate the impact that these conflicts may have on NIH-sponsored research. Institutional conflicts of interest may arise when institutions' financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of senior officials pose risks of undue influence on decisions involving the institutions' research.

No Federal regulations require NIH grantee institutions to identify and report institutional conflicts to NIH. We surveyed 250 grantee institutions and requested information on any institutional financial interests related to NIH grants awarded in FY 2008. Despite the lack of Federal requirements, 70 of 156 responding NIH grantee institutions (less than half) had written policies and procedures addressing these interests. We also found that although not required for institutional conflicts, 69 of 156 responding NIH grantee institutions had written policies and procedures addressing such conflicts. Fifty-nine of the sixty-nine institutions defined, in writing,

what constitutes an institutional conflict. We recommended that NIH promulgate regulations that address institutional financial conflicts of interest, and, until regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures related to institutional financial interests and conflicts. In response to our report, NIH stated that it is reviewing public comments to finalize regulations on financial conflicts of interest, and, therefore, it neither concurred nor nonconcurred with our recommendation. *Institutional Conflicts of Interest at NIH Grantees*. OEI-03-09-00480. Full Report

Public Health > NIH > Appropriations Funding

Appropriations Funding for National Heart, Lung, and Blood Institute Contract HHSN268-2008-00012C With Information Management Services, Inc.

During FYs 2008 and 2009, NIH's National Heart, Lung, and Blood Institute (NHLBI) did not comply with "time" requirements and may not have complied with "amount" requirements specified in appropriations statutes in administering contract HHSN268-2008-00012C (the contract) with Information Management Services, Inc.

Because the contract was a nonseverable service contract (i.e., represents a single undertaking and provides for a single outcome), NHLBI was required to record the full amount of the contract using fiscal year 2008 appropriated funds. By not doing so, NHLBI potentially violated the Anti-Deficiency Act, which prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law. We found that NHLBI did comply with "purpose" requirements of appropriations statutes. An agency may obligate appropriations for goods and services when (1) the purpose of the obligation or expenditure is authorized, (2) the obligation occurs within the time limits for which the appropriation is available, and (3) the obligation and expenditure are within the amounts provided by Congress. Federal statutes specify that a fiscal year appropriation may be obligated to meet only a legitimate, or bona fide, need arising in or continuing to exist in the appropriation's period of availability.

We recommended that NHLBI (1) record \$2.7 million of the \$3.4 million Contract obligation against FY 2008 funds and deobligate funds appropriated for years other than FY 2008 and (2) report an Anti-Deficiency Act violation if FY 2008 funds are not available. NIH concurred with our findings and recommendations. *Appropriations Funding for National Heart, Lung, and Blood Institute Contract HHSN*268-2008-00012C With Information Management Services, Inc.

A-03-10-03121. Full Report

Public-Health-Related Legal Actions and Investigations

Health Education Assistance Loan Program

Under the Health Education Assistance Loan (HEAL) program, HRSA guarantees commercial loans to students seeking education in health-related fields. The students are allowed to defer repayment of the loans until after they have graduated and begun to earn income. Although the Department of Health & Human Services' (HHS) Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve 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 exclusion from Medicare, Medicaid, and all other Federal health care programs for nonpayment of these loans. Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered nor can any other provider receive reimbursement for services ordered or prescribed by the individual. OIG has authority to exclude individuals who have defaulted on HEAL loans from participation in Federal health care programs.

HEAL Exclusions

During the period covered by this report, 52 individuals and related entities were excluded as a result of PSC referral of their cases to OIG. Individuals who have been excluded as a result of default may enter into settlement agreements whereby the exclusions are stayed while they pay specified amounts each month to satisfy their debts. If they default on these settlement agreements, they may be excluded until the entire debts are repaid, and they may not appeal the exclusions. After being excluded for nonpayment of their HEAL debts, 2,315 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure includes the 23 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 \$173.3 million. Of that amount, \$2.6 million is attributable to this reporting period.

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

- Washington Chiropractor \$29,014
- Texas Osteopath \$51,447
- California Medical Doctor \$104,311
- Virginia Medical Doctor \$ 23,281
- California Medical Doctor \$643,013

Human Services

Foster Care

Human Services > Foster Care > Allowability of State Claims for Federal Share

Allegheny County Title IV-E Foster Care Claims From October 1997 Through September 2002

Pennsylvania improperly claimed an estimated \$28.3 million of the \$146.1 million Federal share it claimed for Title IV-E reimbursement on behalf of Allegheny County children from October 1997 through September 2002.

The \$28.3 million included \$17.3 million in unallowable maintenance costs and \$11 million in unallowable associated administrative costs. We also set aside \$27.9 million for determinations of allowability by the State and the Administration for Children & Families (ACF). Title IV-E of the Social Security Act, as amended, authorizes Federal funds for State foster care programs. For children who meet Title IV-E requirements, ACF provides the Federal share of States' costs, including those for maintenance and administration and training.

We recommended that the State (1) refund \$28.3 million to the Federal Government, (2) work with ACF to determine the allowability of \$27.9 million related to claims that included allowable and unallowable services; (3) work with ACF to identify and resolve any unallowable claims for maintenance payments made after September 2002 and refund the appropriate amount; (4) discontinue claiming Title IV-E reimbursement for ineligible children and ineligible services; (5) direct Allegheny County to develop rate-setting procedures that separately identify maintenance and other costs; and (6) direct Allegheny County to describe the services provided when claiming sundry costs. The State disagreed with our findings and recommendations. *Audit of Allegheny County Title IV-E Foster Care Claims From October 1997 Through September 2002*. A-03-08-00554. Full Report

Head Start

Human Services > ACF > Head Start > Health and Safety Requirements

District of Columbia Department of Parks and Recreation's Compliance With Health and Safety Regulations for Head Start Programs

The Head Start program-funded activities of the District of Columbia Department of Parks and Recreation did not fully comply with Federal and State requirements on ensuring the health and safety of children in its care.

