



Department of Health & Human Services

Office of
Inspector
General

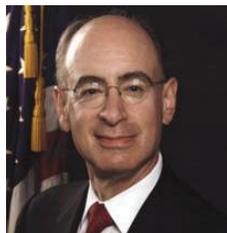
Semiannual
Report
to **Congress**

April 1 - September 30, 2010

OIG

Office of Inspector General

Message From the Inspector General



This report, submitted to Congress 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 September 30, 2010.

As HHS's programs continue to expand in size and complexity, and as we devote significant time and resources toward implementation of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), it is more important than ever to set forth what fundamentally guides OIG as we go about doing the vitally important work of ensuring program integrity.

In this regard, our organization developed a Core Values Statement highlighting the importance of integrity, credibility, and impact in all facets of our work. Our founding statute is now more than 30 years old, and, while our mission to prevent and detect fraud, waste, and abuse and promote economy and efficiency remains our lodestar, we also have witnessed the steady accretion of broader and more complex responsibilities. Below are significant activities in which we have engaged over the past 6 months that reflect our core values at OIG.

Integrity—Acts with independence and objectivity

This value is reflected in our efforts to implement the American Recovery and Reinvestment Act of 2009 (Recovery Act). We have performed internal control assessments of the Department's grant award and monitoring processes and issued 23 recipient capability audits during this reporting period. Through these activities, we have independently and objectively provided HHS with vital information regarding the ability of grantees to manage large grant awards and ensure the integrity of these significant expenditures. Additionally, the new tools afforded to our office under the Affordable Care Act include important new integrity provisions such as enrollment safeguards that will prevent bad actors from obtaining Medicare and Medicaid billing privileges. Once enrolled in the system, OIG now has the authority to suspend payments to those who defraud the system and to impose stiffer penalties for health care fraud.

Credibility—Builds on a tradition of excellence and accountability

Our office works closely with members of Congress and their staff to provide information that is credible and accurately reflects our work regarding the efficiency and effectiveness of the operation of departmental programs. During this reporting period, our office testified before Congress on six occasions. Our testimony provides Congress with recommendations on how to improve program operations and enhance program integrity. Over the past 6 months, we testified on topics regarding cutting fraud, waste, and abuse in Medicare and Medicaid; integrity of Medicare's coverage of durable medical equipment; preventing and recovering Government payment errors; safety of the food supply; and investigative findings regarding operation of the Indian Health Service's Aberdeen Area.

Impact— Yields results that are tangible and relevant

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 as part of its Strike Force activities. During this reporting period, Strike Force efforts have resulted in the filing of charges against 88 individuals or entities, 89 convictions, and \$71.3 million in investigative receivables. This past July, our Special Agents participated in an unprecedented takedown in all seven Strike Force cities that resulted in charges against 94 doctors, health care company owners, executives, and others for more than \$251 million in alleged false billing.

In addition to our enforcement impact, we have made recommendations that contribute directly toward Medicare and Medicaid integrity and improving public health and safety. Work during this reporting period includes recommendations on important issues such as collection activities of Medicare contractors, calculation of the Medicare error rate for payments to certain providers, invalid prescriber identifiers on Medicare Part D claims, deficiencies in Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) comprehensive screening services, and the ability of the Food and Drug Administration to monitor foreign clinical trials. I am also pleased to report that over the past 6 months, OIG issued reports with about \$171.3 million in questioned costs recommendations and about \$362.7 million in funds recommended to be put to better use. During this reporting period, HHS agencies agreed to recover about \$438.6 million in questioned costs and to put about \$39.2 million to better use. (A portion of the amounts agreed to in this period were from recommendations in audit reports issued in prior periods.)

As we address an expanding mission to protect HHS's vital health and human service programs, I would once again 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
Inspector General

Highlights

Summary of Accomplishments

For fiscal year (FY) 2010, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) reported expected recoveries and estimated savings of about \$25.9 billion consisting of \$1.1 billion in audit receivables, \$3.8 billion in investigative receivables (which includes \$576.9 million in non-HHS investigative receivables resulting from OIG work, e.g., the States' share of Medicaid restitution) and \$21 billion from legislative and other cost-saving actions that were supported by recommendations in OIG audits and evaluations.

Also for this FY, OIG reported exclusions of 3,340 individuals and entities from participation in Federal health care programs; 647 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 378 civil actions, which included False Claims Act (FCA) and unjust enrichment lawsuits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters.

The following are highlights of some of OIG's efforts during the semiannual period ending September 30, 2010.

Health Care Fraud Prevention & Enforcement Action Team

Medicare Fraud Strike Force Activities

The interagency Health Care Fraud Prevention & Enforcement Action Team (HEAT), which is comprised of top-level law enforcement and professional staff from HHS, OIG, and the Department of Justice (DOJ), builds on existing partnerships to identify and prevent fraud and enforce current anti-fraud laws around the country. The initiative is enhancing efforts like the Medicare Fraud Strike Force teams that coordinate law enforcement operations with other Federal, State, and local law enforcement entities. Strike Forces began in March 2007 and currently operate in seven major cities—Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; and Tampa, Florida. During this semiannual reporting period, Strike Force efforts have resulted in the filing of charges against 88 individuals or entities, 89 convictions, and \$71.3 million in investigative receivables.

In a recent example of a Strike Force outcome, Dr. Jose Castro-Ramirez and Suresh Chand were sentenced to 14 years and 6 years and 9 months in prison, respectively, and ordered to pay \$9,769,113 in joint and several restitution after being convicted of charges related to health care

fraud. Between January 2003 and March 2007, Chand and his co-conspirators paid Medicare beneficiaries cash kickbacks, and provided other inducements such as prescription drugs in exchange for their Medicare numbers and signatures on documents which falsely stated that they received services. The submission of these fraudulent documents resulted in false claims for physical and occupational therapy services that were never provided. Castro signed medical records then billed Medicare for physical therapy, occupational therapy and other services that were either not medically necessary or not rendered.

Medicare Contractors

Collection of Medicare Overpayments Identified by Program Safeguard Contractors

In our reviews of Program Safeguard Contractors (PSC), we examined PSCs' identification and referral of Medicare overpayments to claims processors for collection. In our first study, we found that PSCs referred \$835 million in overpayments to claims processors for collection in 2007. However, 2 of 18 PSCs were responsible for 62 percent of this amount. In our second study, we found that overpayments referred for collection by PSCs in 2007 did not result in significant recoveries for the Medicare program. PSCs referred 4,239 overpayments in 2007, but only 7 percent (\$55 million of \$835 million) had been collected by claims processors as of June 2008. Of the \$55 million collected, 27 percent was for Part A claims; 56 percent was for Part B claims other than durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and 17 percent was for Part B DMEPOS claims. ([OEI-03-08-00030](#); [OEI-03-08-00031](#))

Medicare and Medicaid Prescription Drugs

AstraZeneca Pays \$520 million to Resolve False Claims Violations

AstraZeneca, LP and AstraZeneca Pharmaceuticals, LP (collectively, AstraZeneca) agreed to pay \$520 million plus interest and enter into a 5-year Corporate Integrity Agreement (CIA) to resolve their civil FCA liability in connection with the promotion of the atypical antipsychotic drug Seroquel. AstraZeneca was alleged to have promoted Seroquel between January 2001 and December 2006 for uses that were not approved by the Food and Drug Administration (FDA) as safe and effective. AstraZeneca also was alleged to have violated the Federal anti-kickback statute by offering and paying illegal remuneration to doctors in connection with services rendered by the doctors relating to the unapproved uses of Seroquel.

Other Part A and Part B Highlights

Inpatient Rehabilitation Facilities' Compliance With Medicare's Transfer Regulation

Based on our sample results for FYs 2004 through 2007, we estimated that inpatient rehabilitation facilities (IRF) were overpaid \$34 million for claims that were improperly coded as discharges to home rather than transfers to other facilities. Under Medicare's transfer regulation, Medicare pays the full prospective payment to an IRF that discharges a beneficiary to home and pays a lesser amount for a transfer case. Whether Medicare pays for a discharge or a transfer depends on the patient status code indicated on the IRF's claim. Even though a new edit in the Centers for Medicare & Medicaid Services' (CMS) Common Working File (CWF) detected the miscoded claims, fiscal intermediaries (FI) did not adjust the claims to prevent overpayments. We recommended, among other things, that CMS recover \$1.2 million in overpayments identified in our sample, instruct its contractors to review the unsampled claims and identify and recover additional overpayments estimated at \$32.8 million, and instruct its contractors to take appropriate action in response to future CWF edit alerts. CMS agreed with our recommendations. ([A-04-09-00059](#))

Inpatient Rehabilitation Facilities' Transmission of Patient Assessment Instruments

For 2006 and 2007, IRFs did not always receive reduced payments for claims with patient assessment instruments that were transmitted to CMS more than 27 days after the beneficiaries' discharges. Such claims should have been reduced by 25 percent. Based on our sample results, we estimated that IRFs were overpaid \$20.2 million for claims with late patient assessment instruments. IRFs may have received an additional \$19 million in overpayments by initially transmitting the instruments within the deadline but subsequently retransmitting them after the deadline to correct errors. CMS guidance does not address the applicability of the 25-percent penalty in these situations. We recommended that CMS take several actions, including (1) adjusting the sampled claims for overpayments of \$424,000, (2) reviewing the nonsampled claims (which have overpayments estimated at \$19.8 million and set-aside payments estimated at \$18.7 million) and recovering any overpayments, and (3) establishing written policies on whether modified patient assessment instruments that are transmitted after the deadline are subject to the 25-percent payment penalty. CMS concurred. ([A-01-09-00507](#))

Analysis of Errors Identified in the Fiscal Year 2009 Comprehensive Error Rate Testing Program

This analysis found that six types of Medicare health care providers accounted for \$4.4 million, or 94 percent, of the \$4.7 million in improper payments identified by CMS's Comprehensive Error Rate Testing (CERT) contractor for FY 2009. The provider types were inpatient hospitals, durable medical equipment (DME) suppliers, hospital outpatient departments, physicians, skilled nursing facilities, and home health agencies. Our analysis of the erroneous claims identified by the CERT contractor found that insufficient documentation, miscoded claims, and

medically unnecessary services and supplies accounted for about 98 percent of the improper payments attributable to the six types of providers. CMS concurred with our recommendation to use the results of our analysis in identifying (1) the types of payment errors indicative of programmatic weaknesses and (2) any additional corrective actions needed to strengthen the CERT program. ([A-01-10-01000](#))

Medicare Part D

Invalid Prescriber Identifiers on Medicare Part D Drug Claims

We found that Medicare drug plans and enrollees paid pharmacies \$1.2 billion in 2007 for more than 18 million prescription drug claims that contained 527,749 different invalid prescriber identifiers. These invalid identifiers either (1) were not listed as valid identifiers in the National Provider Identifier (NPI), Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or (2) had been deactivated or retired before January 1, 2006. For 17 percent of the drug claims that contained invalid prescriber identifiers, the identifiers did not conform to length or format requirements. Our review also revealed that only 10 identifiers accounted for 17 percent of all drug claims with invalid prescriber identifiers in 2007. These drug claims represented \$237 million in payments by Medicare drug plans and enrollees. One of the top ten invalid prescriber identifiers was recorded on almost 1.8 million PDE records for more than 150,000 beneficiaries enrolled with 248 different Medicare drug plan sponsors. These plan sponsors and enrollees paid pharmacies almost \$105 million for drug claims with this single invalid identifier. In addition, 5 of the top 10 invalid identifiers appeared on individual claims for very expensive drugs, with payment amounts totaling more than \$10,000 per claim. ([OEI-03-09-00140](#))

Less-Than-Effective Medicare Part D Drugs

We found that for calendar years (CY) 2006 and 2007, a CMS system edit appropriately identified and rejected the vast majority of Medicare Part D sponsors' prescription drug event (PDE) data associated with less-than-effective drugs. However, the edit accepted PDE data totaling \$43.3 million associated with less-than-effective drugs because the Part D program used an incomplete list of these drugs as the basis for the edit. Less-than-effective drugs are drugs that the FDA approved before 1962 and that FDA subsequently found to be less than effective. There is no definitive list of these drugs. CMS agreed with our recommendation to determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs. CMS partially agreed with our recommendation to help ensure that Part D drugs comply with Federal requirements by collaborating with FDA on a list of less-than-effective drugs, disseminating the list to all sponsors, and using the list to reject such PDE data. CMS stated that FDA should be responsible for maintaining and disseminating the list of less-than-effective drugs. ([A-07-09-04138](#))

Medicaid

Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services

Most children in nine selected States are not fully benefitting from Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) comprehensive screening services. In our review, we found that 76 percent of children in these States, or 2.7 million children, did not receive all of the required number of medical, vision, and hearing screenings. Fifty-five percent of children in the nine States received a medical screening during the study period. Of these children, 59 percent lacked at least one component of a complete medical screening. These factors taken together indicate that very few children received the correct number of complete screenings required by law. ([OEI-05-08-00520](#))

Other Health Care Investigations

Nine Health Care Employees Sentenced After Death of At-Risk Child

Nine employees at MultiEthnic Behavioral Health Services, Inc., (MEBH) were sentenced to prison terms ranging from 15 months to 17½ years and were ordered to pay joint and several restitution ranging from \$316,000 to \$1,216,000 based on charges related to health care fraud and the death of an at-risk child who was under MEBH's care. Federal and local investigators found that MEBH employees did not provide any services to the at-risk child with cerebral palsy, even though she was under their care. The child suffered severe bed sores and extreme weight loss as she slowly starved to death. MEBH employees then attempted to conceal the incident by destroying old records and creating new false records of the child's care. The defendants' fraudulent activity also included creating false documentation for visits that did not occur, forging guardian signatures, destroying records, and fabricating other medical documents.

Businesses Agree to Pay \$7.3 Million to Settle Stark Law Violations

Physician-owned United Shockwave Services, Ltd; United Urology Centers, LLC; and United Prostate Centers, LLC (collectively, United) agreed to pay \$7,359,500 and, along with United Therapies, LLC, enter into a 5-year CIA to resolve their CMPL liability. The settlement resolves allegations that United violated the anti-kickback statute by soliciting remuneration from hospitals in exchange for patient referrals. Specifically, it was alleged that United threatened hospitals that it would refer patients to competing hospitals if they did not agree to a contract with United, or promised additional referrals to hospitals that did contract with United.

Public Health

Challenges to FDA's Ability To Monitor and Inspect Foreign Clinical Trials

We found that in FY 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. The Food, Drug, and Cosmetic Act (FDCA) requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products prior to approval for sale in the United States. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. We found that 80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials. Further, over half of clinical trial subjects and sites were located outside the United States. We found that the FDA inspected less than 1 percent of foreign clinical trial sites. Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials. ([OEI-01-08-00510](#))

FDA Inspections of Domestic Food Facilities

We identified significant weaknesses in FDA's inspections of food facilities. FDA inspects food facilities to ensure food safety and compliance with regulations. FDA should take some type of regulatory action when an inspection identifies violations that are significant enough to warrant an "official action indicated" (OAI) classification. This regulatory action could include issuing a warning letter; holding a regulatory meeting; or initiating an enforcement action, such as a seizure or an injunction. We found that FDA inspects less than a quarter of food facilities each year. In addition, more than half of all food facilities have gone 5 or more years without an FDA inspection. Moreover, for 36 percent of the facilities that received OAI classifications, FDA took no additional steps to ensure that the violations were corrected. ([OEI-02-08-00080](#))

Background on Recommendations

At all levels, OIG works in close cooperation with HHS and its operating and staff divisions, DOJ, other agencies in the executive branch, Congress, and States to bring about successful prosecutions, negotiated settlements, recovery of funds, and systemic improvements, which often include greater beneficiary protections, improved program oversight, or funds put to better use. Systemic results are usually achieved through modifications to administrative policies, processes, or procedures; changes to existing regulations and law; or improvements in information technology.