This is one of a series of audits that address the health and safety of children in Head Start programs. We are conducting these types of audits in response to the \$2.1 billion in American Recovery and Reinvestment Act of 2009 (Recovery Act) funds appropriated for the Head Start program in FYs 2009 and 2010. The District of Columbia Department of Parks and Recreation was a delegate agency for Head Start program grantee United Planning Organization (UPO), a community action agency for Washington, DC. As of July 2009, the files on all 43 of the delegate Grantee's employees (1) lacked evidence of a completed child protection register check, (2) lacked evidence of compliance with 1 or more other Federal or State preemployment requirements, and (3) were not maintained on the facility premises. The delegate Grantee's 15 drivers did not meet all Federal driver-specific preemployment and training requirements.

Finally, the delegate Grantee's 10 childcare facilities did not meet all Federal Head Start and State requirements for protecting children from unsafe materials and equipment and did not provide a fully secure environment for the children in their care.

The delegate Grantee has since left the Head Start program, and UPO has closed 5 of the 10 facilities. The delegate Grantee's failure to comply with requirements jeopardized the health and safety of children in its care.

We recommended that UPO develop and consistently follow procedures for the five remaining facilities to ensure that (1) all employee files contain evidence of checks of the child protection register and evidence of completed background checks, no applicants are hired if they have been convicted of an offense listed in District regulations, and each facility maintains background check documentation on each employee on the premises; (2) all drivers have met Federal driver-specific requirements; (3) all unsafe materials and equipment are stored in locked areas out of the reach of children, all necessary repairs are addressed in a timely manner, all unsafe conditions are addressed, and all facilities meet State licensing requirements; and (4) all facilities are secure. UPO concurred with our recommendations and described its actions to address the deficiencies that we identified. *Review of District of Columbia Department of Parks and Recreation's Compliance With Health and Safety Regulations for Head Start Program*. A-03-09-00363. Full Report

¹ Relevant offenses are listed in District of Columbia regulations at 29 DCMR § 328.1(e).

Job and Family Services

Human Services > State Claims for Federal Share > Child Welfare Services

Ohio Department of Job and Family Services Claims for Costs Reported by the Hamilton County Department of Job and Family Services

The Ohio Department of Job and Family Services (State agency) reported \$59 million (Federal share) in unallowable costs for services provided by child welfare organizations from July 1, 2001, through June 30, 2004, that it claimed to ACF for Hamilton County.

We conducted this audit at the request of ACF after the State agency identified \$216 million in unallowable costs reported by the Hamilton County Department of Job and Family Services (County agency). The County agency inappropriately allocated the child welfare organizations' costs through indirect cost pools. The State agency inappropriately claimed the costs because it relied on the County agency's reported program costs and did not ensure that the County agency allocated the costs in accordance with the cost allocation plan and other Federal requirements.

We recommended that the State agency (1) refund \$59 million to the Federal Government for County agency costs inappropriately claimed through the cost pools and (2) ensure that the County agency appropriately allocates and reports allowable costs in accordance with the cost allocation plan and other Federal requirements. The State agency generally concurred with our findings and recommendations. Review of Ohio Department of Job and Family Services Claims for Costs Reported by the Hamilton County Department of Job and Family Services. A-05-08-00098. Full Report

Child-Support Enforcement

Congress annually appropriates funds to OIG to detect, investigate, and prosecute noncustodial parents who fail to pay court-ordered child support. These activities are priorities for OIG. OIG works closely with the Office of Child Support Enforcement (OCSE); 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.

■ Child-Support Task Forces

In 1998, OIG and OCSE initiated Project Save Our Children, a child support initiative that united the efforts of multiagency, multijurisdictional investigative task forces for child-support enforcement. The task forces are designed to identify, investigate, and prosecute egregious criminal nonsupport cases on the Federal and State levels by coordinating law enforcement, criminal justice, and child-support office resources. Task force screening units receive child support cases from the States; conduct

preinvestigative analyses; and forward the cases to the investigative task force units, where they are assigned and investigated. The task force approach streamlines the process by which the cases best suited for criminal prosecution are identified, investigated, and resolved.

Child-Support Investigations

OIG investigations of child-support cases, nationwide, resulted in 32 convictions and court-ordered restitution and settlements of \$1.2 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support follow.

- Georgia Jason Raleigh Thomas was ordered to make restitution in the amount of \$57,175 to the Chatham County Office of Child Support Enforcement following a guilty plea for failure to pay legal child-support obligations. Prior to his arrest, Thomas had been served in May 2003 with a temporary order of child support by the Superior Court of Chatham County, and had also been given a contempt order and income-deduction order by the court on March 10, 2006. In December 2007, the paternity of the child in question was resolved with Thomas' signing of a paternity acknowledgement, and his giving permission for the child's surname to be changed to his own.
- South Dakota Jeremiah Wood was sentenced to 18 months of incarceration and restitution in the amount of \$18,155 in connection with his guilty plea to one felony count of failure to pay legal child-support obligations. Records indicate that Wood was ordered to make child-support payments commencing in 2000 in support of his child, who resided in the District of South Dakota. According to the South Dakota Division of Child Support, Wood failed to comply with the court order in this matter and was over \$10,000 in arrears, despite his awareness of his obligation and his ability to pay.

Departmentwide Issues

Departmental Financial Statement Audit

The Chief Financial Officers Act of 1990 (CFO Act), as amended, requires OIG or an independent external auditor, as determined by OIG, to audit the HHS financial statements in accordance with applicable standards. Independent external auditors provided an unqualified opinion on the FY 2010 HHS financial statements. This means that for the 12th consecutive year, the statements were reliable and fairly presented. However, the report on internal controls noted two material weaknesses, and the report on compliance with laws and other matters noted noncompliance with Federal Financial Management Improvement Act of 1996 (FFMIA).