OIG relies on HHS management and other governmental policymakers to decide which program recommendations are implemented. Although many OIG recommendations are directly implemented by organizations within HHS, some are acted on by States, which collaborate with HHS to administer, operate, and/or oversee designated programs, such as Medicaid. HHS and the States sometimes do not immediately implement OIG's

recommendations for various reasons, including administrative complexities, the current policy environment, or a lack of statutory authority. In such cases, Congress may step in to weave OIG's recommendations into legislative actions, many of which result in substantial funds being made available for better use or in program improvements.

The body of this *Semiannual Report* describes the results of selected reviews and other efforts finalized during the period. Information about the estimated current or potential monetary impact of our recommendations is found in the appendixes. Some current outcomes relate to reports issued and corresponding actions taken in prior periods. Specifically, Appendix B includes data on management decisions that were made during the period to disallow questioned costs, thus creating audit receivables. Some of the questioned costs disallowed were identified as findings in reports that were issued in prior semiannual periods.

In addition to publishing the semiannual reports to Congress, OIG annually publishes the [*Compendium of Unimplemented Recommendations*](#), which consolidates significant unimplemented monetary and nonmonetary recommendations that have been addressed previously to HHS and its pertinent operating and staff divisions. The *Compendium* provides information about outstanding recommendations that, if implemented, have the potential to result in cost savings and improvements to program efficiency and effectiveness. These recommendations, which are selected from audits and evaluations, require one or more of three types of actions: administrative, regulatory, or legislative. OIG performs routine followup with the Department to determine the status of actions being taken in response to our recommendations.

Legislative and Regulatory Review

Pursuant to the Inspector General Act of 1978 (IG Act), § 4(a)(2), OIG reviews existing and proposed legislation and regulations relating to HHS's programs and operations and makes recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that OIG conducts are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. OIG's reports of such reviews describe our findings, which include questioned costs, inefficiencies, vulnerabilities to fraud, inconsistencies, errors in application, or weaknesses in oversight or supporting systems. OIG's corresponding recommendations advise HHS and the pertinent operating or staff divisions of the type of actions we believe are needed to effectively respond to the findings. Recommendations may be administrative, regulatory, legislative, or a combination.

The narratives in this *Semiannual Report to Congress* describe findings and recommendations from recently completed OIG reviews, many of which focus on existing laws and regulations. In our *Compendium of Unimplemented Office of Inspector General Recommendations*, which is published annually, we describe priority findings and recommendations from past periods that remain to be implemented, along with pertinent citations of existing laws and regulations. In

our annual *Work Plan*, which is published at the start of each fiscal year, we provide citations to laws and regulations that are the subject of ongoing or future reviews.

OIG also reviews proposed legislation and regulations related to HHS programs and operations. HHS routinely involves its operating and staff divisions, including OIG, in the review and development of HHS regulations through a well-established HHS process. Moreover, OIG's audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. OIG participates in a longstanding HHS process for developing and reviewing HHS's legislative proposals. In addition, OIG provides independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

Congressional Testimony

During this semiannual period, OIG witnesses testified six times at hearings conducted by committees of Congress. Excerpts follow.

May 6, 2010: Safety of the Nation's Food Supply

Jodi Nudelman, OIG Regional Inspector General for Evaluation and Inspections, testified before the Subcommittee on Oversight and Investigations of the U.S. House of Representatives, Committee on Energy and Commerce on the safety of the Nation's food supply. The following is an excerpt.

Our recent report [*FDA Inspections of Domestic Food Facilities*] is a part of a larger body of OIG work that demonstrates that more needs to be done to ensure the safety of the Nation's food supply. In a report on food traceability, we found that only 5 of 40 selected products could be traced through each stage of the food supply chain. In addition, more than half of the facilities that handled these food products failed to meet FDA recordkeeping requirements. In another report, we found that 5 percent of selected facilities failed to register their facilities with FDA as required. Of those facilities that did register, almost half failed to provide accurate information in FDA's registry. Finally, we completed a report that found that FDA did not always follow its procedures when overseeing certain pet food recalls and noted that FDA does not have the statutory authority to mandate [pet food] recalls. [Full text.](#)

June 15, 2010: Reducing Fraud, Waste, and Abuse in Medicare

Lewis Morris, Chief Counsel to the Inspector General, testified before the Subcommittees on Health and Oversight of the U.S. House of Representatives, Ways and Means Committee, on reducing fraud, waste and abuse in Medicare. The following is an excerpt.

Fraud, waste, and abuse cost taxpayers billions of dollars each year and put beneficiaries' health and welfare at risk. The impact of these losses and risks is

exacerbated by the growing number of people served by these programs and the increased strain on Federal and State budgets. With new and expanded programs under the Affordable Care Act, it is critical that we strengthen oversight of these essential health care programs. [Full text.](#)

July 15, 2010: Preventing and Recovering Government Payment Errors

Robert A. Vito, Acting Assistant Inspector General, CMS Audits, testified before the U.S. Senate Committee on Homeland Security and Government Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, on Preventing and Recovering Government Payment Errors. The following is an excerpt.

Recent OIG work illustrates that because of ... vulnerabilities, Medicare has paid for substantial numbers of questionable claims for prescription drugs under Part D. OIG's June 2010 report, *Invalid Prescriber Identifiers on Medicare Part D Drug Claims*, reveals that CMS and its plan sponsors have not adequately performed one of the most basic oversight checks in Medicare Part D—ensuring that a drug was prescribed by a physician. As a result, Part D sponsors and beneficiaries paid pharmacies \$1.2 billion in 2007 for claims in which the prescriber identifiers listed on the claims did not correspond to practicing physicians. Because prescriber identifiers are a key indicator on Part D claims that link prescribing physicians, dispensing pharmacies, and Medicare beneficiaries, they play a critical role in program integrity efforts. Without a valid prescriber identifier, CMS and its contractors cannot determine whether a physician even prescribed a drug, much less verify that the physician was appropriately licensed or had not been excluded from the Medicare program. Furthermore, invalid prescriber identifiers inhibit OIG investigations by making it more difficult to identify questionable prescribing patterns and the parties responsible for potential fraud. [Full text.](#)

September 15, 2010: Medicare's Coverage of Durable Medical Equipment

Daniel R. Levinson, Inspector General, testified before the Subcommittee on Health of the U.S. House of Representatives Committee on Energy and Commerce on the integrity of Medicare's coverage of DMEPOS. The following is an excerpt.

It has been too easy for fraudulent DMEPOS suppliers to obtain Medicare billing privileges. The enrollment standards that I have described are intended to ensure that only legitimate and qualified businesses are enrolled as Medicare suppliers. Unfortunately, we have found that all too often, unscrupulous suppliers are able to gain entry to the system and defraud Medicare.... Thus far in fiscal year 2010, OIG investigations of DMEPOS fraud have resulted in more than 80 convictions with ordered recoveries of more than \$90 million.... Since 1997, OIG has issued several reports that have assessed supplier compliance with standards by conducting unannounced site visits. We have consistently found that Medicare enrollment standards and oversight are not sufficient to prevent noncompliant and sham suppliers

from obtaining Medicare provider numbers and billing privileges. Some Medicare-enrolled suppliers fail to maintain even the most basic Medicare standards—for example, maintaining a physical facility or being open during reasonable business hours. [Full text.](#)

September 22, 2010: Cutting Waste, Fraud, and Abuse in Medicare and Medicaid

Daniel R. Levinson, Inspector General, testified before the Subcommittee on Health of the House Committee on Energy and Commerce on cutting waste, fraud, and abuse in Medicare and Medicaid. The following is an excerpt.

Waste of funds and abuse of the health care programs ... cost taxpayers billions of dollars. In FY 2009, [CMS] estimated that overall, 7.8 percent of the Medicare fee-for-service claims it paid (\$24.1 billion) did not meet program requirements. Although these improper payments do not necessarily involve fraud, the claims should not have been paid.... OIG's work has ... demonstrated that Medicare and Medicaid pay too much for certain services and products and that aligning payments with market costs could produce substantial savings. For example, in 2007, OIG reported that Medicare reimbursed suppliers for pumps used to treat pressure ulcers and wounds based on a purchase price of more than \$17,000, but that suppliers paid, on average, approximately \$3,600 for new models of these pumps. Similarly, we found that in 2007, Medicare allowed, on average, about \$4,000 for standard power wheelchairs that cost suppliers, on average, about \$1,000 to acquire. These pricing disparities also affect beneficiaries, who are responsible for 20 percent copayments on items and services covered under Medicare Part B. [Full text.](#)

September 28, 2010: Indian Health Service's Aberdeen Area

Testimony of Gerald Roy, Deputy Inspector General for Investigations, before the U.S. Senate Committee on Indian Affairs on investigative oversight of the Indian Health Service's (IHS) Aberdeen Area. The following is an excerpt from that testimony.

Over the last 10 years, my office opened nearly 300 investigations related to, or affecting IHS. Many of these cases also involved allegations of Medicare or Medicaid fraud. In the course of these investigations, OIG has identified three general areas of vulnerability that threaten IHS. These areas are: (1) mismanagement, (2) employee misconduct, and (3) drug diversion. [Full text.](#)

Outline of Major Parts and Appendixes

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Part IV:	Public Health, Human Services, and Departmentwide Issues
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Appendix B:	Recommendations for Questioned Costs and Funds To Be Put to Better Use
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Part I: Medicare Reviews

Part I: Medicare Reviews

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

Part I: Medicare Reviews

Medicare Part A and Part B

Hospitals:

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Emergency Department Adjustments for Inpatient Psychiatric Facilities

Based on our sample results, we estimated that Medicare contractors made \$1.7 million in Part A overpayments to hospital-based inpatient psychiatric facilities (IPF) for calendar years (CY) 2006 and 2007 on behalf of beneficiaries who had been admitted to the IPFs upon discharge from the acute-care section of the same hospital. Our review found that hospital-based IPFs incorrectly coded the source of admission on 75 of 100 sampled claims. As a result, Medicare contractors made \$3,000 in overpayments to the IPFs for the emergency department services in our sample.

The Centers for Medicare & Medicaid Services (CMS) makes an additional Medicare payment to an IPF for the first day of a beneficiary's stay to account for emergency department costs. However, CMS does not make this payment if the beneficiary was discharged from the acute-care section of a hospital to its hospital-based IPF. Hospitals must enter the correct code on their Medicare claim forms to ensure that the hospital-based IPF does not receive an additional payment for the costs of emergency department services that Medicare covers in its payment to the acute-care hospital.

We recommended that CMS (1) instruct its Medicare contractors to recover the \$3,000 in overpayments for the sampled claims; (2) instruct its Medicare contractors to immediately reopen the nonsampled claims, review our information on these claims (which have overpayments estimated at \$1.7 million), and recover any overpayments; (3) instruct its Medicare contractors to emphasize to hospital-based IPFs the importance of using the correct code to identify beneficiaries who were discharged from the acute-care section of the same hospital; (4) establish edits in the Common Working File (CWF) to prevent and detect overpayments to IPFs that use incorrect source-of-admission codes on claims; and (5) consider conducting periodic postpayment reviews of claims submitted after our review to identify any claims that were billed and paid with incorrect source-of-admission codes. CMS concurred with our recommendations and described the corrective actions that it was taking or planned to take. ([A-01-09-00504](#))

Medicare > Hospitals > Inpatient Psychiatric Facilities

Payments for Interrupted Stays at Inpatient Psychiatric Facilities

Based on a sample of 100 claims, we estimated that Medicare fiscal intermediaries (FI) made \$3.9 million in improper payments to IPFs nationwide in CYs 2006 and 2007 for claims on behalf of beneficiaries who had been discharged from another IPF within the prior 3 days. To discourage inappropriate discharges and readmissions to IPFs, CMS has established a 3-day policy for interrupted stays. An interrupted stay occurs when a beneficiary is discharged from an IPF and admitted to the same or a different IPF within 3 consecutive days. In such a case, the “readmission” is considered a continuation of the initial stay. CMS provides an exception to the 3-day policy when the beneficiary is admitted to a different IPF within 3 days and the second IPF is unaware of the beneficiary’s immediately preceding stay in the first IPF.

We recommended that CMS (1) instruct its FIs to recover \$19,000 for the 75 sampled claims with payment errors; (2) review our information on the unsampled claims for IPF interrupted stays, which had potential overpayments estimated at \$3.8 million, and work with its FIs to recover any overpayments; (3) establish system edits to prevent and detect overpayments to IPFs that admitted beneficiaries from another IPF and did not bill the claim as part of an interrupted stay; (4) instruct its FIs to initiate the necessary system modifications to process and pay IPF interrupted stays correctly; (5) consider reviewing claims submitted after our review to identify any incorrectly paid claims; and (6) revise its billing instructions to address appropriate billing for the second part of interrupted stays involving two separate IPFs when the second IPF is aware of the preceding stay. CMS concurred with our recommendations. ([A-01-09-00508](#))

Medicare > Hospitals > Inpatient Rehabilitation Facilities

Inpatient Rehabilitation Facilities’ Compliance With Medicare’s Transfer Regulation

Inpatient rehabilitation facilities (IRF) did not always code claims in compliance with Medicare’s transfer regulation during fiscal years (FY) 2004 through 2007. Pursuant to Medicare’s transfer regulation, Medicare pays the full prospective payment to an IRF that discharges a beneficiary to home. In contrast, Medicare pays a lesser amount for a transfer case. Whether Medicare pays for a discharge to home or a transfer depends on the patient status code indicated on the IRF’s claim. On April 1, 2007, in response to our prior recommendations, CMS implemented an edit in the CWF to identify transfers improperly coded as discharges.

Of the 220 claims in our sample, 213 claims pertained to transfers to facilities that were subject to Medicare’s transfer regulation but were improperly coded as discharges. These 213 claims resulted in overpayments of \$1.2 million. Based on our sample results, we estimated that FIs overpaid \$34 million to IRFs for the 4-year period that ended September 30, 2007. Also, even though the new CWF edit detected miscoded claims, FIs did not take appropriate action to adjust the claims and prevent incorrect payments.

We recommended that CMS (1) recover the \$1.2 million in overpayments identified in our sample, (2) instruct FIs to review the unsampled claims and identify and recover additional overpayments estimated at \$32.8 million, (3) instruct FIs to take appropriate action in response to future CWF edit alerts, (4) follow up with FIs to ensure that they took appropriate action in response to CWF edit alerts, and (5) consider reviewing claims paid after our audit period to identify any improperly coded transfers. CMS agreed with our recommendations and described the corrective actions that it planned to take. ([A-04-09-00059](#))

Medicare > Hospitals > Inpatient Rehabilitation Facilities

Inpatient Rehabilitation Facilities' Transmission of Patient Assessment Instruments

IRFs did not always receive reduced case-mix-group payments for claims with patient assessment instruments that were transmitted to CMS's National Assessment Collection Database (the Database) more than 27 days after the beneficiaries' discharges. To administer the prospective payment system, CMS requires IRFs to electronically transmit a patient assessment instrument for each IRF stay to the Database, which the Iowa Foundation for Medical Care (the Foundation) maintains. If an IRF transmits the instrument more than 27 calendar days from (and including) the beneficiary's discharge date, the IRF's payment rate for the applicable case-mix group should be reduced by 25 percent.