Financial Reporting Systems, Analyses, and Oversight—FFMIA requires Federal agencies to have an integrated financial management system that provides effective

and efficient interrelationships among software, hardware, personnel, procedures, controls, and data contained within the systems and compliance with the United States Standard General Ledger at the transaction level and applicable Federal accounting standards. HHS's lack of an integrated financial management system continues to impair its ability to support and analyze account balances reported. Because of continued weaknesses in the financial management systems, management must compensate for the weaknesses by implementing and strengthening additional controls to ensure that errors and irregularities are detected in a timely manner.

Review of internal controls disclosed a series of weaknesses that impact HHS's ability to report accurate financial information on a timely basis. For example, the audit found that HHS did not have adequate controls in place to monitor undelivered orders, which represent remaining amounts of obligated funds that had not been delivered or appropriately deobligated. As of September 30, 2010, the audit identified approximately 102,500 transactions totaling about \$1.8 billion that were more than 2 years old without activity. Additionally, during FY 2010, OIG, the Office of General Counsel, and management from HHS and the operating divisions completed reviews of various multiyear contracts and found that the contracts were funded in a manner that was inconsistent with the legal requirements.

Financial Information Systems—Issues in the design and the operation of key controls in both general and application controls were noted. In particular, weaknesses were identified in information security program and application configuration management. For example, external and internal system vulnerabilities such as weak password configurations, insecure system configuration, and unnecessary system services continue to exist and pose a significant risk. Change-management procedures were insufficient to ensure that only properly authorized changes were implemented into production systems. In addition, audit log monitoring and contingency management were identified as deficiencies that warrant attention.

HHS piloted a new Consolidated Financial Reporting System that should correct many of the findings related to financial systems, analyses and oversight in FY 2010. HHS implemented the new reporting system for the first quarter FY 2011 successfully and will use it for the FY 2011 HHS Consolidated Financial Statements, issued as of and for the period ending September 30, 2011. HHS expects to have the issues identified for Financial Management Information Systems corrected by September 30, 2012. HHS is currently updating its agencywide corrective action plan to address noncompliance with FFMIA.

Refer to: Department of Health & Human Services Fiscal Year 2010 Agency Financial Report, section II. Daniel R. Levinson, Inspector General, Report on the Financial Statement Audit of the Department of Health & Human Services for Fiscal Year 2009. A-17-09-00001 (pp. II-8, II-16, II-50).

■ Non-Federal Audits

In this semiannual period, OIG's National External Audit Review Center reviewed 1,579 reports that covered \$823.3 billion in audited costs. Federal dollars covered by these audits totaled \$175 billion, about \$84.8 billion of which was HHS money.

Office of Management and Budget (OMB) Circular A-133 establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under this circular, covered entities must conduct annual organizationwide "single audits" of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities' management of Federal funds. OIG's oversight of non-Federal audit activity informs Federal managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or followup. We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs, and profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession. OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports.

The non-Federal audit reports reviewed and issued during this reporting period are categorized in the following table.

OIG reports issued:	
Not requiring changes or with minor changes	1,497
Requiring major changes	71
With significant technical inadequacies	11
Total	1,579

The 1,579 reports included 4,249 recommendations for improving management operations. In addition, these audit reports provided information for 68 special memorandums that identified concerns for increased monitoring by management.

Contract Audits

The National Defense Authorization Act for FY 2008, § 845, requires each Inspector General appointed under the Inspector General Act of 1978 to submit, as part of the semiannual report submitted to Congress pursuant to section 5 of such Act, information on final, completed contract audit reports issued to the contracting activity containing significant audit findings issued during the period covered by the

semiannual report concerned. This edition of the Semiannual Report includes the following significant contract audits:

- Centers for Disease Control and Prevention's Compliance with Appropriations Laws and Acquisition Regulations. Contractor B Audit: no questioned costs. Contractor C audit: no questioned costs. Contractor D audit: \$1,599,612 in unsupported costs. Contractor E audit: \$230,520 in unsupported costs. For report names and numbers, see p. IV-1.
- Appropriations Funding for National Heart, Lung, and Blood Institute Contract HHSN268-00012C With Information Management Services, Inc. \$3,460,870 in funds put to better use recommendations; no questioned cost recommendations. For report summary and number, see p. IV-7.

■ Grantee Fraud and Misconduct

Wisconsin – Elizabeth B. Goodwin, Ph.D., a former Associate Professor at the University of Wisconsin, Laboratory of Genetics, was ordered to pay \$50,000 in restitution after pleading guilty to a criminal offense related to fraud and false statements. Goodwin admitted to manipulating data in a Federal grant progress report to convince reviewers that she was making more scientific progress with her research than was actually the case. Goodwin also admitted that her conduct constituted misconduct in science, and she agreed to be voluntarily excluded for 3 years from any involvement in Federal Government research. This case was jointly investigated with the Federal Bureau of Investigation (FBI).

Recovery Act Retaliation Complaint Investigation

Section 1553 of the Recovery Act prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. Section 1553 also requires OIGs to include in their semiannual reports to Congress the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. During this reporting period, OI discontinued one Recovery Act whistleblower retaliation complaint investigation. The complaint was against a collegiate educational facility in the Southeastern United States.

■ Legislative and Regulatory Reviews

The Inspector General Act of 1978 (IG Act) requires us to review existing and proposed legislation and regulations relating to HHS's programs and operations and make recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that we conduct are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. Our reports of such reviews describe findings, which include questioned costs, inefficiencies, vulnerabilities to fraud,

inconsistencies, errors in application, or weaknesses in oversight or supporting systems. Our corresponding recommendations tell HHS and its pertinent operating or staff divisions what administrative, regulatory, or legislative actions we believe are needed to effectively respond to the findings. Our regularly published core publications reflect the relationship between our work and laws and regulations.