We found that IRFs did not receive reduced case-mix-group payments for 113 of the 200 sampled claims with patient assessment instruments that were transmitted to the Database after the 27-day deadline. Based on these sample results, we estimated that FIs made \$20.2 million in overpayments to IRFs for dates of service in calendar years 2006 and 2007. Additionally, for 79 claims, IRFs initially transmitted patient assessment instruments to the Database within the 27-day deadline but subsequently retransmitted these instruments after the deadline to correct errors. CMS guidance does not address the applicability of the 25-percent penalty in these situations. We estimated that FIs may have made an additional \$19 million in overpayments to IRFs for claims with these instrument retransmissions.

We recommended that CMS (1) adjust the 113 sampled claims for overpayments of \$424,000; (2) determine whether any of the \$323,000 potential payment penalty should apply to the 79 sampled claims with modified patient assessment instruments that were transmitted after the 27-day deadline; (3) immediately reopen the nonsampled claims, review our information on these claims (which have overpayments estimated at \$19.8 million and set-aside payments estimated at \$18.7 million), and recover any overpayments; (4) alert IRFs to the importance of reporting the correct patient assessment instrument transmission dates on their claims; (5) consider establishing a process that would allow the Fiscal Intermediary Shared System (FISS) to interface with the Database to identify, on a prepayment basis, IRF claims with incorrect patient assessment instrument transmission dates; (6) ensure that FIs have access to Foundation reports that document late or missing patient assessment instrument transmissions and use these reports to conduct periodic postpayment reviews; (7) revise the FISS edit to count the discharge date as day 1 in the 27-day counting sequence used to apply the 25-percent

payment penalty; and (8) establish written policies to address whether patient assessment instruments that are retransmitted after the 27-day deadline to correct errors in the initial timely transmissions are subject to the 25-percent payment penalty. CMS concurred with our recommendations and described the steps that it had taken or planned to take to address the issues we identified. ([A-01-09-00507](#))

Medicare > Hospitals > Inpatient Services Payments

High-Dollar Payments for Inpatient Services

Of the 415 high-dollar Medicare Part A payments (\$200,000 or more) that a Medicare contractor made to hospitals for inpatient services for CYs 2003 through 2005, 306 were appropriate. The 109 remaining payments included net overpayments totaling \$3 million. At the start of our audit, hospitals had not refunded \$1.9 million of these net overpayments.

Contrary to Federal guidance, hospitals inaccurately reported the number of billing units of service, reported incorrect procedure codes, and reported excessive charges that resulted in inappropriate outlier payments. Hospitals attributed most of the incorrect claims to clerical errors or to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The contractor made these incorrect payments because neither the FISS nor the CWF had sufficient edits in place to prevent or detect incorrect payments.

We recommended that the contractor (1) recover the \$1.9 million in net overpayments, (2) determine and recover the overpayment for one inpatient claim still under adjudication, (3) use the results of this audit in its provider education activities, and (4) consider implementing controls to identify and review all payments greater than \$200,000 for inpatient services. The contractor concurred with our recommendations and described corrective actions that it had taken or planned to take. ([A-07-09-04148](#))

Medicare > Hospitals > Outpatient Services Payments

High-Dollar Payments for Outpatient Services

Of the 104 high-dollar Medicare Part B payments (\$50,000 or more) that a Medicare contractor made to hospitals for outpatient services for CYs 2003 through 2005, 27 were appropriate. The 77 remaining payments included overpayments totaling \$6.1 million. At the start of our audit, hospitals had not refunded \$2.2 million of the overpayments.

The hospitals attributed the incorrect payments to clerical errors or to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The contractor made these incorrect payments because neither the FISS nor the CWF had sufficient edits in place during CYs 2003 through 2005 to prevent or detect the overpayments.

We recommended that the contractor recover the \$2.2 million in identified overpayments and use the results of this audit in its provider education activities. The contractor concurred with our recommendations and described its corrective actions. ([A-07-10-04154](#))

Nursing Homes:

Medicare > Nursing Homes > Part B Services

Part B Mental Health Services During Non-Part A Nursing Home Stays

Based on a medical review, we found that 39 percent of claims for mental health services that Medicare Part B allowed during non-Part A nursing home stays in 2006 did not meet the program requirements for coverage. Specifically, services were medically unnecessary, undocumented or inadequately documented, or miscoded. These errors resulted in an estimated \$74 million in inappropriate Part B payments, of the \$211 million allowed in 2006. Claims for psychotherapy services made up the majority of these inappropriately paid claims, which is consistent with findings from the CMS 2006 Comprehensive Error Rate Testing (CERT) report.

Non-Part A stays occur in nursing homes when the stay is not paid for under the Medicare Part A skilled nursing facility benefit. If the beneficiary's nursing home stay is not covered under Part A, Part B may still provide coverage for mental health services provided during the stay. We also found that 71 percent of the sampled mental health claims contained inaccurate diagnosis codes or lacked adequate documentation to support diagnosis codes, although these codes did not directly affect reimbursement. No recommendations were made in the report. ([OEI-06-06-00580](#))

Medicare > Nursing Homes > Part B Services

Part B Enteral Nutrition Therapy Services During Non-Part A Nursing Home Stays

Based on a medical review of Medicare Part B enteral nutrition therapy (ENT) claims for ENT provided during non-Part A nursing home stays in 2006, we found that 21 percent of the claims were either inappropriate (5 percent) or inadequately documented (16 percent). The errors resulted in an estimated \$39 million in inappropriate Part B payments among the \$284 million allowed for all ENT claims during non-Part A nursing home stays in 2006. Claims for pumps and pump supply kits represented 70 percent of the inadequately documented sampled services.

Non-Part A stays occur in nursing homes where the stay is not paid for under the Medicare Part A skilled nursing facility benefit. If a beneficiary's nursing home stay is not covered under Part A, Part B may still provide coverage for ENT provided during the stay.

We also found that 13 percent of the allowed ENT claims associated with pumps were questionable. Although these claims met contractors' payment and coverage guidelines for

slow delivery rates of less than 100 millimeters per hour, residents' medical records did not include medical conditions (e.g., diabetes, risk of aspiration, or fluctuating glucose levels) that justified the need for the more expensive pump delivery method over the gravity method, which could provide for a slow rate. Medicare contractor payment and coverage guidelines do not require the documentation of a medical condition specifically justifying pump use over the gravity method when a slow rate of administration is indicated. No recommendations were made. ([OEI-06-07-00090](#))

Practitioners and Suppliers:

[Medicare](#) > [Practitioners and Suppliers](#) > [Physicians](#)

Place-of-Service Coding for Physician Services

We found that physicians did not always correctly code nonfacility places of service on Medicare Part B claims. Based on our sample results, we estimated that Medicare contractors nationwide overpaid physicians \$13.8 million for incorrectly coded services provided during CY 2007. To account for the increased overhead expense that physicians incur by performing services in nonfacility locations, such as physicians' offices, Medicare reimburses physicians at a higher rate for certain services performed in these locations and at a lower rate for services performed in facility settings, such as hospital outpatient departments or ambulatory surgical centers. Physicians are required to identify the place of service on the health insurance claim forms that they submit to Medicare contractors. However, for 90 of the 100 services in our sample, physicians used nonfacility place-of-service codes on their claims for services that were actually performed in hospital outpatient departments or ambulatory surgical centers.

We recommended that CMS instruct its Medicare contractors to (1) recover \$4,700 in overpayments for the sampled services; (2) immediately reopen the claims associated with the nonsampled services, review our information on these claims (which had estimated overpayments of \$13.8 million), and work with the physicians who provided the services to recover any overpayments; (3) continue to strengthen their education process and reemphasize to physicians and their billing agents the importance of correctly coding the place of service; and (4) continue to work with program safeguard contractors (PSC) and other Medicare contractors to develop a data match that will identify physician services at high risk for place-of-service miscoding and recover any identified overpayments. CMS concurred with our recommendations and described the corrective actions that it was taking or planned to take. ([A-01-09-00503](#))

Questionable Billing for Physician Services for Hospice Beneficiaries

Questionable billing for Part B physician services provided to hospice beneficiaries amounted to nearly \$566,000 in 2009. This means that Medicare paid this amount to physicians directly through Part B for services related to a beneficiary's terminal illness, while Medicare also paid for services from the same physician for the terminal illness under Part A. Although we did not find that this problem is widespread, billing for physician services for hospice care is a potential program vulnerability given that Medicare may be billed under Part A and Part B.

The Medicare hospice benefit allows a beneficiary with a terminal illness to forgo curative treatment for the illness and instead receive palliative care, which is the relief of pain and other uncomfortable symptoms. Medicare pays for physician services through Part A or Part B, depending on a physician's relationship with the hospice. If a beneficiary's attending physician is an employee or under contract with the hospice provider, Medicare pays the hospice for physician services under Part A, and the hospice compensates the physician through salary or some other arrangement. If a beneficiary's attending physician is not an employee or under contract with the hospice provider, Medicare pays the physician for physician services under Part B.

We identified 9,272 questionable Part B claims for physician services provided to hospice beneficiaries in 2009. These claims were submitted by 3,116 physicians on behalf of 4,280 Medicare beneficiaries. Six of the ten physicians with the highest questionable Part B payments resided in Florida. In addition, 664 hospices were associated with Part B questionable claims. Of the 10 hospices associated with the highest questionable Part B payments, 8 were in Florida. We will refer the questionable claims to CMS for appropriate action. ([OEI-02-06-00224](#))

Inappropriate Medicare Payments for Transforaminal Epidural Injection Services

Based on a medical review of a stratified random sample of 433 transforaminal epidural injection services allowed by Medicare in 2007, 34 percent did not meet Medicare requirements, resulting in approximately \$45 million in improper payments. Medicare allowed an additional \$23 million in associated facility claims for transforaminal epidural injections performed in error. In addition, services provided in offices were more likely to have a documentation error than those provided in ambulatory surgical centers or hospital outpatient departments.

Transforaminal epidural injections are a type of interventional pain management technique used to diagnose or treat pain. Transforaminal epidural injections may be used to treat pain that starts in the back and radiates down the leg, such as that from a herniated disc pressing on a nerve. Medicare Part B physician payments for transforaminal epidural injections increased from \$57 million in 2003 to \$141 million to 2007. This represents an increase of almost 150 percent.

Medicare Part B contractors are responsible for implementing program safeguards to reduce payment error. To safeguard payments, they may create local coverage determinations (LCD), implement electronic edits, or conduct medical review. We found that in 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards. Only one contractor enforced all of its LCD requirements with edits. No contractor staff reported performing a medical review.

Based on the results of our review, we recommended that CMS conduct provider education, directly and through contractors, about proper documentation and strengthen program safeguards to prevent improper payment for transforaminal epidural injection services. In addition, we recommended that CMS take appropriate action regarding the undocumented, medically unnecessary, and miscoded services identified in our sample. CMS concurred with our recommendations and outlined steps to improve its oversight of payments for transforaminal epidural injection services. ([OEI-05-09-00030](#))

Medicare > Practitioners and Suppliers > Medical Equipment Suppliers

Medicare Payments for Durable Medical Equipment Claims With the KX Modifier

Our reviews, which covered items with dates of service in 2007 in the four CMS-designated jurisdictions across the country, found that the KX modifier was not effective in ensuring that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) had the required supporting documentation on file. For Medicare payment, certain DMEPOS require additional documentation in addition to a physician's order and proof of delivery. Suppliers must use the KX modifier on their Medicare claims to indicate that the claims meet Medicare coverage criteria and that the suppliers have all the required documentation on file. Our reviews included Medicare paid claims for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure-reducing support surfaces (groups 1 and 2) that included the KX modifier. Our specific findings follow:

- Jurisdiction A. Based on our sample results, we estimated that the Medicare contractor paid approximately \$54 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included proof of delivery, physicians' orders, followup documentation showing the DMEPOS items were being used or being compliantly used, sleep studies, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$5,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 24 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve supplier compliance with the KX modifier and potentially save an estimated \$54 million. The contractor

concurred with our first three recommendations but did not concur with the fourth recommendation. ([A-01-09-00528](#))

- Jurisdiction B. Based on our sample results, we estimated that the Medicare contractor paid approximately \$55 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The types of missing documentation included proof of delivery, physicians' orders, use or compliant use followup documentation, sleep studies, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$4,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 28 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$55 million. The contractor concurred with our recommendations. ([A-05-09-00094](#))
- Jurisdiction C. Based on our sample results, we estimated that the Medicare contractor paid approximately \$137 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included proof of delivery, physicians' orders, use or compliant use followup documentation, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$4,500 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of 14 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$137 million. The contractor acknowledged the unallowable payments and listed the corrective actions that it intended to take. ([A-04-09-04039](#))
- Jurisdiction D. Based on our sample results, we estimated that the Medicare contractor paid approximately \$70 million to suppliers that did not have the required documentation on file to support the DMEPOS items claimed. The missing documentation included physicians' orders, use or compliant use followup documentation, proof of delivery, and physicians' statements. We recommended that the Medicare contractor (1) recover approximately \$6,000 in payments for sampled DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sampled items and recover any additional unallowable payments, (3) notify CMS of the suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$70 million. The Medicare contractor concurred with our recommendations. ([A-09-09-00111](#))

Medical Equipment and Supply Claims With Identical Referring Physician and Supplier National Provider Identifiers

We found that Medicare allowed \$87 million for medical equipment and supply claims with identical referring physician and supplier national provider identifiers (NPI) between May 23, 2008, and September 30, 2009.

CMS began requiring suppliers to include NPIs for the supplier and the referring physician on Medicare claims on May 23, 2008. However, CMS instituted a temporary provision allowing suppliers to use their own NPIs in the referring provider field if they could not obtain the referring physician's NPI. This review serves as a followup to a February 2009 Office of Inspector General (OIG) report that noted that the provision represents a claims-processing vulnerability. CMS's claims-processing systems did not verify that the equipment and/or supplies associated with these payments were ordered by an eligible physician, as required. We recommended in that report that CMS determine the earliest date to end the provision while maintaining beneficiary access to services. On January 3, 2011, CMS intends to implement changes to its claims-processing system that will end the temporary provision. However, the implementation date of these edits has been postponed twice. As of April 2010, nearly 2 years after the temporary provision was effective, suppliers became able to submit claims without the referring physician's NPI.

We found that Medicare payments for medical equipment and supply claims with identical referring physician and supplier NPIs were concentrated in certain Healthcare Common Procedure Coding System (HCPCS) codes and geographic locations. Ten HCPCS codes accounted for half of the \$87 million that we identified. Medicare paid for this type of claim under about 1,200 HCPCS codes during the period of our review. We also found that 10 counties represented 19 percent of the Medicare payments that we identified nationwide. In contrast, these 10 counties represented only 9 percent of Medicare payments for all medical equipment and supplies provided during the period of our review. Of the 10 counties, 3 are among the 7 areas that the Health Care Fraud Prevention and Enforcement Action Team (HEAT) have identified as areas of significant Medicare fraud.

Also, 26 percent of suppliers that received Medicare payments for claims with identical referring physician and supplier NPIs were paid by Medicare for this type of claim almost exclusively. These suppliers accounted for almost half (48 percent) of the Medicare payments we identified. Fourteen percent of suppliers that received Medicare payments for claims with identical referring physician and supplier NPIs submitted this type of claim in all 6 quarters we reviewed. These suppliers accounted for more than half (53 percent) of the Medicare payments we identified. Medicare payments for claims with identical referring physician and supplier NPIs declined over the first 7 months that the temporary provision was effective, but generally increased thereafter.

Although the \$87 million that Medicare allowed for medical equipment and supply claims with identical referring physician and supplier NPIs was permissible under the temporary CMS provision, the vulnerability remains. Therefore, we continue to believe that CMS should end the temporary provision at the earliest possible date. This report contained no recommendations. ([OEI-04-10-00110](#))

Medicare > Practitioners and Suppliers > Medical Equipment Suppliers

A Review of Claims for Capped Rental Durable Medical Equipment

From 2006 to 2008, Medicare erroneously allowed \$2.2 million for routine maintenance and servicing of capped rental durable medical equipment (DME) and nearly \$4.4 million for repairs for capped rental DME during rental periods. We also found that in 2007, Medicare allowed nearly \$27 million for repair claims for beneficiary-owned capped rental DME that failed to meet payment requirements.

DME is medical equipment that can withstand repeated use, serves a medical purpose, is not useful in the absence of an illness or injury, and is appropriate for home use. The Deficit Reduction Act of 2005 (DRA) effectively eliminated Medicare coverage of routine maintenance and servicing for beneficiary-owned DME with rental periods that began after January 1, 2006, and Medicare has never allowed payments for maintenance and servicing or repairs for beneficiary-rented equipment. Also, Medicare should not pay for claims that lack documentation of necessity, service, or delivery, nor should it pay for repairs to DME still under manufacturer or supplier warranties.

Medicare allowed an additional \$29 million (49 percent of all allowed claims) for questionable repair claims for beneficiary-owned capped rental DME in 2007. Additionally, supplier practices adversely affected some beneficiaries with repairs exceeding \$5,000.

We recommended that CMS (1) implement an edit to deny claims for routine maintenance and servicing of capped rental DME with rental periods beginning after January 1, 2006; (2) implement an edit to deny claims for repair of beneficiary-rented capped rental DME; (3) improve enforcement of existing payment requirements for beneficiary-owned capped rental DME; (4) consider whether to require Medicare Administrative Contractors (MAC) to track accumulated repair costs of capped rental DME; (5) develop and implement safeguards to ensure that beneficiaries have access to the services they require; and (6) take appropriate action on erroneously allowed claims for maintenance and servicing, repair, and payment errors.

In its written comments on the report, CMS agreed that maintaining strong and effective controls to ensure accurate payment of capped rental DME claims is essential. CMS responded positively to each of our six recommendations and indicated that, in general, it will work to improve its comprehensive oversight of capped rental maintenance and servicing.

([OEI-07-08-00550](#))

Part B Prescription Drugs:

Medicare > Part B Prescription Drugs > Reimbursement Policy

Comparison of Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement

Pursuant to section 1847A(d)(3) of the Social Security Act (the Act), OIG must notify the Secretary of Health & Human Services (the Secretary) if the average sales price (ASP) for a particular drug exceeds the drug's average manufacturer price (AMP) by a threshold of 5 percent. If that threshold is met, the Act states that the Secretary shall disregard the ASP for that drug and substitute the payment amount for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. During this semiannual period, we issued our 16th and 17th reports comparing ASPs to AMPs; however, CMS has yet to make any changes to reimbursement as a result of OIG findings.

- Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010. We identified a total of 26 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2009. If reimbursement amounts for these 26 codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$2.7 million during the first quarter of 2010.

Of the 26 HCPCS codes that met the threshold for price adjustment, 16 had AMP data for every drug product that CMS used to establish reimbursement amounts. Of these 16 drugs, 8 were also eligible for price adjustments in one or more of the previous 4 quarters, with 3 drugs meeting the 5-percent threshold in all 5 quarters under review. The remaining 10 of 26 HCPCS codes also met the 5-percent threshold in the third quarter of 2009 but did not have AMP data for every drug product that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for an additional 66 HCPCS codes because AMP data were not submitted for any of the drug products that CMS used to calculate reimbursement. Manufacturers for 16 percent of those drug products 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 manufacturers that fail to submit required data. ([OEI-03-10-00150](#))

- Comparison of Fourth-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010. We identified 35 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2009. If reimbursement amounts for these 35 codes had been based on 103 percent of the AMPs during the second quarter of 2010, Medicare expenditures would have been reduced by \$4.3 million during that quarter alone.

Of the 35 HCPCS codes that met the threshold for price adjustment, 11 had AMP data for every drug product that CMS used to establish reimbursement amounts. Of these 11 drugs, 7 were also eligible for price adjustments in one or more of the previous 4 quarters. The remaining 24 of 35 HCPCS codes also met the 5-percent threshold in the fourth quarter of 2009 but did not have AMP data for every drug product that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for an additional 62 HCPCS codes because AMP data were not submitted for any of the drug products that CMS used to calculate reimbursement. Manufacturers for 16 percent of those drug products 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 manufacturers that fail to submit required data. ([OEI-03-10-00350](#))

Medicare > Part B Prescription Drugs > Manufacturer Noncompliance

Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements

In 2008, more than half of the drug manufacturers that were required to submit quarterly AMPs to CMS failed to comply with reporting requirements in at least 1 quarter. Manufacturers were even less likely to comply with monthly AMP reporting requirements, with more than three-fourths of them submitting late, incomplete, or no AMPs in at least 1 month of 2008.

Pursuant to the Social Security Act and Federal regulations, certain drug manufacturers must provide CMS with the AMP for each of their covered outpatient drugs within 30 days after the end of each month and each quarter. These AMPs play a critical role in Government payments for prescription drugs. AMPs provided quarterly by manufacturers are used to calculate drug rebate amounts under Medicaid and ceiling prices under the 340B drug program. In the future, AMPs reported monthly may be used by CMS to establish Federal upper limit (FUL) amounts in the Medicaid program and by States to set Medicaid reimbursement rates for prescription drugs. Manufacturers that fail to provide timely AMP data may be subject to Civil Monetary Penalties (CMP) and/or termination from the drug rebate program.

CMS takes action against manufacturers with missing and late quarterly AMP data, including reminding noncompliant manufacturers to submit quarterly data, terminating manufacturers that repeatedly fail to submit quarterly AMPs, and referring manufacturers with consistently late quarterly data to OIG for potential CMPs. However, CMS does not take any such action against manufacturers with missing and late monthly AMPs. Although CMS tracks manufacturers with no monthly AMP data, staff remind noncompliant manufacturers to submit overdue data only if those manufacturers initiate contact. Furthermore, CMS has yet to terminate or refer to OIG any manufacturer for failure to comply with monthly AMP reporting requirements.

To promote full compliance with quarterly and monthly AMP reporting requirements and to help ensure that Medicaid and covered 340B entities do not overpay for prescription drugs, we recommended that CMS (1) take action against manufacturers that submit incomplete quarterly AMP data and (2) take action against manufacturers that fail to submit monthly AMP data in a timely manner. CMS concurred with both recommendations and stated that it will begin referring manufacturers that submit incomplete quarterly and monthly data to OIG for CMP consideration. OIG looks forward to expanding its collaboration with CMS on administrative remedies for noncompliance with AMP reporting requirements. ([OEI-03-09-00060](#))

End Stage Renal Disease Drugs:

[Medicare](#) > [ESRD](#) > [Drug Prices](#)

Facility Acquisition Costs and Future Medicare Payment Concerns for End Stage Renal Disease Drugs

We found that of the 11 separately billable end stage renal disease (ESRD) drugs under review (including the 2 drugs accounting for the majority of expenditures), 7 have seen a decrease in their average acquisition costs over the last several years. During this same period, the index on which CMS will soon base payment changes for ESRD drugs increased by 39 percent.

Medicare pays ESRD dialysis facilities based on a prospective payment system (PPS), known as the composite rate. Drugs not covered under the composite rate, such as epoetin alfa and darbepoetin alfa, must be billed separately and are referred to as separately billable drugs. Medicare pays for most separately billable drugs furnished by independent and hospital-based dialysis facilities at 106 percent of their ASP.

On January 1, 2011, Federal law will require CMS to begin implementation of a new system that combines composite rate payments with payments for items and services that are separately billable (including separately billable drugs) to create a single, bundled payment. Federal law will require that once the base rate for ESRD bundled payments takes effect, it be annually updated to reflect the changes over time in the prices of goods and services used to provide ESRD care. CMS has decided to base these price updates on wage and price proxy data from the Bureau of Labor Statistics (BLS). For the ESRD drugs portion of the new bundled rate, CMS plans to use the Producer Price Index (PPI) for Prescription Drugs to estimate price changes.

This report (1) compares Medicare payment amounts for selected separately billable ESRD drugs to average acquisition costs for these drugs at dialysis facilities in the first quarter of 2009, (2) examines how facility acquisition costs for selected separately billable ESRD drugs have changed over the past several years, and (3) determines whether the method that CMS plans to use to update payments for separately billable ESRD drugs after 2011 is an accurate predictor of changes in facility acquisition costs.

We found that aggregate acquisition costs for ESRD drugs at both types of dialysis facilities were below ASP-based Medicare payment amounts. We also found that if CMS had used the PPI for Prescription Drugs to update payment amounts for epoetin alfa since 2003, total program payments to all independent dialysis facilities for the drug in the first quarter of 2009 alone would have been \$113 million higher than actual payments under the current ASP-based system.

We recommend that CMS develop a more accurate method for estimating changes in the prices of ESRD drugs. CMS did not concur with our recommendation, saying that it believes that future ESRD drug price growth will more closely reflect market-based price drivers, such as those measured by the PPI for Prescription Drugs. ([OEI-03-09-00280](#))

Medicare Contractors:

[Medicare](#) > [Contractors](#) > [Information Security](#)

Contractor Information Security Program Evaluations for Fiscal Year 2007

A CMS-contracted accounting firm's reviews of Medicare contractor information security program evaluations were adequate in scope and sufficiency, but we could not determine the extent and sufficiency of the work done for the data center technical assessments because of several issues with the working papers.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that each Medicare contractor have its information security program evaluated annually by an independent entity. To comply with this provision, CMS contracted with a certified public accounting firm to evaluate information security programs at the MACs, FIs, and carriers. CMS also contracted with another firm to perform technical assessments at Medicare data centers.

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. We also recommended that CMS annually test security control areas in which a considerable number of gaps have consistently been identified in the past 2 FYs at all CMS Medicare data centers. CMS concurred with our recommendations.

([A-18-07-30291](#))

Medicare > Contractors > Improper Payments

High-Utilization Claims for Blood-Glucose Test Strips and Lancets

Based on our sample results, we estimated that the DMEPOS MAC for Jurisdiction A inappropriately allowed for payment of approximately \$49.2 million in claims for CY 2007 for home blood glucose test strip and/or lancet supplies (test strips and lancets) that we identified as high-utilization claims. We estimated that the contractor inappropriately paid approximately \$39.2 million of this amount to DME suppliers. The contractor could have saved Medicare an estimated \$39.2 million for CY 2007 if it had controls to ensure that claims for 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 reimbursement of a claim for a quantity of test strips and lancets that exceeds the utilization guidelines (high-utilization claim).

To help achieve potential savings in future years, we recommended that the contractor (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; and (3) enforce Medicare documentation requirements for claims for test strips and/or lancets by identifying DME suppliers with a high volume of high-utilization claims, performing prepayment reviews of those DME suppliers, and referring them to OIG or CMS for further review or investigation when necessary. The contractor provided information on actions that it had taken to address our recommendations. ([A-09-08-00043](#))

Medicare > Contractors > Overpayment Identification and Referral

Overpayments Identified by Program Safeguard Contractors

PSCs, which are engaged by CMS to conduct a variety of activities to ensure the integrity of Medicare payments, referred \$835 million in overpayments to claims processors for collection in 2007. However, of 18 PSCs, only 2 were responsible for 62 percent of the amount. Moreover, the amount of overpayment dollars that PSCs referred for collection was not always related to the size of PSCs' oversight responsibility.

PSCs' identification and referral of overpayments to claims processors for collection is an important PSC activity because it can lead to the recovery of funds for the Medicare program. In this report, we identified the number, dollar amount, and claim type of Medicare overpayments that PSCs referred to claims processors for collection in CY 2007. This report and its companion report (summarized below), *Collection Status of Medicare Overpayments Identified*

by Program Safeguard Contractors, OEI-03-08-00030, are our response to a request from a committee of the U.S. House of Representatives.

All 18 PSCs referred 4,239 overpayments to claims processors for collection in 2007. PSCs differed substantially in the dollar amount of overpayments that they referred for collection in 2007. PSCs referred from \$3 million to \$266 million in overpayments for collection, with a median of \$15 million. We also found that, while Part B payments represented 29 percent of PSCs' oversight responsibility (\$87 billion of \$296 billion), Part B overpayments accounted for 89 percent of PSCs' overpayment dollars referred for collection (\$747 million of \$835 million). Part A payments represented 71 percent of PSCs' oversight responsibility (\$209 billion of \$296 billion), and Part A overpayments accounted for 11 percent of PSCs' overpayment dollars referred for collection (\$88 million of \$835 million).

CMS is transitioning PSCs to seven Zone Program Integrity Contractors (ZPIC). Each ZPIC will be responsible for all claim types in its geographic zone.

We recommended that CMS determine why certain PSCs have low levels of overpayment dollars referred for collection, considering their broad oversight responsibility. We also recommended that CMS determine why certain PSCs have low Part A overpayment dollars referred for collection compared with their Part B overpayment dollars referred for collection. CMS concurred with both recommendations and stated that the change to the new ZPIC contracting strategy should address OIG's concerns. ([OEI-03-08-00031](#))

Medicare > Contractors > Overpayment Recoveries

Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors

Overpayments referred for collection by PSCs in 2007 did not result in significant recoveries to the Medicare program. PSCs referred 4,239 overpayments totaling \$835 million to claims processors in 2007, but only 7 percent (\$55 million of \$835 million) had been collected by claims processors as of June 2008. Of the \$55 million collected, 27 percent was for Part A claims; 56 percent was for Part B claims excluding DMEPOS; and 17 percent was for Part B DMEPOS claims.

In this report, we determined the collection status, as of June 2008, of overpayments referred by PSCs for collection in CY 2007. At the time of our review, PSCs were not required to keep track of the amount claims processors collect on PSC overpayment referrals. CMS is transitioning PSCs to seven ZPICs and is providing ZPICs an incentive to keep track of the amount claims processors collect on ZPIC overpayment referrals. CMS is now providing incentives to claims processors to provide collection information to ZPICs. According to CMS staff, CMS also expects ZPICs in high-fraud regions to focus on quick response to fraud and administrative actions.

As of June 2008, 53 percent (\$446 million) of the \$835 million in overpayment dollars that PSCs referred to claims processors for collection in 2007 was sent to the Department of the Treasury's cross-servicing program for collection. However, this program does not have a high rate of return. Claims processors reported that collection was not complete for \$40 million, or 5 percent of the \$835 million in overpayments that PSCs referred for collection. Another 5 percent of the PSC overpayment dollars likely will not be collected by claims processors because the provider stopped billing, filed bankruptcy, went out of business, or was deceased. Collection was on hold, pending investigation or appeal for 17 percent of the PSC overpayment dollars. As of June 2008, 6 percent of the PSC overpayment dollars was no longer owed by providers because of revisions claims processors made to overpayment collection amounts and appeal decisions that were favorable to providers. Finally, claims processors could not provide data for one of four PSC overpayment referrals, which accounted for 8 percent of the PSC overpayment dollars. Claims processors reported that they did not receive or that they could not provide any collection information for 1,060 of 4,239 overpayments.