- Our Semiannual Report to Congress describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- Our *Compendium of Unimplemented Recommendations*, which is published annually, describes priority findings and recommendations from past periods that remain to be implemented, along with pertinent citations of existing laws and regulations.
- Our annual Work Plan, which is published at the start of each fiscal year, provides citations to laws and regulations that are the subject of ongoing or future reviews.

We also review proposed legislation and regulations related to HHS programs and operations. HHS routinely involves us and its other operating and staff divisions in the review and development of HHS regulations through a well-established HHS process. Our audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

Appendixes:

A: Reporting Requirements

B: Questioned Costs and Funds Put to Better Use

C: Peer Review Results

D: Sanction Authorities

E. Acronyms and Abbreviations

Appendix A: Reporting Requirements

The Inspector General Act of 1978

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

Section		
of the Act	Requirement	Location
Section 4	_	
(a)(2)	Review of legislation and regulations	Part IV. See page IV-16.
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 Recommendations: www.oig.hhs.gov/publications.html
(a)(4)	Matters referred to prosecutive authorities	Legal and Investigative Section
(a)(5)	Summary of instances in which information was refused	None
(a)(6)	List of audit reports	Submitted to Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report

Section		
of the Act	Requirement	Location
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	Appendix B
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	Appendix B
(a)(10)	Summary of previous audit reports without management decisions	Appendix B
(a)(11)	Description and explanation of revised management decisions	Appendix B
(a)(12)	Management decisions with which the Inspector General is in disagreement	None
(a)(13)	Information required by the Federal Financial Management Improvement Act of 1996	Reported annually in the spring <i>Semiannual Report</i> . See page IV-13.
(a)(14)- (16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS OIG of other OIGs.	Appendix C

Other Reporting requirements

§ 845	Significant contract audits required to	Departmentwide Issues, See page
	be reported pursuant to the National	IV-15.
	Defense Authorization Act for	
	FY 2008 (P.L. No. 110-181), § 845.	
	, , ,	

Appendix B: Questioned Costs and Funds To Be Put to Better Use

The following statistical tables summarize the Office of Inspector General's (OIG) monetary recommendations and the Department of Health & Human Services' (HHS) responses to those recommendations. This information is provided in accordance with sections 5(a)(8) and (a)(9) of the Inspector General Act (5 U.S.C. App. §§ 5(a)(8) and (a)(9)) and the Supplemental Appropriations and Rescissions Act of 1980.

Table 1: Audit Reports With Questioned Costs

Questioned costs are those costs questioned by OIG audits because of an alleged violation of a provision of a law, regulation, contract, grant, or other agreement governing the expenditure of funds. Costs are questioned because the expenditure was not supported by adequate documentation or because the expenditure was unnecessary or unreasonable.

OIG includes those questioned costs that HHS program officials, in a management decision, have agreed should not be charged to the Federal Government, commonly referred to as disallowed costs, as part of the expected recoveries in the Accomplishments section at the beginning of the *Semiannual Report*. Superscripts indicate end notes.

A stable Damasta	Number	Dollar Value	Dollar Value
Audit Reports	of Reports	Questioned	Unsupported
Section 1			
Reports for which no management			
decision had been made by the beginning			
of the reporting period ¹	175	\$859,558,000	\$88,104,000
Reports issued during the reporting period	68	\$493,208,000	\$3,169,000
Total Section 1	243	\$1,352,766,000	\$91,273,000
Section 2			
Reports for which a management decision			
was made during the reporting period ^{2, 3}			
Disallowed costs	132	\$222,380,000	\$6,138,000
Costs not disallowed	6	\$8,848,000	\$10,000
Total Section 2	138	\$231,228,000	\$6,148,000
Section 3			
Reports for which no management			
decision had been made by the end of the			
reporting period			

Audit Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Total Section 1			
Minus Total Section 2	105	\$1,121,538,000	\$85,125,000

Audit Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 4			
Reports for which no management			
decision was made within 6 months of			
issuance ⁴	64	\$742,254,000	\$84,116,000

Table 2: Funds Recommended To Be Put to Better Use

Recommendations from audit reports that funds be put to better use are recommendations that funds could be used more efficiently if management took action to implement an OIG recommendation through reductions in outlays, deobligation of funds, and/or avoidance of unnecessary expenditures. Table 2 reports HHS program officials' decisions to take action on these audit recommendations. Implemented recommendations are reported in the fall Semiannual Reports.

Audit Reports	Number of Reports	Dollar Value
Section 1		
Reports for which no management decision had been made		
by the beginning of the reporting period ¹	28	\$4,280,541,000
Reports issued during the reporting period	6	\$549,817,000
Total Section 1	34	\$4,830,358,000
Section 2		
Reports for which a management decision was made		
during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	11	\$1,213,303,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management	1	\$4,764,000
Total Section 2	12	\$1,218,067,000
Section 3		
Reports for which no management decision had been made		
by the end of the reporting period ²		
Total Section 1		
Minus Total Section 2	22	\$3,612,291,000

End Notes to Tables 1 and 2

Table 1 End Notes

¹ The opening balance was adjusted upward by \$50 million because of a reevaluation of previously issued audit recommendations.

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

- A-02-08-01002, Review of High-Dollar Medicare Payments to Hospitals for Inpatient Claims Processed by National Government Services for the Period January 1, 2003, Through December 31, 2005. The Centers for Medicare & Medicaid Services (CMS) completed its review of high-dollar claims processed during calendar years (CY) 2003-2005 and identified an additional \$1,593,363 in overpayments.
- A-03-03-00220, *Review of Family Planning Service Costs Claimed by Delaware's Medicaid Managed Care Program*. Based on a review of additional documentation provided by the State to support family planning claims, CMS determined that the original disallowance of \$2,916,288 should be reduced by \$2,003,492.
- A-04-95-02111, Review of Hospice Eligibility at the Hospice of the Florida Suncoast, Inc.
 CMS reversed its 1998 decision to recover overpayments totaling \$14,800,000
 because it had not been able to determine that beneficiaries were not eligible for coverage.
- A-04-06-00026, Review of Medicaid Services to Incarcerated Juveniles in the State of Georgia For Federal Fiscal Years 2003 and 2004. CMS, after a review of additional information submitted by the State and in consultation with the OIG, reduced its original disallowance by \$1,653,356.
- A-07-07-00243, Review of the Qualified Pension Plan at CareFirst of Maryland, Inc., a
 Terminated Medicare Contractor, for the Period January 1, 2002, to December 31, 2005.
 CMS negotiated a settlement with a terminated Medicare contractor to reduce
 CMS's share of the contractor's Medicare pension assets by \$1,325,834 to reflect
 lump sum pension payouts that had been made by the contractor.

Not detailed are net reductions to previously reported disallowed costs totaling \$523,114.

³ Included are management decisions to disallow \$39.8 million in questioned costs that were identified by non-Federal auditors in audits of States and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office Management and Budget (OMB) Circular A-133. By law, OIG is responsible for ensuring that work performed by these non-Federal

auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 64 audits was not completed within 6 months of issuance of the report. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period:

CIN: A-06-07-00041	REVIEW OF AMP CALCULATION, MFR A, MAR 2008, \$268,000,000.
CIN: A-06-07-00039	REVIEW OF AMP CALCULATION, MFR C, MAR 2008, \$101,000,000.
CIN: A-03-07-00560	PA FOSTER CARE MAINTENANCE PAYMENTS, PHILADELPHIA, UNDER \$300, MAY 2008, \$56,513,439.
CIN: A-09-06-00023	REVIEW OF LOS ANGELES COUNTY APPROVAL PROCESS OF RELATIVE FOSTER FAMILY HOMES, OCT 2009, \$45,520,603.
CIN: A-01-09-00507	NATIONWIDE REVIEW OF INPATIENT REHABILITATION FACILITIES PATIENT ASSESSMENT INSTRUMENTS, JUN 2010, \$39,247,645.
CIN: A-04-09-00059	REVIEW OF INPATIENT REHABILITATION CARE FACILITIES MEDICARE CLAIMS FOR COMPLIANCE WITH CMS TRANSFER CLASSIFICATION REQUIREMENTS FOR 10/1/03 THROUGH 9/30/07, JUN 2010, \$34,051,807.
CIN: A-09-02-00054	AUDIT OF STATE OF CALIFORNIA DSH PROGRAM FOR FY 1998, MAY 2003, \$33,318,976.
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL BASED HEALTH SERVICES, CT, MAY 2003, \$32,780,146.
CIN: A-06-07-00040	REVIEW OF AMP CALCULATION, MFR B, MAR 2008, \$27,700,000.
CIN: A-01-07-00013	REVIEW OF MEDICAID SUPPLEMENTAL PAYMENT TO UMASS MEMORIAL HEALTH CARE, INC., DEC 2009, \$14,789,242.
CIN: A-09-01-00098	AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950.
CIN: A-03-06-00564	PA FOSTER CARE MAINTENANCE PAYMENT, PHILADELPHIA, OVER \$300/DAY, DEC 2007, \$11,693,989.
CIN: A-03-05-00550	AUDIT OF PA FOSTER CARE MAINTENANCE PAYMENTS, CASTILLE SAMPLE, SEP 2007, \$11,611,822.
CIN: A-03-08-03000	REVIEW OF PROCUREMENTS MADE BY NIH FOR THE DEPARTMENT OF DEFENSE, MAY 2009, \$6,300,000.
CIN: A-04-08-03521	AUDIT OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN TN FOR THE PERIOD OCTOBER 1, 1998 TO DECEMBER 31, 2007, FEB 2009, \$5,768,243.

CIN: A-01-08-00511	REVIEW OF SEPARATELY BILLED CLINICAL LABORATORY SERVICES PROVIDED TO ESRD BENEFICIARIES BY FMCNA, MAR 2010, \$5,410,712
CIN: A-01-06-00007	REVIEW OF RHODE ISLAND'S MEDICAID ADMINISTRATIVE COST CLAIMS, FY 2004 - FY 2005, MAR 2008, \$5,092,735.
CIN: A-02-09-02019	REVIEW OF ADOPTION ASSISTANCE DUPLICATE CLAIMS, SEP 2010, \$4,811,735.
CIN: A-04-08-03523	REVIEW OF TITLE IV-E ADOPTION ASSISTANCE MAINTENANCE PAYMENTS IN FL FOR THE PERIOD OCTOBER 1, 2004 THROUGH SEPTEMBER 30, 2007, MAY 2009, \$4,413,264.
CIN: A-04-08-06002	FLORIDA'S 2003 TO 2005 COMPLIANCE WITH THE RYAN WHITE CARE ACT PAYER OF LAST RESORT REQUIREMENT, MAY 2010, \$4,400,613.
CIN: A-09-01-00085	AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFY 1998, SEP 2002, \$3,776,054.
CIN: A-10-96-00001	REVIEW OF ESRD PAYMENTS TO GROUP HEALTH COOPERATIVE OF PUGET SOUND, APR 1997, \$2,763,498.
CIN: A-07-08-03114	REVIEW OF MISSOURI ACF TRAINING COSTS, AUG 2009, \$2,556,099.
CIN: A-07-09-03119	MO CLAIM FOR TITLE IV-E TRAINING COSTS FOR SALARIES AND BENEFITS, JUL 2009, \$741,872.
CIN: A-07-09-03121	MO TITLE IV-E TRAINING COSTS FOR RESIDENTIAL TREATMENT CENTERS AND FOSTER CARE PARENTING, SEP 2009, \$569,663.
CIN: A-05-09-00047	HEAD START MATCHING COSTS, COMMUNITY ACTION COMMITTEE OF LANCASTER FAIRFIELD COUNTY, JAN 2010, \$547,019.
CIN: A-05-06-00038	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, IN, MAR 2007, \$461,430.
CIN: A-01-08-00014	AUDIT OF MEDICAID ADMINISTRATIVE COSTS CLAIMED BY THE COMMONWEALTH OF MASSACHUSETTS, OCTOBER 1, 2005 THROUGH SEPTEMBER 30, 2007, FEB 2010, \$448,968.
CIN: A-06-06-00072	REVIEW OF COST FOR TEXAS MEDICAL FOUNDATION AUDITEE, MAY 2008, \$403,581.
CIN: A-05-01-00096	PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355.
CIN: A-07-09-03120	MO CLAIM FOR TITLE IVE TRAINING COSTS FOR LONG TERM TRAINING, FEB 2010, \$301,187.
CIN: A-07-05-01013	PAYMENTS FOR M+C ORGANIZATION FOR INSTITUTIONAL BENEFICIARIES, OCT 2005, \$293,885.
CIN: A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS, MI, AUG 2006, \$257,859.
CIN: A-05-01-00094	PAYMENTS TO KAISER OF OAKLAND FOR INSTITUTIONAL BENEFICIARIES, OCT 2002, \$229,656.