We recommended that CMS regularly collect all necessary information to determine the overpayments PSCs and ZPICs refer to claims processors for collection, the collection status of these overpayments, and the percentage of overpayments in each category of collection status. We also recommended that CMS require that PSCs, ZPICs, and claims processors have controls in their tracking systems to ensure that all overpayment referrals and data related to their collection status can be found. CMS should also determine what happened to the 1,060 overpayments that PSCs referred to claims processors in 2007, for which claims processors could not provide any collection information. CMS concurred with all three recommendations. ([OEI-03-08-00030](#))

Medicare > Contractors > Overpayment Recoveries

Collection Rate for Overpayments Made to Medicare Suppliers in South Florida

We found that the collection rate of PSC-identified DMEPOS overpayments in South Florida was only 1 percent. This is compared with a national collection rate for all claim types of 7 percent and a national DMEPOS collection rate of 3 percent as identified in the study, *Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors* (OEI-03-08-00030), described above.

For this memorandum report, we conducted further analysis on data obtained during the earlier study. Previous OIG work has identified south Florida (Miami-Dade, Broward, and Palm Beach counties) as an area vulnerable to DMEPOS fraud and abuse. Therefore, we focused our additional analysis on PSC-identified DMEPOS overpayments in south Florida.

The median overpayment was \$527,420 and 25 percent of the overpayments were more than \$1 million each. While only 1 percent of the PSC-identified DMEPOS overpayment dollars in south Florida was collected, another 91 percent was referred for collection to the Department of the Treasury which historically does not have a high rate of return. In addition, by December

2008, only 1 of the 315 suppliers associated with south Florida DMEPOS overpayments was still active in the Medicare program; the remaining suppliers were either revoked or inactive. The fact that these suppliers are no longer billing the Medicare program makes overpayment collection difficult.

Given that south Florida DMEPOS overpayments identified by the PSC resulted in low returns for the Medicare program, we concluded that overpayment identification and collection may not be the most effective program integrity tool for DMEPOS claims especially in south Florida and other high-fraud areas. Ensuring that claims are legitimate and appropriate before payment would eliminate the need to expend resources for postpayment collection efforts that are not likely to yield high returns. ([OEI-03-09-00570](#))

Medicare > Contractors > Overpayment Recoveries

Payments to Providers Terminated From the Medicare Program

In two reviews, we found that Medicare contractors did not always recover overpayments for services furnished on or after the effective termination dates of provider Medicare agreements or during termination-related Denial of Payment for New Admissions (DPNA) sanction periods. CMS can impose DPNA sanctions on skilled nursing facilities (SNF) that fail to comply with Medicare requirements. Payments for services provided on or after the termination date of a provider agreement or for services provided to beneficiaries initially admitted during a DPNA sanction period are generally not allowable. The results of our reviews, which covered providers terminated between January 1, 2003, and January 31, 2007, follow:

- For 5 of the 64 terminated providers whose payments we reviewed, the contractor had not recovered \$1.2 million in overpayments that were subject to recovery. The contractor had not recovered \$1.16 million of this total because it did not follow its procedures to retroactively identify payments for post-termination services. The contractor had not recovered the remaining \$62,000 because it had not yet implemented written DPNA-related procedures. The contractor confirmed that the overpayments were subject to recovery. We recommended that the contractor recover the \$1.2 million in overpayments and follow its procedures to retroactively identify and recover overpayments for services furnished on or after the providers' effective termination dates. The contractor agreed with our recommendations and said that it was recovering the overpayments. ([A-05-09-00035](#))
- For 11 of the 262 terminated providers whose payments we reviewed, the contractor had not recovered \$2 million in overpayments that were subject to recovery. The contractor had not recovered the overpayments because it did not follow its procedures to retroactively identify payments for post-termination services. The contractor confirmed that the overpayments were subject to recovery. We recommended that the contractor recover the \$2 million in overpayments and follow its procedures to retroactively identify and recover

overpayments for services furnished on or after the providers' effective termination dates. The contractor agreed with our recommendations. ([A-05-09-00076](#))

Medicare > Contractors > Overpayment Recoveries

Dates of Service After Beneficiaries' Deaths

Based on our sample results, we estimated that CMS did not identify and recover \$8.2 million in overpayments for Medicare Part B claims with dates of service after the beneficiaries' deaths. CMS did not make or had already recovered overpayments for Medicare claims on behalf of 96 of the 150 deceased beneficiaries in our sample, including all of the Part A claims sampled. However, CMS did not identify and recover all overpayments for Part B (DME and physician/supplier) claims with dates of service after the 54 remaining sampled beneficiaries' deaths.

Federal regulations state that Medicare will not pay for any expenses incurred for items or services that are not reasonable and necessary. Because medically necessary services cannot be provided after a beneficiary dies, payments for claims with dates of service after a beneficiary's death are overpayments. Because of the inherent difficulties in receiving timely and accurate information from third parties, Medicare makes overpayments for claims for services, equipment, and supplies with dates of service after beneficiaries' deaths. To identify such overpayments, CMS requires its PSCs to perform annual deceased-beneficiary postpayment reviews. The PSCs obtain data for these reviews from their own beneficiary eligibility records or from CMS deceased-beneficiary files, which contain the dates of death for all beneficiaries who died in the preceding 2 calendar years.

We recommended that CMS (1) recoup \$15,000 in overpayments identified in our sample, (2) use our Part B data to identify and collect potential overpayments estimated at \$8.2 million for the nonsampled beneficiaries, (3) provide PSCs with complete date-of-death information, (4) correct the CWF process to ensure that dates of death from home health claims are entered in the CWF, (5) work with the Social Security Administration to obtain verified dates of death to assist in identifying overpayments, and (6) establish a CWF edit to check all prior claims for a deceased beneficiary for overpayments once a date of death is added to the CWF. CMS concurred with our recommendations. ([A-01-09-00519](#))

Medicare > Contractors > Analysis of Errors

Analysis of Errors Identified in the Fiscal Year 2009 Comprehensive Error Rate Testing Program

We found that 6 types of health care providers accounted for \$4.4 million, or 94 percent, of the \$4.7 million in improper payments identified by CMS's CERT contractor for FY 2009. The provider types were inpatient hospitals, DME suppliers, hospital outpatient departments, physicians, SNFs, and home health agencies (HHA).

As part of the Medicare error rate process, CMS's CERT contractor conducted medical record reviews of a random sample of paid claims from all types of providers. Based on the results of those reviews, CMS reported to Congress that the national Medicare error rate for FY 2009 was 7.8 percent, or \$24.1 billion. The Improper Payments Information Act of 2002 (IPIA) requires that CMS estimate improper Medicare fee-for-service (FFS) payments each year.

Our analysis of the erroneous claims identified by the CERT contractor found that 3 types of errors accounted for about 98 percent of the \$4.4 million in improper payments attributable to the 6 types of providers:

- insufficient documentation, e.g., missing clinical notes or test results and missing, incomplete, or illegible physician orders, which resulted in improper payments totaling \$2.6 million;
- miscoded claims, which resulted in improper payments totaling \$0.9 million; and
- medically unnecessary services and supplies, which resulted in improper payments totaling \$0.8 million.

We recommended that, as part of its analysis of the FY 2009 CERT improper payments, CMS use the results of our analysis in identifying (1) the types of payment errors indicative of programmatic weaknesses and (2) any additional corrective actions needed to strengthen the CERT program. CMS concurred with our recommendation. ([A-01-10-01000](#))

Medicare Part D (Prescription Drug Program)

[Medicare](#) > [Part D](#) > [Prescriber Identifiers](#)

Invalid Prescriber Identifiers on Medicare Part D Drug Claims

OIG found that \$1.2 billion in Medicare Part D prescription drug claims contained invalid prescriber identifiers in 2007. Invalid identifiers were used on more than 18 million prescription drug claims. These identifiers either (1) were not listed as valid identifiers in the NPI, Drug Enforcement Administration (DEA) number, or Unique Physician Identification Number (UPIN) registry databases or (2) had been deactivated or retired before January 1, 2006.

Part D drug plans must submit an electronic record to CMS for each covered prescription filled for their enrollees. This electronic record, called a prescription drug event (PDE) record, contains drug cost and payment data fields that enable CMS to make payments to plans and oversee the Part D benefit. CMS requires that PDE records contain an identifier for the drug's prescriber. Identifiers that may be used include NPIs, DEA numbers, and UPINs. Each type of prescriber identifier has specific length and format requirements. For 17 percent of the PDE records that contained invalid prescriber identifiers, the identifiers did not conform to length or format specifications. These PDE records represented \$213 million in payments by Medicare drug plans and enrollees in 2007.

Our review also revealed that 10 of 527,749 invalid identifiers accounted for 17 percent of all drug claims with invalid prescriber identifiers in 2007. Medicare Part D plans and enrollees paid pharmacies \$237 million in 2007 for drug claims that contained these 10 invalid identifiers. Of the top 10 invalid prescriber identifiers, 1 was recorded on almost 1.8 million PDE records for more than 150,000 beneficiaries enrolled with 248 different Medicare drug plan sponsors. These plan sponsors and enrollees paid pharmacies almost \$105 million for drug claims with this single invalid identifier. Of the top 10 invalid identifiers, 5 appeared on individual claims for very expensive drugs, with payment amounts totaling more than \$10,000 per claim. The majority of PDE records that contained one of the top 10 invalid prescriber identifiers were submitted by a single large pharmacy benefit manager and mail-order pharmacy.

Prescriber identifiers are valuable Part D program safeguards. These identifiers are the only data on Part D drug claims to indicate that legitimate practitioners have prescribed medications for Medicare enrollees. Based on our findings, we concluded that CMS and Part D plans do not have adequate procedures in place to detect invalid values in the prescriber identifier field. To address this vulnerability, we recommended that CMS conduct periodic reviews to ensure the validity of prescriber identifiers used on PDE records. We also recommended that CMS require Part D plans to institute procedures to (1) identify invalid identifiers in the prescriber identifier field on Part D drug claims and (2) flag for review Part D drug claims that contain invalid identifiers in the prescriber identifier field. CMS concurred with our recommendations. ([OEI-03-09-00140](#))

Medicare > Part D > Less-Than-Effective Drugs

Less-Than-Effective Medicare Part D Drugs

Of approximately \$115 billion in gross drug costs included in Medicare Part D sponsors' PDE data for CYs 2006 and 2007, CMS accepted PDE data totaling \$43.3 million associated with less-than-effective drugs. Pursuant to Federal requirements, Medicare Part D should not have covered these drugs. Less-than-effective drugs are drugs that the Food and Drug Administration (FDA) approved before 1962 and that FDA subsequently found to be less than effective.

CMS's Drug Data Processing System subjects sponsors' PDE data to an edit designed to reject less-than-effective drugs. Although the edit identified and rejected the vast majority of PDE data associated with less-than-effective drugs, the edit did not identify and reject PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. There is no definitive list of less-than-effective drugs.

We recommended that CMS (1) determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs and (2) 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 less-than-effective drugs, regularly disseminating this list to all sponsors, and using this list to reject PDE data for less-than-effective drugs.

CMS agreed with our first recommendation and partially disagreed with our second recommendation, stating that FDA should be responsible for maintaining and disseminating the list of less-than-effective drugs. We modified our second recommendation to reflect FDA's role in identifying less-than-effective drugs. ([A-07-09-04138](#))

Other Medicare-Related Reviews

[Other Reviews](#) > [Program Integrity](#) > [Adverse Actions](#)

CMS Reporting to the Healthcare Integrity and Protection Data Bank

Although CMS took adverse actions, it did not report all of the actions to the Healthcare Integrity and Protection Data Bank (HIPDB) as required. CMS takes several types of adverse actions that are required to be reported to the HIPDB, including revocations and suspensions of laboratory certifications; terminations of providers from participation in Medicare; and CMPs against all types of providers, managed care plans, and prescription drug plans.

The HIPDB is a national data bank administered by the Health Resources and Services Administration (HRSA) that contains reports of adverse actions against health care practitioners, providers, and suppliers. The HIPDB plays an important role in preventing the employment of fraudulent or abusive health care providers, so it is important that the information it contains be complete and accurate. Federal and State government agencies and health plans are required to report certain adverse actions to the HIPDB. The Social Security Act defines the types of adverse actions that must be reported to the HIPDB. These include licensure and certification actions, exclusions from participation in Federal and State health care programs, criminal convictions, civil judgments related to health care, and any other adjudicated actions or decisions that the Secretary establishes by regulation.

CMS failed to report 148 adverse actions imposed against laboratories in 2007 and 30 adverse actions imposed against managed care and prescription drug plans between January 1, 2006, and July 31, 2009. None of the adverse actions against DME suppliers taken after 2008 had been reported to HIPDB at the time of our review; however, as of April 30, 2009, the HIPDB contained 5,125 adverse actions against DME suppliers imposed from 1998–2008. None of the 45 nursing homes terminated from participating in Medicare from 2004 through 2008 were reported to the HIPDB until 2009, well after the required reporting timeframe. The Division of National Systems, the group within CMS responsible for reporting adverse actions against certified provider types, did not report any actions between 2001 and 2008.

We recommended that CMS report all adverse actions to the HIPDB as required. To accomplish this, CMS should educate staff and contractors about the types of adverse actions required to be reported and the timeframes for reporting. In its written comments on the report, CMS concurred with our recommendation. CMS described planned efforts to report adverse actions imposed against nursing facilities, laboratories, and DME suppliers, including working with

HRSA to develop technical procedures and educating staff and contractors about HIPDB reporting. ([OEI-07-09-00290](#))

[Other Reviews](#) > [Beneficiary Rights](#) > [Language Access](#)

Guidance and Standards on Language Access Services

The Office for Civil Rights' (OCR) guidance and the Culturally and Linguistically Appropriate Services in Health Care (CLAS) standards address the provision of language access services. OCR guidance recommends a four-factor assessment to help determine what language access services to offer. The Office of Minority Health's (OMH) CLAS standards can help providers become responsive to the cultural and linguistic needs of diverse populations. Four of the fourteen CLAS standards focus on the provision of language access services. These standards are (1) providing services during all business hours, (2) providing verbal offers and written notices of rights to services, (3) assuring the competence of language assistance provided by staff, and (4) providing written materials and signage translated into appropriate languages. Language access services are designed to promote effective communication between Limited English Proficient (LEP) persons and non-LEP persons. Language access services can include oral interpretation; written translation; and other provisions that enhance communication, such as translated signs. The lack of language access services enables communication barriers to persist between LEP persons and non-LEP persons.

- **Medicare Providers.** Sixty-nine percent of Medicare providers conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. However, only 33 percent of Medicare providers offered services consistent with all four of OMH's CLAS standards on language access services. Seventy-three percent of providers reported benefits to offering language access services and 54 percent reported obstacles. Few providers reported data on the costs of providing language access services and the data provided were not comparable. To improve Medicare providers' awareness and implementation of CLAS standards and to help providers offer language access services, we recommended that (1) OCR inform providers about OMH's CLAS standards, (2) OMH increase outreach to providers to familiarize them with CLAS standards, and (3) OMH offer model translated written materials and signs to providers. OCR and OMH concurred with our recommendations. CMS indicated that it did not have any substantive comments. ([OEI-05-10-00050](#))
- **Medicare Plans.** Eighty-eight percent of Medicare plans conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. Only sixty-seven percent of Medicare plans offered services consistent with all four of OMH's CLAS standards on language access services, largely because Medicare plans did not verbally inform LEP persons of their right to language access services. Forty-nine percent of Medicare plans reported benefits to offering language access services and 57 percent reported obstacles. We could not compare data on the costs of providing language access services because plans use different methods to calculate costs.