CIN: A-07-06-01035	AUDIT OF QUALITY IMPROVEMENT ORGANIZATION, IOWA, OCT 2007, \$208,974.
CIN: A-03-09-00021	REVIEW OF MEDICARE PART D DRUG PAYMENTS TO VIRGINIA FOR SERVICE DATES JANUARY 1 - MARCH 8
	2006, JUL 2010, \$168,500.
CIN: A-09-05-00077	REVIEW OF PACIFICARE'S USE OF ADDITIONAL
	CAPITATION UNDER THE MMA OF 2003, MAR 2006, \$135,000.
CIN: A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE
	COSTS FOR FEDERAL FISCAL YEARS 2006 THRU 2008, JUL
CINI. A OF 01 00001	2009, \$124,046.
CIN: A-05-01-00091	PAYMENTS TO UNITED HC OF FLA FOR INSTITUTIONAL BENEFICIARIES, SEP 2002, \$121,023.
CIN: A-04-07-01045	COSTS CLAIMED FOR ESRD NETWORK 6 OPERATIONS,
CII (. 11 01 07 010 IO	AUG 2009, \$116,728.
CIN: A-09-10-02005	POWER MOBILITY DEVICE CLAIMS BY D&M SALES, LLC
	FOR CALENDAR YEARS 2006-2008, SEP 2010, \$113,941.
CIN: A-05-97-00017	FHP, INC., HMO INSTITUTIONAL STATUS PROJECT, JUN
	1998, \$109,114.
CIN: A-05-01-00079	PAYMENTS TO BLUE CARE MID-MI FOR INSTITUTIONAL
CIN: A-05-01-00090	BENEFICIARIES, JUN 2002, \$100,692. PAYMENTS TO AETNA U.S. HEALTHCARE PA FOR
CIIV. 71-03-01-00070	INSTITUTIONAL BENEFICIARIES, JUL 2002, \$87,516.
CIN: A-03-08-00011	REVIEW OF DUPLICATE PAYMENTS TO PHARMACIES FOR
	MEDICARE PART D DRUGS (PDE-DEMO): BARON DRUGS,
	SEP 2009, \$79,489.
CIN: A-02-06-01023	AUDIT OF QUALITY IMPROVEMENT ORGANIZATION,
CIN: A-05-01-00089	NEW YORK, MAR 2008, \$77,358. ADDITIONAL BENEFITS REVIEW ON MANAGED CARE
CIN: A-03-01-00089	ORGANIZATION, OCT 2002, \$77,000.
CIN: A-09-06-00039	MEDICARE INTEGRITY - AUDIT OF QUALITY
	IMPROVEMENT ORGANIZATION, WASHINGTON STATE,
	FEB 2008, \$73,636.
CIN: A-01-10-00600	REVIEW OF VERMONT'S COMPLIANCE WITH CMS
	REIMBURSEMENT OF MEDICARE PART D DRUG
	DEMONSTRATION PROJECT REQUIREMENTS, SEP 2010,
CIN: A-05-01-00086	\$70,027. PAYMENTS TO HMO OF NE PA FOR INSTITUTIONAL
CH 1. 11 00 01 00000	BENEFICIARIES, MAY 2002, \$62,432.
CIN: A-01-08-00601	REVIEW OF COSTS CLAIMED BY RETIREE DRUG SUBSIDY
	PLAN SPONSOR BLUE CROSS BLUE SHIELD OF
	MASSACHUSETTS, INC. FOR PLAN YEAR ENDED
CINI A 04 07 00000	DECEMBER 31, 2006, APR 2009, \$33,300.
CIN: A-04-06-00023	REVIEW OF QUALITY IMPROVEMENT ORGANIZATIONS, TENNESSEE, JUL 2008, \$30,654.
CIN: A-08-03-73541	SOUTH DAKOTA FOUNDATION FOR MEDICAL CARE, JAN
	2003, \$28,573.