We recommended that OMH collaborate with CMS to inform Medicare plans that they should notify LEP persons both verbally and in writing of their right to receive language access services. CMS has an established infrastructure for communicating with Medicare plans. OMH and CMS both concurred with our recommendation. ([OEI-05-10-00051](#))

Part II: Medicaid Reviews

Part II: Medicaid Reviews

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

Part II: Medicaid Reviews

Hospitals

Medicaid > Hospitals > Disproportionate Share Payments

Medicaid Disproportionate Share Hospital Payment Distribution

During Federal fiscal years (FY) 2003 through 2007, most of the seven selected States (Kansas, Louisiana, Missouri, New Jersey, New York, North Carolina, and Texas) reimbursed State-owned institutions for mental disease (IMD) and other State-owned hospitals the highest proportion of uncompensated care costs. The Medicaid disproportionate share hospital (DSH) program requires States to make special payments, known as DSH payments, to hospitals that serve unusually large numbers of low-income and/or uninsured patients. The Federal Government reimburses States for a percentage of their DSH payments.

We classified hospitals according to four categories: State-owned IMDs, other State-owned hospitals, local public hospitals, and private hospitals. In comparing DSH payments between hospital categories, we found that three of the seven States reimbursed State-owned IMDs the highest proportion of uncompensated care costs, three other States reimbursed other State-owned hospitals the highest proportion of uncompensated care costs, and one State reimbursed private hospitals the highest proportion of uncompensated care costs.

In analyzing the relationship between DSH payments and uncompensated care costs for all of the hospitals classified as DSH hospitals in the seven States, we found that, in the aggregate, State-owned IMDs received DSH payments averaging 92 percent of their uncompensated care costs, other State-owned hospitals received DSH payments averaging 95 percent of their uncompensated care costs, local public hospitals received DSH payments averaging 69 percent of their uncompensated care costs, and private hospitals received DSH payments averaging 38 percent of their uncompensated care costs.

We recommended that the Centers for Medicare & Medicaid Services (CMS) evaluate how DSH payments are distributed among hospital categories and consider requesting congressional legislation to ensure a more even distribution of payments based on uncompensated care costs. CMS concurred with our recommendation and noted that recent congressional action may affect DSH payments. ([A-07-09-04150](#))

Other Services, Equipment, and Supplies

[Medicaid](#) > [Services](#) > [Children](#)

Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services

Most children in nine selected States are not fully benefitting from Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) comprehensive screening services. Services provided under the EPSDT benefit are intended to screen, diagnose, and treat children eligible for EPSDT services at early, regular intervals to avoid or minimize childhood illness. EPSDT services cover four health-related areas: medical, vision, hearing, and dental. Complete medical screenings under the EPSDT benefit must include the following five age appropriate components: a comprehensive health and developmental history, a comprehensive unclothed physical examination, appropriate immunizations according to age and health history, appropriate laboratory tests, and health education. This study focused on medical, vision, and hearing screenings.

Seventy-six percent of children, or 2.7 million children, in 9 selected States did not receive all of the required number of medical, vision, and hearing screenings. Forty-one percent of children did not receive any required medical screenings. In addition, more than half of children did not receive any required vision or hearing screenings. Fifty-five percent of children in the nine States received a medical screening during the study period. Of these children, 59 percent lacked at least one component of a complete medical screening. The component that children were missing most often was appropriate laboratory tests.

Officials from all nine selected States identified strategies to improve participation in the EPSDT and the completeness of medical screenings. However, additional efforts are required.

Based on these findings, we recommended that CMS (1) require States to report vision and hearing screenings, (2) collaborate with States and providers to develop effective strategies to encourage beneficiary participation in EPSDT screenings, (3) collaborate with States and providers to develop education and incentives for providers to encourage complete medical screenings, and (4) identify and disseminate promising State practices for increasing children's participation in EPSDT screenings and providers' delivery of complete medical screenings.

CMS concurred with most of our recommendations and stated that it is undertaking efforts in conjunction with States and national experts to improve the provision of EPSDT services. Specifically, CMS concurred, in part, with our first recommendation and concurred with our other three recommendations. ([OEI-05-08-00520](#))

Arizona's Medicaid Claims for School-Based Health Services

Arizona did not always claim Federal reimbursement for Medicaid school-based health services in accordance with Federal and State requirements. Of the 100 sampled student-months from the period January 1, 2004, to June 30, 2006, 46 had 1 or more school-based health services that were not allowable. Based on our sample results, we estimated that the State was improperly reimbursed at least \$21.3 million in Federal Medicaid funds for school-based health services. Medicaid pays for medical services provided to children under Part B of the Individuals with Disabilities Education Act of 2004 (IDEA) through a child's individualized education plan. In addition to meeting other Federal and State requirements, school-based health services must be (1) actually furnished, (2) fully documented, (3) provided by an individual who meets Federal and State qualification requirements, (4) prescribed or referred by a physician or another appropriate professional, and (5) provided to eligible recipients.

We recommended that Arizona (1) refund to the Federal Government \$21.3 million for unallowable school-based health services, (2) review periods after our audit period and make appropriate financial adjustments for any unallowable school-based health services, (3) strengthen its oversight of the Direct Service Claiming program to ensure that claims for school-based health services comply with Federal and State requirements, and (4) revise its policy manuals to ensure compliance with Federal and State requirements. Arizona concurred with our second, third, and fourth recommendations but did not concur with our recommended refund. We continue to recommend that Arizona refund the \$21.3 million. ([A-09-07-00051](#))

New Jersey's Medicaid Claims for School-Based Health Services

In two reviews, we found that New Jersey's claims for reimbursement of Medicaid school-based health services submitted by its billing agents did not fully comply with Federal and State requirements. In addition to meeting other Federal and State requirements, school-based health services must be (1) referred or prescribed by a physician or another appropriate professional, (2) provided by an individual who meets Federal and State qualification requirements, (3) fully documented, (4) actually furnished, and (5) documented in the child's individualized education plan. During our audit periods, New Jersey contracted with separate billing agents to help administer its Medicaid school-based health services program under contingency-fee-based agreements. The results of our reviews follow:

- [Billing agent A](#). Based on our sample results for the period July 27, 2003, through October 4, 2006, we estimated that New Jersey was improperly reimbursed \$8 million in Federal Medicaid funds. Of the 100 school-based health claims in our sample, 51 did not comply with Federal and State requirements. The 51 claims pertained to services that were not (1) provided or supported, (2) in compliance with referral or prescription requirements,

(3) in compliance with Federal provider qualification requirements, or (4) documented in the child's plan.

We recommended that New Jersey refund \$8 million to the Federal Government, provide proper and timely guidance on Federal Medicaid criteria to its school-based health providers, and improve its monitoring of school-based health providers' claims to ensure compliance with Federal and State requirements. New Jersey disagreed with our recommended refund and provided additional documentation for claims questioned in our draft report. New Jersey also questioned our sampling methodology. After reviewing the additional documentation, we revised our findings and reduced the recommended refund to \$8 million. We maintain that our sampling methodology was valid. ([A-02-07-01051](#))

- **Billing agent B.** Based on our sample results for the period April 6, 2005, through June 27, 2007, we estimated that New Jersey was improperly reimbursed \$5.6 million in Federal Medicaid funds. Of the 100 school-based health claims in our sample, 36 did not comply with Federal and State requirements. The 36 claims pertained to services that were not (1) provided or supported, (2) in compliance with referral or prescription requirements, (3) in compliance with Federal provider qualification requirements, and (4) documented in the child's plan.

We recommended that New Jersey refund \$5.6 million to the Federal Government and consider the results of this review in its evaluation of our prior recommendations to ensure that its school-based health providers comply with Federal and State requirements. New Jersey disagreed with our recommended refund and provided additional documentation for claims questioned in our draft report. New Jersey also questioned our sampling methodology. After reviewing the additional documentation, we revised our findings and reduced the recommended refund to \$5.6 million. We maintain that our sampling methodology was valid. ([A-02-07-01052](#))

Prescription Drugs

[Medicaid > Prescription Drugs > Federal Share](#)

Medicaid Compound Drug Expenditures in California

California's claims for reimbursement of Medicaid compound drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. Of the \$29.5 million (Federal share) reviewed, \$383,000 represented expenditures for compound drug ingredients that were not eligible for Medicaid coverage because the drugs were dispensed after their termination dates. In addition, the State claimed \$1.3 million for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Federal reimbursement. Medicaid generally covers outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the Medicaid drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient

drugs, indicates each drug's termination date if applicable, and specifies whether the Food and Drug Administration (FDA) has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

We recommended that California (1) refund \$383,000 for expenditures for compound drug ingredients that were not eligible for Medicaid coverage, (2) work with CMS to resolve \$1.3 million in expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage, and (3) ensure that claimed Medicaid compound drug expenditures comply with Federal requirements. California agreed with our second recommendation and did not specifically address our other recommendations. ([A-09-08-00034](#))

Medicaid Administration

Medicaid > Administration > Provider Enrollment

Excluded Medicaid Providers: Analysis of Enrollment

Of 188 providers from 26 States who had been excluded by OIG subsequent to their enrollment, 8 had disclosed false ownership information at the time of enrollment. Another 8 of the 188 had criminal convictions before they enrolled and committed health care-related crimes after they enrolled. Of the 188 excluded providers, 88 had Federal or State tax liens before or after they enrolled in Medicaid and 24 had a history of tax debt, criminal convictions, or false disclosures before they enrolled.

We examined the providers' backgrounds before and after they enrolled to gather information related to potential weaknesses in States' provider enrollment procedures. In addition, we surveyed the 26 States that enrolled the 188 providers about the procedures they used to enroll the providers and the process they currently use to enroll providers.

Pursuant to Federal regulations at 42 CFR § 455.104 and 42 CFR § 455.106, States require providers to disclose information on ownership and control of an entity and criminal convictions related to Federal health care programs. However, the regulations do not require States to verify this information. We found that States impose few enrollment requirements beyond those mandated by Federal regulations. Over half of the excluded providers were subject to no State enrollment requirements beyond the Federal regulations when they enrolled in Medicaid. CMS agreed with our results. ([OEI-09-08-00330](#))

Medicaid > Administration > Payment Error Rate

Oversight and Evaluation of the Fiscal Year 2007 Payment Error Rate Measurement Program

We were unable to determine whether the Payment Error Rate Measurement (PERM) program produced a reasonable estimate of improper FY 2007 fee-for-service and managed care payments for both Medicaid and the Children's Health Insurance Program (CHIP) because (1) CMS's statistical contractor sampled payments from State universes that were or may have been incomplete or inaccurate, (2) the estimate of improper CHIP payments did not meet the required precision levels, and (3) CMS did not review States' repricing actions.

The Improper Payments Information Act of 2002 (IPIA) 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. CMS developed the PERM program to comply with requirements for measuring improper Medicaid program and CHIP payments. The PERM program has measured improper payments made in the fee-for-service, managed care, and eligibility components of Medicaid and CHIP since FY 2007.

We recommended that CMS (1) continue to work with the States, CMS regional offices, and the statistical contractor on reconciling the PERM universes to State financial reports; (2) work with the Office of Management and Budget (OMB) to establish new PERM precision-level requirements; (3) request the States to verify the accuracy of all repriced claims and submit documentation supporting the repricing; and (4) test repriced claims for accuracy. CMS agreed with our findings and proposed corrective actions. ([A-06-08-00078](#))

Medicaid > Administration > Payment Error Types

Analysis of Improper Payments Identified in the Payment Error Rate Measurement Program

Of 1,356 PERM program medical review errors that we analyzed for FYs 2006 and 2007, 4 types accounted for 78 percent of the errors and 95 percent of the net improper Medicaid overpayments. The four error types were insufficient documentation, no documentation, services that violated State policies, and medically unnecessary services. Of the 202 PERM program data-processing errors that we analyzed for the same period, 4 types accounted for 8 percent of the errors and 64 percent of the net improper Medicaid overpayments. The four error types were pricing errors, noncovered services, rate cell errors for managed care claims, and errors in the logic edits of claim-processing systems. The PERM program annually measures improper payments based on sampled Medicaid claims in 17 States (including the District of Columbia as a State); each State is chosen once every 3 years.

We recommended that, for future years, CMS develop and provide to the States analytical data similar to the data in this report and encourage the States to use the data to help ensure that payments, including those funded by the American Recovery and Reinvestment Act of 2009

(Recovery Act), comply with Federal requirements. CMS concurred and said that it would implement the recommendation starting with the FY 2010 measurement cycle. ([A-06-09-00079](#))

Medicaid > Administration > Federal Share

Reporting Medicaid Overpayments in Michigan

In two reviews summarized below, we determined that Michigan did not report all Medicaid overpayments in accordance with Federal requirements. Federal law requires States to refund the Federal share of a Medicaid overpayment made to a provider, and Federal regulations require States to refund the Federal share at the end of the 60-day period following the date of discovery, whether or not the State has recovered the overpayment.

- Fiscal years 2008 and 2009. For Federal fiscal years 2008 and 2009, we estimated that Michigan did not report Medicaid overpayments totaling \$2.3 million (\$1.3 million Federal share) in accordance with Federal requirements. The State also did not report all Medicaid overpayments within the 60-day time requirement. Because the State did not report some overpayments and was not prompt in reporting others, the Federal Government incurred a potentially higher interest expense. We recommended that the State (1) include unreported Medicaid overpayments of \$2.3 million on Form CMS-64 and refund \$1.3 million to the Federal Government and (2) develop and implement internal controls to correctly report and refund the Federal share of identified Medicaid overpayments on Form CMS-64. The State concurred with our recommendations. ([A-05-09-00103](#))
- First quarter of fiscal year 2010. Our review found that for the quarter ended December 31, 2009, Michigan did not report \$3 million (\$2.2 million Federal share) in Medicaid overpayments in accordance with Federal requirements because of a clerical error. The State did not properly report these overpayments because it had not developed and implemented internal controls to ensure that overpayments were reported on Form CMS-64. We recommended that the State (1) include unreported Medicaid overpayments of \$3 million on Form CMS-64 and refund \$2.2 million to the Federal Government and (2) develop and implement internal controls to correctly report and refund the Federal share of identified Medicaid overpayments. The State concurred with our recommendations and said that it had included the \$3 million on a subsequent Form CMS-64. ([A-05-10-00061](#))

Medicaid > Administration > Recovery Act

Tennessee's Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program

We found that Tennessee's claim for Federal reimbursement of expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program for the quarter ended December 31, 2008, was adequately supported by actual recorded expenditures. The Recovery Act provides fiscal relief to States to protect and maintain State Medicaid programs in a period

of economic downturn. For the recession adjustment period (October 1, 2008, through December 31, 2010), the Recovery Act provides an estimated \$87 billion in additional Medicaid funding based on temporary increases in States' Federal medical assistance percentages (FMAP). For the majority of Medicaid expenditures claimed, CMS reimburses States based on the FMAP, which varies depending on a State's relative per capita income. For the quarter ended December 31, 2008, Tennessee's regular FMAP for Medicaid expenditures was 64.28 percent, and the temporarily increased FMAP was 73.25 percent. This report contains no recommendations. ([A-04-09-04040](#))

Medicaid > Administration > Recovery Act

Compliance With the Recovery Act's Political Subdivision Requirement

New York State complied with the political subdivision requirement for receiving the increased FMAP under the Recovery Act. Specifically, the State did not require its social services districts (i.e., political subdivisions) to contribute a greater percentage of the non-Federal share of Medicaid expenditures than the percentage required under the State Medicaid plan on September 30, 2008. A State is not eligible for the increased FMAP if it requires its political subdivisions to pay a greater percentage of the non-Federal share of Medicaid expenditures than the percentage required under the State Medicaid plan on September 30, 2008. This report contains no recommendations. ([A-02-09-01029](#))

Medicaid > Administration > Recovery Act

Compliance With the Recovery Act's Medicaid Eligibility Requirements

As described below, five States that we reviewed complied with Recovery Act eligibility requirements during the first three quarters of Federal FY 2009. Accordingly, we made no recommendations. Pursuant to the Recovery Act, States generally are not eligible for FMAP increases for quarters during the recession adjustment period in which their Medicaid eligibility standards, methodologies, or procedures are more restrictive than those in effect on July 1, 2008.

- Louisiana, Minnesota, New Hampshire, and Rhode Island. In all four States, the Medicaid eligibility standards, methodologies, and procedures during the audit period were not more restrictive than those in effect on July 1, 2008. ([A-06-09-00100](#); [A-05-10-00014](#); [A-01-10-00002](#); [A-01-09-00007](#))
- Texas. Texas made one policy change after July 1, 2008, that resulted in more restrictive Medicaid eligibility standards, methodologies, and procedures during the audit period. However, in accordance with the Recovery Act, the State reinstated the less restrictive policy before July 1, 2009. The State also made administrative policy changes that did not affect the eligibility process. ([A-06-09-00099](#))

Compliance With the Recovery Act's Prompt Pay Requirements

With one exception that was concurrently resolved, we found New York and Pennsylvania to be in sufficient compliance with prompt pay requirements for receiving an increased FMAP under the Recovery Act. Federal regulations require States to pay 90 percent of all clean claims from practitioners within 30 days of the date of receipt. A clean claim is a claim that can be processed without obtaining additional information from the provider or a third party. The results of our reviews follow.

- New York. For the 6-month period January 1 through June 30, 2009, New York State complied with the prompt pay requirement for receiving an increased FMAP. Specifically, the State paid 100 percent of the 125,618,625 clean claims that it received from applicable providers within 30 days of the date of receipt. This report has no recommendations. ([A-02-09-01037](#))
- Pennsylvania. Pennsylvania complied with the prompt pay requirement for receiving an increased FMAP for claims received on all days from February 16, 2009, through September 30, 2009. In addition, all practitioner, nursing facility, and hospital claims received after May 31, 2009, met the requirements for an increased Federal share. The State did not meet the 30-day prompt pay requirement for claims received on any day from January 20, 2009, through February 15, 2009, and for claims received on November 29, 2008, and December 13, 2008. However, during our review, the State requested a waiver of the prompt pay requirement for claims submitted by practitioners that were received by the State before February 18, 2009. CMS granted the waiver; therefore, we have no recommendations. ([A-03-09-00204](#))

Compliance With the Recovery Act's Medicaid Expenditure Base Requirements

Reviews in two States of the Recovery Act's Medicaid expenditure base requirements had mixed results as described below. Pursuant to the Recovery Act, States must have policies and procedures in place to segregate Medicaid expenditures that qualify for the temporarily increased FMAP during the recession adjustment period and to ensure that those Medicaid expenditures that do not qualify are not claimed for reimbursement at the temporarily increased FMAP. We reviewed two States' compliance with this requirement for the period October 1, 2008, through March 31, 2009, as follows:

- Colorado. Colorado's \$142 million in claims associated with the temporarily increased FMAP was computed using the Medicaid expenditure base specified in the Recovery Act, and the expenditures were supported by the State's accounting records. Colorado had policies and procedures in place to segregate Medicaid expenditures that qualified for the temporarily increased FMAP and to ensure that those Medicaid expenditures that did not

qualify were not claimed for reimbursement at the temporarily increased FMAP. However, the State had not documented all of its policies and procedures. We recommended that Colorado document all of its policies and procedures for claiming the temporary FMAP increase. The State partially concurred with our recommendation. ([A-07-09-02767](#))

- Delaware. Delaware's \$60 million in claims associated with the temporarily increased FMAP was computed using the Medicaid expenditure base specified in the Recovery Act, and the expenditures were supported by the State's accounting records. The State had policies and procedures in place to segregate Medicaid expenditures that qualified for the temporarily increased FMAP and to ensure that those Medicaid expenditures that did not qualify were not claimed for reimbursement at the temporarily increased FMAP. The State had correctly documented and disseminated these policies and procedures. This report contains no recommendations. ([A-03-09-00202](#))

Medicaid > Administration > Recovery Act

New Jersey's Compliance With the Recovery Act's Reserve Fund Requirements

Our review found that New Jersey complied with the Recovery Act reserve fund requirement for receiving the increased FMAP. Specifically, the State did not use additional Medicaid funding to supplement any reserve account. Under the Recovery Act, a State is not eligible for the increased FMAP if any amounts attributable (directly or indirectly) to such an increase are deposited in or credited to any reserve, or "rainy day," fund. We made no recommendations. ([A-02-09-01030](#))

Other Medicaid-Related Issues

Other Issues > Gulf Coast Hurricanes

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

We were not able to express an opinion on \$26 million that Louisiana awarded to health care professionals from March 1 through December 31, 2007, because we discovered after our fieldwork was complete that practitioner contracts may have been improperly signed. In addition, of the \$5.3 million that the State awarded to 100 sampled awardees during the period, \$1.4 million was not awarded to 20 awardees in accordance with the grant terms. Based on our sample results, we estimated that the State did not award \$5.8 million of grant funds to 85 awardees in accordance with the grant terms. The \$50 million Federal grant, which covered the period March 1, 2007, through September 30, 2012, funded payments to licensed health care professionals for their retention and recruitment in communities impacted by Hurricane Katrina.

We recommended, among other things, that the State (1) cancel the undistributed awards related to the \$1.4 million in grants that were not awarded according to the grant terms and (2) credit the grant account for distributed awards. The State generally agreed with our findings and recommendations. ([A-06-08-00026](#))

Other Issues > Gulf Coast Hurricanes

Hurricane-Related Uncompensated Care Claims in Louisiana

Louisiana did not always claim reimbursement for services provided by one hospital in accordance with Federal and State laws and regulations or with the approved provisions of the uncompensated care pool (UCCP) plan. In response to Hurricane Katrina, the Deficit Reduction Act of 2005 authorized Federal funding for the total costs of medically necessary uncompensated care furnished to evacuees and affected individuals without other coverage in eligible States. CMS approved Louisiana's UCCP plan to reimburse providers for medically necessary services provided to Hurricane Katrina evacuees and affected individuals and to Hurricane Rita evacuees without other coverage.

Of the \$3.7 million in costs claimed for services provided to 86 patients, \$3.4 million was unallowable. Louisiana claimed the unallowable costs because it (1) did not have procedures to ensure that it claimed uncompensated care costs only for services covered under the Medicaid plan; (2) relied on the hospital to verify that the costs claimed were based on actual inpatient days; (3) did not offset its uncompensated care claim by payments received from other sources on behalf of the patients; and (4) did not have procedures to verify that patients whose costs were claimed under the Hurricane Rita UCCP were, in fact, evacuees.

We recommended that Louisiana refund to CMS the \$3.4 million in unallowable costs claimed. Because the State's authorization to obtain Federal reimbursement for hurricane-related uncompensated care has ended, we made no procedural recommendations. The State disagreed with our findings and recommendation. Nothing in the State's comments caused us to revise our findings or recommendation. ([A-06-09-00084](#))

Other Issues > CHIP > Federal Share

Medicaid and Children's Health Insurance Program Concurrent Enrollees in Florida

Based on our sample results, we estimated that from April 1, 2007, through March 31, 2008, Florida claimed \$5.3 million in Federal financial participation (FFP), or matching funds, for CHIP enrollees who were concurrently enrolled in CHIP and Medicaid for a total 65,121 enrollment-months. If an individual is eligible for Medicaid, he or she is ineligible for CHIP. The Federal Government uses enhanced FMAPs to determine the amount of FFP for State expenditures in CHIP. The concurrent enrollments occurred primarily because (1) Medicaid enrollment can be retroactive for up to 3 months, during which time the individual may also

have been enrolled in CHIP, and (2) the State agency's partners did not have adequate internal controls to prevent or correct concurrent enrollments promptly.

We recommended that the State (1) make a financial adjustment of \$5.3 million on Form CMS-21 for FFP claimed on behalf of CHIP enrollees who were also enrolled concurrently in Medicaid, (2) make regular financial adjustments on future Forms CMS-21 to correct FFP claimed on behalf of CHIP enrollees who are enrolled concurrently in Medicaid, and (3) develop additional policies and procedures to prevent or recoup CHIP payments made on behalf of individuals who are enrolled concurrently in Medicaid. The State disagreed with our overall findings. ([A-04-09-03046](#))

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

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

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

Medicare- and Medicaid-Related Outreach

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.

Advisory Opinions

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 April 1, 2010, through September 30, 2010, OIG received 19 advisory opinion requests and issued 11 advisory opinions. OIG advisory opinions are available at: <http://www.oig.hhs.gov/fraud/advisoryopinions.asp>.

Provider Self-Disclosure Protocol

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abusive practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The "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.

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

On April 15, 2008, OIG published another Open Letter to Health Care Providers. The letter sets forth certain refinements to the October 1998 Self-Disclosure Protocol. To improve the self-disclosure process, OIG, among other steps, streamlined its internal self-disclosure procedures. In addition, OIG explained that it will generally not require a self-disclosing entity to enter into a Corporate Integrity Agreement (CIA) or certification of compliance agreement (CCA) when a resolution has been negotiated pursuant to the protocol. A CIA is an agreement between the provider and OIG that is entered into in exchange for OIG's agreement not to seek an exclusion of that provider from participation in Medicare, Medicaid, and other Federal health care programs. CIAs are monitored by OIG and require providers to enhance existing compliance programs or establish new ones. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct. OIG may also negotiate a CCA in lieu of a comprehensive CIA, under appropriate circumstances. The CCA requires that the provider maintain its existing compliance program and agree to certain compliance obligations that mirror those found in a comprehensive CIA.

OIG published its most recent Open Letter to Health Care Providers on March 24, 2009, that narrowed the scope of the self-disclosure protocol in regard to violations of the physician self-referral ("Stark") law and explained that OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. The Open Letter also established a minimum settlement amount for anti-kickback disclosures of \$50,000.

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

See also:

Compliance Guidance: <http://www.oig.hhs.gov/fraud/complianceguidance.asp>

Open Letters: <http://www.oig.hhs.gov/fraud/openletters.asp>

During this reporting period, self-disclosure cases resulted in \$20 million in Department of Health & Human Services (HHS) receivables. The following are examples:

- **Massachusetts** – Elder Service Plan of the North Shore (ESPNS) and East Boston Neighborhood Health Center (EBNHC) agreed to pay \$308,709 and \$200,962, respectively, to resolve their Civil Monetary Penalties Law (CMPL) liability for contracting with an excluded dentist, Dr. Steven Ramos, for dental services that he provided to Medicare and Medicaid beneficiaries. Both parties had contracted with Dr. Ramos from May 2006 through February 2009. EBNHC self-disclosed to OIG that it had contracted with Dr. Ramos while he was excluded. During the course of investigating EBNHC's self-disclosure, OIG discovered that ESPNS also contracted with the excluded Dr. Ramos.
- **Colorado** – Colorado West HealthCare System (d/b/a/ Community Hospital) and its subsidiary, Doctors' Clinic Building, Inc., (collectively, "Colorado West") agreed to pay the United States \$420,175 in order to resolve their liability under the CMPL for conduct disclosed under the OIG's Self-Disclosure Protocol. In a total of 13 submissions between

September 2007 and March 2009, Colorado West disclosed that it had entered into six categories of contractual arrangements (i.e., medical director arrangements, emergency room services, office leases, on-call physician arrangements, continuing medical education services, and diagnostic test interpretations) that violated the Stark Law and, in some instances, potentially implicated the anti-kickback statute in connection with physicians' referrals of Medicare beneficiaries to Colorado West.

Office of Inspector General 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 E for an explanation of OIG's sanction authorities). These sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of CMPs for submitting false or fraudulent claims to a Federal health care program or for violating the anti-kickback statute, the Stark Law, or the "patient dumping" provision of the Social Security Act.

During this reporting period, OIG administered 1,446 sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries.

Details and examples follow.

Program Exclusions

During this semiannual reporting period, OIG excluded 1,405 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 <http://exclusions.oig.hhs.gov/>.

For example:

- **Maryland** – Physical therapist Marwan Khayat was excluded indefinitely based on the voluntary surrender of his physical therapy license to the Maryland Board of Physical Therapy Examiners. After the board initiated an investigation into Khayat's conduct, Khayat admitted to having a brief sexual relationship with a patient and engaging in inappropriate sexual contact with two female patients during treatment sessions.
- **Kansas** – Shelley Harding, a certified alcohol and drug abuse counselor, owner, and operator of a counseling center in Kansas, was excluded for a minimum of 30 years based on her health care fraud conviction. Between June 2001 and February 2006, Harding, doing business as A New Beginning, submitted materially false and fraudulent claims and caused others to submit materially false and fraudulent claims to Medicaid for community-based drug and alcohol abuse services for 81 children. Harding was sentenced to 24 months' incarceration and ordered to pay \$3,758,951 in restitution.
- **Idaho** – Dwight Manwaring was excluded for an indefinite period based on the voluntary surrender of his license to practice as a registered nurse in Idaho. While working as a nurse

in a nursing home, staff members observed Manwaring removing a Fentanyl patch from an 89-year old Alzheimer's patient. Fentanyl is a narcotic pain medication. A subsequent drug screen performed on Manwaring produced a positive result for Fentanyl.

- **Florida** – Manuel Casal, owner/operator of durable medical equipment (DME) company K.M. Medical Services, Inc., was excluded for a minimum of 50 years based on his conviction for health care fraud. Between June 2005 and December 2005, Casal billed Medicare for various health care benefits, items, and services that were not medically necessary or were not provided to beneficiaries. Casal was sentenced to 3 years and 10 months' incarceration and ordered to pay \$668,079 in restitution.
- **Texas** – James Chaney, a previous owner of a DME company, was excluded for a minimum of 25 years based on his conviction for aiding and abetting the unlawful obtaining of individually identifiable health information of an individual with the intent to sell, transfer, or use that health information for commercial advantage or personal gain. Over a 2-year period, Chaney purchased over 1,000 files from various DME companies that contained Medicare beneficiary information. He sold these beneficiaries' medical information to another owner of several DME companies, who used it to bill Medicare for DME that was not purchased by or delivered to beneficiaries. Chaney was sentenced to 60 months' incarceration and ordered to pay \$1,746,024 in restitution.