CIN: A-07-02-00150	PAYMENTS TO COVENTRY, PITTSBURG FOR
	INSTITUTIONAL BENEFICIARIES, JUN 2003, \$26,000.
CIN: A-05-01-00078	PAYMENTS TO HEALTH NET, TUCSON, AZ FOR
	INSTITUTIONAL BENEFICIARIES, APR 2002, \$21,233.
CIN: A-08-04-76779	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003,
	\$18,925.
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR
	INSTITUTIONALIZED BENEFICIARIES, MAY 2002, \$18,842.
CIN: A-05-01-00095	PAYMENTS TO HUMANA OF ARIZONA FOR
	INSTITUTIONAL BENEFICIARIES, JUN 2002, \$18,645.
CIN: A-07-03-00151	REVIEW OF MEDICARE PAYMENTS FOR BENEFICIARIES
	WITH INSTITUTIONAL STATUS, JUN 2003, \$18,400.
CIN: A-07-04-01011	PAYMENTS FOR UNITED HEALTHCARE FOR
	INSTITUTIONAL BENEFICIARIES, MAR 2005, \$13,128.
CIN: A-05-06-00043	REVIEW OF OHIO KEPRO, FEB 2008, \$11,874.
CIN: A-05-01-00070	PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL
	STATUS, MISSOURI GROUP HEALTH PLAN, JAN 2002,
	\$11,089.
CIN: A-06-08-00064	LOUISIANA - CDC BIOTERRORISM AND EMERGENCY
	PREPAREDNESS, SEP 2010, \$10,892.
CIN: A-09-09-00111	MEDICARE PAYMENTS FOR DME CLAIMS WITH KX

TOTAL CINS: 64

TOTAL AMOUNT: \$742,254,019

Table 2 End Notes

MODIFIERS, SEP 2010, \$5,941.

CIN: A-06-09-00033	REVIEW OF ADDITIONAL REBATES OF NEW BRAND NAME
	DRUGS, MAR 2010, \$2,500,000,000.
CIN: A-02-07-02000	OPEN AND INACTIVE GRANTS ON THE PAYMENT
	MANAGEMENT SYSTEM, ACF, FEB 2009, \$472,155,156.
CIN: A-09-09-00111	MEDICARE PAYMENTS FOR DME CLAIMS WITH KX MODIFIERS,
	SEP 2010, \$70,000,000.
CIN: A-04-06-03508	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, FLORIDA,
	JAN 2008, \$7,881,447.
CIN: A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS - MI, AUG 2006,
	\$4,397,133.
CIN: A-06-00-00073	MANAGED CARE ADDITIONAL BENEFITS, NYLCARE HEALTH
	PLANS OF THE SOUTHWEST, CY 2000, MAR 2002, \$4,000,000.

¹ The opening balance was adjusted upward by \$127,000.

² Because of administrative delays, some of which were beyond management control, resolution of the following 15 audits was not completed within 6 months of issuance of the report. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period:

REVIEW OF WORKFORCE STABILIZATION GRANT FOR THE CIN: A-06-08-00026 GREATER NEW ORLEANS AREA, MAR 2010, \$1,435,000. CIN: A-09-09-00055 MEDICAID, REVIEW OF CALIFORNIA DRUG EXPENDITURES (MANUAL CLAIMS), JUN 2010, \$1,096,464. CIN: A-05-06-00038 UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, IN, MAR 2007, \$871,677. CIN: A-03-10-03302 BID PROPOSAL AUDIT, SEP 2010, \$354,689. BID PROPOSAL AUDIT, SEP 2010, \$115,180. CIN: A-03-10-03301 CIN: A-05-01-00070 PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, MISSOURI GROUP HEALTH PLAN, JAN 2002, \$98,689. CIN: A-05-06-00023 UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, MN, SEP 2006, \$28,240. CIN: A-05-10-00081 BID PROPOSAL AUDIT, SEP 2010, \$23,047. CIN: A-09-09-01007 REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS

FOR FEDERAL FISCAL YEARS 2006 THRU 2008, JUL 2009, \$17,764.

TOTAL CINS: 15

TOTAL AMOUNT: \$3,062,474,486

Appendix C: Peer Review Results

The Inspector General Act of 1978, as amended, requires Offices of Inspector General (OIG) to report the results of peer reviews of their operations conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by the OIG of other OIGs in the semiannual period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). The required information follows.

Office of Audit Services Peer Review Results

During this semiannual reporting period, no peer reviews were conducted by another OIG organization on the Department of Health & Human Services (HHS) OIG's Office of Audit Services (OAS) and OAS did not conduct a peer review on other OIGs. Listed below is information concerning OAS's peer review activities during prior reporting periods.

Date	Reviewing Office	Office Reviewed	Findings
June 2009	U.S. Postal Service OIG	HHS-OIG, OAS	The system of quality control for the audit organization of HHS OIG in effect for the year ending September 30, 2008, has been suitably designed and complied with to provide HHS OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. HHS OIG received a peer review rating of pass.
December 2009	HHS OIG, OAS	U.S. Department of Defense (DoD) OIG	The system of quality control for the audit organization of DoD OIG in effect for the year ending March 31, 2009, has been suitably designed and

Date	Reviewing Office	Office Reviewed	Findings
			complied with to provide DoD OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive
			a rating of pass, pass with deficiencies, or fail. DoD OIG received a peer review rating of pass. HHS OIG recommended that
			DoD OIG continue to improve its system of quality control, including audit supervision, audit documentation, and report content, by ensuring
			compliance with audit standards and its policies and procedures. The DoD OIG indicated that it has completed the corrective actions to improve its quality control system that were underway during December 2009.
			daming December 2007.

Office of Investigations Peer Review Results

During this semiannual reporting period, no peer reviews were conducted by another OIG organization on HHS OIG's Office of Investigations (OI). OI conducted a peer review on another OIG. Listed below is information concerning OI's peer review activities during the current and prior reporting periods.

Date	Reviewing Office	Office Reviewed	Findings
March	U.S. Department	HHS OIG, OI	The system of internal
2009	of Labor OIG		safeguards and management
			procedures for the investigative

Date	Reviewing Office	Office Reviewed	Findings
			function of HHS OIG in effect for the year ending September 30, 2008, was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.
January 2010	HHS OIG, OI	U.S. Department of Justice (DOJ) OIG	The system of internal safeguards and management procedures for the investigative function of DOJ OIG in effect for the year ending September 30, 2009, was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.
January 2011	HHS OIG, OI	U.S. Department of Housing and Urban Development (HUD)	The system of internal safeguards and management procedures for the investigative function of HUD OIG in effect through February 2011 was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.

Appendix D:

Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, sets forth specific requirements for semiannual reports to be made to the Secretary for transmittal to Congress. A selection of other authorities appears below.

Program Exclusions

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

The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) added another basis for the imposition of a permissive exclusion, that is, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program, including managed care programs under Medicare and Medicaid, as well as Medicare's prescription drug program.

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

Patient Dumping

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

the hospital must provide either treatment to stabilize the condition or an appropriate transfer to another medical facility.

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

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

Civil Monetary Penalties Law

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

For the purposes of the civil monetary penalties law, "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 law and its implementing regulations also authorize actions for a variety of other violations, including submission of claims for items or services furnished by an excluded person; requests for payment in violation of an assignment agreement; violations of rules regarding the possession, use, and transfer of biological agents and toxins; and payment or receipt of remuneration in violation of the anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

The Affordable Care Act added more grounds for imposing civil monetary penalties. These include, among other conduct, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program (including Medicare and Medicaid managed care programs and Medicare Part D) for which the Affordable Care Act authorizes a penalty of up to \$50,000 for each false statement, as well as activities relating to fraudulent marketing by managed care organizations, their employees, or their agents.

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, in order to induce or in return for (1) referring an individual to a person or an entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs or (2) purchasing; leasing; ordering; or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item payable under the Federal health care programs of the Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b)).

Individuals and entities that engage in unlawful referral or kickback schemes may be subject to criminal penalties under the general criminal anti-kickback statute; a civil monetary penalty under OIG's authority pursuant to the Social Security Act, § 1127(a)(7) (42 U.S.C. § 1320a-7a); and/or program exclusion under OIG's permissive exclusion authority under the Social Security Act, § 1128(b)(7) (42 U.S.C. § 1320a-7(b)(7)).

False Claims Amendments Act of 1986 – Under the Federal False Claims Amendments Act of 1986 (FCA) (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$5,500 and \$11,000 for each false claim it knowingly submits or causes to be submitted to a Federal program. Similarly, a person or an entity is liable under the FCA if it knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid.

The FCA defines "knowing" to include not only the traditional definition but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the FCA, no specific intent to defraud is required. Further, the FCA contains a qui tam, or whistleblower, provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries. The FCA was again amended in 2009 in response to recent Federal court decisions that narrowed the law's applicability. Among other things, these amendments clarify the reach of the FCA to false claims submitted to contractors or grantees of the Federal Government.

Appendix E:

Acronyms and Abbreviations

Following are selected acronyms and abbreviations used in this publication.

Terms, Titles, and Organizations

340B drug pricing program (section 340B of the Public Health Service Act)

ACF Administration for Children & Families

ADAP AIDS Drug Assistance Program

AHRQ Administration for Healthcare Research & Quality

AIDS acquired immunodeficiency syndrome

AMP average manufacturer price
AoA Administration on Aging
ASC ambulatory surgical center

ASP average sales price

CDC Centers for Disease Control and Prevention
CDPAP Consumer Directed Personal Assistance Program
CERT Comprehensive Error Rate Testing (program)

CHIP Children's Health Insurance Program

CIA corporate integrity agreement

CMP civil monetary penalty

CMS Centers for Medicare & Medicaid Services

CWF Common Working File

CY calendar year

DEA Drug Enforcement Administration

DME durable medical equipment
DOJ Department of Justice

FAR Federal Acquisition Regulation
FRI Fodoral Bureau of Investigation

FBI Federal Bureau of Investigation FDA Food and Drug Administration

FEHB Federal Employees Health Benefits (program)

FMAP Federal medical assistance percentage

Form Medicaid Statement of Expenditures for the Medical Assistance Program

CMS-64

FY fiscal year

HAC hospital acquired condition

HCPCS Healthcare Common Procedure Coding System

HEAL Health Education Assistance Loan

HEAT Health Care Fraud Prevention and Enforcement Action Team

HHS Department of Health & Human Services

HIV human immunodeficiency virus

HRSA Health Resources and Services Administration

IHS Indian Health ServiceIRS Internal Revenue ServiceMA Medicare Advantage

MAC Medicare administrative contractor MFCU Medicaid Fraud Control Unit

MMIS Medicaid Management Information System

NDC National Drug Codes [Directory]
NIH National Institutes of Health

OCSE Office of Child Support Enforcement

OIG Office of Inspector General

OMB Office of Management and Budget OPM Office of Personnel Management

OPPS outpatient prospective payment system

PDE prescription drug event

P.L. Public Law

PERM Payment Error Rate Measurement (program)

PPI Producer Price Index PSC Program Support Center

QIO Quality Improvement Organization

RUG resource utilization group SNF skilled nursing facility U.S.C. United States Code

Public Laws

Affordable Care Act Patient Protection and Affordable Care Act of 2010, P.L. No.

11-148, as amended by the Health Care and Education

Reconciliation Act of 2010, P.L. No. 111-52

ACA See Affordable Care Act above.

CARE Act Ryan White Comprehensive AIDS Resources Emergency Act of 1990,

P.L. No. 101-381

CFO Act Chief Financial Officer Act of 1990, P.L. No. 101-576

EMTALA Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272

FCA False Claims Act Amendments of 1986, P.L. No. 99-562 (Updated in P.L.

No. 111-203)

FDCA Federal Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717 **FFMIA** Federal Financial Management Improvement Act of 1996, P.L. No. **HIPAA** Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191 IG Act Inspector General Act of 1978, as amended by P.L. No. 111-25, 5 U.S.C. App. **MIPPA** Medicare Improvements for Patients and Providers Act, P.L. No. 110-275 MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 PHS Act Public Health Service Act of 1944 Recovery American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 Act

Social Security Act of 1935, P.L. No. 74-271

Not

Abbreviated