Civil Monetary Penalties Law

The CMPL authorizes OIG to impose administrative penalties and assessments against a person who, among other things, submits or causes to be submitted claims to a Federal health care program that the person knows or should know are false or fraudulent. During this reporting period, OIG concluded cases involving more than \$18.3 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

- **California** – Tenet Healthcare Corporation and Tenet HealthSystem KNC, Inc. (doing business as USC Norris Cancer Hospital) (collectively, "Tenet"), who are currently subject to a 5-year CIA with the OIG, agreed to pay \$1.9 million to resolve its liability under the CMPL. Tenet, pursuant to the CIA's Reportable Event disclosure requirements, revealed to OIG that between December 2003 and October 2007, it submitted claims not entitled to Federal health care program reimbursement for clinical research-related items or services rendered at USC Norris Cancer Hospital. Specifically, Tenet improperly received government reimbursement for: (1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted; (2) items or services intended to be free of charge in the research informed consent; (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or (4) items or services that were otherwise not covered under the Centers for Medicare & Medicaid Services (CMS) Clinical Trial Policy.
- **Illinois** – United Shockwave Services, Ltd; United Urology Centers, LLC; and United Prostate Centers, LLC (collectively, United) agreed to pay \$7,359,500 and, along with United

Therapies, LLC, enter into a 5-year CIA to resolve their CMPL liability. United is a physician-owned enterprise that leases medical equipment and services for the treatment of kidney stones and enlarged prostate glands. The settlement resolves a number of allegations, including that United and certain physician-investors used their ability to control patient referrals to obtain contract business from hospitals in Illinois, Iowa, and Indiana. Specifically, OIG alleged that United threatened hospitals that it would refer patients to competing hospitals if they did not agree to a contract with United, or promised additional referrals to hospitals that did contract with United. Consequently, if hospitals chose to contract with United over competitors to get more referrals, all claims resulting from that relationship were prohibited by the anti-kickback statute. Furthermore, OIG alleged that certain physician-investor referrals to hospitals that had contracts with United also violated the Stark Law.

- **Massachusetts** – Robert J. Kramer and Kramer Physical Therapy Associates, Inc. (collectively, the “Respondents”) agreed to pay \$122,474 to resolve liability under the CMPL for allegedly submitting improper claims to Medicare from July 1, 2003, through June 30, 2006. Specifically, Respondents allegedly billed Medicare for physical therapy services that were not properly supervised by a licensed physical therapist as required by Medicare reimbursement rules. The Respondents previously entered into a settlement agreement with Massachusetts wherein they paid \$14,797 to resolve their liability for allegedly submitting the same type of improper claims to Medicaid during the same time period.
- **Missouri** – St. John’s Regional Medical Center (St. John’s) agreed to pay \$274,815 to resolve its CMPL liability in a self-disclosed improper financial relationship between a wholly owned subsidiary of St. John’s and a physician. OIG contended that the subsidiary allowed the physician, a referral source for St. John’s, to be regularly delinquent in rent under a written lease agreement in violation of the Stark Law and anti-kickback statute. St. John’s also allegedly paid the physician for services without a written contract in place.
- **North Dakota** – Lake Region Lutheran Home (d/b/a Heartland Center), a 98-bed skilled nursing facility (SNF), agreed to pay \$133,973 to OIG to resolve its CMPL liability for employing a licensed practical nurse who was excluded from all Federal health care programs between August 2002 and December 2005. A North Dakota Board of Nursing analyst referred the case to OIG’s Fargo, North Dakota, Field office.

Patient Dumping

Some of the CMP cases that OIG resolved between April 1 and September 30, 2010, were pursued under the Emergency Medical Treatment and Labor Act of 1986 (EMTALA), a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of settlements under this statute:

- **Alabama** – Providence Hospital paid \$45,000 to resolve allegations that it improperly refused to transfer a patient suffering an emergent gastrointestinal bleed. A 60-year-old man arrived at another hospital’s emergency department complaining of coffee-ground-like

vomit, severe abdominal pain, and dark-colored stools over the previous 12 hours. The hospital did not have the capacity or specialized services to treat him, so an attempt was made to transfer him to Providence Hospital. Providence refused the transfer request, even though it had the capacity and specialized capabilities to treat the patient. The refusal of the transfer request delayed care and treatment, and it took two more hours to transfer the patient to a more distant hospital. The patient's condition deteriorated, and he died later that day.

- **Illinois** – University of Chicago Medical Center paid \$50,000 to resolve allegations of patient dumping. A 78-year old man arrived at the emergency department by ambulance with his daughter. He was placed in the waiting room in full view of the staff. The medical center did not give the patient a medical examination during the three and three-quarter hours that he waited. The daughter then requested that her father be seen, at which point the staff discovered that the patient had died.

Criminal and Civil Enforcement

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

The successful resolution of false claims often involves the combined investigative efforts and resources of OIG, the Federal Bureau of Investigation (FBI), Medicaid Fraud Control Units (MFCU), and other law enforcement agencies. OIG is responsible for assisting DOJ in bringing and settling cases under the FCA. Many providers elect to settle their cases prior to litigation. As part of their settlements, providers often agree to enter into CIAs 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.

During fiscal year (FY) 2010, the Government's enforcement efforts resulted in 552 criminal actions and 371 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$3.2 billion in HHS and \$570.2 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare; Medicaid; and other Federal, State, and private health care programs. Some of the notable enforcement actions, and other related activities, are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

Special Assistant United States Attorney Program

DOJ and OIG launched a program in which OIG attorneys serve as Special Assistant United States Attorneys. 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 below; others prosecute matters on a case-by-case basis. Both arrangements offer excellent litigation training for OIG attorneys and enhance collaboration between the departments in fighting fraud. Under this program, OIG attorneys have successfully litigated important criminal cases relating to DME, infusion therapy, physical therapy, and other types of Medicare and Medicaid fraud.

Health Care Fraud Prevention and Enforcement Action Team

On May 20, 2009, Secretary of HHS Kathleen Sebelius and Attorney General Eric Holder announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an interagency effort focused specifically on combating health care fraud. HEAT includes senior officials from DOJ and HHS who are strengthening programs, as well as investing in new resources and technologies, to prevent and combat fraud, waste, and abuse. A key component of HEAT task force efforts is expansion of Medicare Fraud Strike Force operations. Strike Forces began in March 2007 and are operating in seven major cities—Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; and Tampa, Florida. The Strike Force teams coordinate law enforcement operations with other Federal, State, and local law enforcement entities. These teams have a proven record of success analyzing real-time data to quickly identify and prosecute fraud almost as it occurs.

During this reporting period, Strike Force efforts have resulted in the filing of charges against 88 individuals or entities, 89 convictions, and \$71.3 million in investigative receivables.

Examples of Strike Force efforts during this reporting period follow:

- **Michigan** – Dr. Jose Castro-Ramirez (Dr. Castro) was sentenced to 14 years in prison and ordered to pay \$9,769,113 in joint and several restitution after being convicted of health care fraud, conspiracy to commit health care fraud, and money laundering. Suresh Chand, the owner and operator of two rehabilitation companies, was sentenced to 6 years and 9 months' incarceration and ordered to pay \$9,769,113 in joint and several restitution after pleading guilty to conspiracy to commit health care fraud and conspiracy to launder money. Between January 2003 and March 2007, Chand and his co-conspirators submitted claims to Medicare for physical and occupational therapy services and other medical services that were never provided. Chand paid licensed physical and occupational therapists to sign fictitious "progress notes" and other documents that appeared to reflect that physical and occupational therapy services had been provided to the beneficiaries, when in fact they had not.

Dr. Castro signed medical records then billed Medicare for physical therapy, occupational therapy, and other services that were either not medically necessary or not rendered.

Evidence at trial proved that Dr. Castro had not overseen any treatment provided to the patients and, in many instances, he never saw the beneficiaries. Evidence presented at trial also showed that Chand provided Dr. Castro with lists of the controlled substances or drugs the beneficiaries preferred, and Dr. Castro wrote thousands of prescriptions for the substances without seeing the patients. Proceeds of the fraud were laundered and distributed through shell corporations owned by Chand and his co-conspirators. Previously, co-defendants Solomon Nathaniel, Syed Aziz, Sandeep Aggarwal, Baskaran Thangarasan, Jay Jha, and Jaquita Lovelace were sentenced to prison terms ranging from 1 day to 5 years and 2 months for their involvement in the scheme.

- **Michigan** – Fifteen defendants, including Medicare beneficiaries, physicians, and infusion therapy clinic owners and employees, were convicted on charges related to their participation in health care fraud schemes at clinics throughout the Detroit metropolitan area. During this reporting period, defendants John Saunders, Wayne Smith, Dr. Toe Myint, Terrence Hicks, Samuel Mott, Jose Martinez, Denisse Martinez, Larry Dickerson, William Reeves, Muhammad Al-Mahdi, and Lill Vargas-Arias were all convicted on charges related to health care fraud and were sentenced to prison terms ranging from time served to 6 years and ordered to pay more than \$3.7 million in joint and several restitution. According to court documents, businesses Xpress Center, Sacred Hope Center, Dearborn Medical & Rehab Center, and RDM Centers employed similar schemes to defraud Medicare, including (1) recruiting and paying beneficiaries to receive services at the clinics that were either not medically necessary or were not provided, (2) providing beneficiaries with prescriptions for medications that the defendants decided were more likely to generate Medicare reimbursements rather than for reasons based on medical need, and (3) submitting false and fraudulent claims to Medicare for these purported services. Co-defendants Victor Dozier, Louis Jackson, and Daisey Martinez were previously sentenced to prison terms ranging from time served to 8 years for their involvement in these schemes.
- **California** – Ajibola Sadiqr, owner and operator of Cooper Medical Supply, pleaded guilty to conspiracy to commit health care fraud and was sentenced to 4 years and 7 months in prison and ordered to pay \$508,134 in restitution. Between January 2006 and September 2009, Sadiqr conspired with Leonard Nwafor, the owner of another DME supply company; patient recruiter Maria Moreno; and others to fraudulently obtain beneficiary information and create illegitimate prescriptions and medical documents to sell to DME companies. Witnesses testified at trial that Moreno purported to be a representative of Medicare or another Government agency and went door-to-door at senior communities to obtain beneficiary information. Sadiqr and his co-conspirators billed Medicare for unnecessary high-end power wheelchairs and other DME using fraudulent prescriptions and medical documents obtained by Moreno or purchased from other sources. Previously, Nwafor was sentenced to 9 years in prison and ordered to pay \$526,243 in restitution and Moreno was sentenced to 1 year and 1 day in prison and ordered to pay \$100,588 in restitution for their respective roles in the scheme.

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- **Florida** – Lissette Borges was sentenced to 3 years and 10 months’ incarceration and ordered to pay \$15,976,849 in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. Borges owned L&A Billing, a billing company that submitted fraudulent claims to Medicare on behalf of several DME companies. Investigators learned that the DME companies provided Borges with a list of physicians and Medicare beneficiaries, and she randomly paired the physicians and beneficiaries together and billed Medicare for medical supplies that were never needed or used. In return for the billing, the DME companies paid Borges a percentage of the amount reimbursed by Medicare.
 - **Texas** – Helen Etinfoh and Paula Whitfield were convicted of health care fraud and conspiracy to commit health care fraud. Whitfield was sentenced to 21 months in prison and ordered to pay \$807,781 in joint and several restitution; Etinfoh is awaiting sentencing. According to evidence presented at trial, Etinfoh paid Whitfield kickbacks to recruit Medicare beneficiaries for her DME company, Luant & Odera. Whitfield visited the homes of beneficiaries and offered them power wheelchairs in exchange for their Medicare information, even though all of them could walk. Etinfoh then used a special hurricane code to bypass the need for a doctor’s order and billed Medicare for DME such as wheelchairs, wheelchair accessories, and motorized scooters that were medically unnecessary for the recruited beneficiaries.

Pharmaceutical Companies

- **Pennsylvania** – AstraZeneca, LP, and AstraZeneca Pharmaceuticals, LP, (collectively, AstraZeneca) agreed to pay \$520 million plus interest and enter into a 5-year CIA to resolve their civil FCA liability in connection with the promotion of the drug Seroquel. Seroquel is an atypical antipsychotic drug approved by the Food and Drug Administration (FDA) for the treatment of schizophrenia and acute manic episodes associated with bipolar disorder. Between January 2001 and December 2006, AstraZeneca is alleged to have promoted Seroquel for uses that were not approved by the FDA as safe and effective, including aggression, anxiety, dementia, depression, and Alzheimer’s disease. AstraZeneca also allegedly violated the Federal anti-kickback statute by offering and paying illegal remuneration to doctors in connection with services rendered by the doctors relating to the unapproved uses of Seroquel.
- **Maryland** – Alparma Inc., and its subsidiary, Alparma Pharmaceuticals, LLC (collectively, Alparma), agreed to pay \$42.5 million plus interest to resolve FCA allegations that it provided illegal kickbacks to increase the marketing of Kadian, its morphine-based drug. Between January 2000 and December 2008, Alparma was alleged to have paid health care providers to induce them to promote or prescribe Kadian and made misrepresentations about the safety and efficacy of the drug. Alparma was alleged to have recruited physicians in a position to prescribe Kadian and entered into sham consulting arrangements with them. Alparma also was alleged to have engaged in other kickback conduct, including: (1) paying above-market fees to referral sources to participate in research projects; (2) conducting an “Interactive Consulting Forum” for which hundreds of

physicians were paid to provide feedback on Kadian; and (3) sponsoring a “Speaker’s Bureau” on which an excessive number of physicians were paid to serve.

Hospitals

- **Ohio** – Parma Community Hospital (Parma), Norton Healthcare (Norton), and St. Jude Medical, Inc., (St. Jude), agreed to pay the Government \$40,000, \$133,300, and \$3,725,000, respectively, to resolve allegations of illegal kickbacks resulting in false claims submitted to Medicare. St. Jude, a heart device manufacturer, was alleged to have offered and paid kickbacks to Norton and Parma, which agreed to buy certain percentages of St. Jude manufactured implantable cardioverter-defibrillators (ICD) and pacemakers. The kickbacks allegedly took the form of account credits towards the hospitals’ future purchases of other St. Jude devices.
- **Ohio** – The Health Alliance of Greater Cincinnati (THA) and University Internal Medicine Associates, Inc. (UIMA), agreed to pay \$2.5 million and \$100,000, respectively, to resolve their liability under the FCA in connection with an illegal kickback scheme. THA was a conglomerate of hospitals, which included Fort Hamilton Hospital (FHH) and The University Hospital (TUH) that operated under a joint operating agreement. THA was alleged to have used a clinical trial intended to investigate outcomes of two elective coronary intervention procedures as a smokescreen for an illegal referral relationship with UIMA that extended beyond participation in the trial. Specifically, UIMA allegedly agreed to provide FHH with patient referrals in exchange for FHH sending all unassigned cardiology patients and patients needing interventional procedures to UIMA cardiologists. The UIMA cardiologist would then allegedly perform the procedures at either FHH or TUH, generating revenue for the THA hospitals. THA officially disbanded in April 2010.

Durable Medical Equipment Suppliers

- **Florida** – Yasmany Benavides was sentenced to 12 years’ imprisonment and ordered to pay \$6,206,697 in joint and several restitution following his conviction for health care fraud and conspiracy to commit health care fraud. From about December 2003 through August 2004, Benavides submitted claims to Medicare on behalf of Lily Orthopedic, Inc., for DME and services that physicians did not prescribe or were not supplied as claimed. Previously, Erich Ruiz was sentenced to 2 years and 6 months’ imprisonment for his involvement in the submission of false claims on behalf of Lily Orthopedic, Inc. Ruiz is also responsible for paying \$4,484,797, a portion of Benavides’ restitution amount.
- **North Carolina** – Kalu Kalu, owner of Enuda Healthsource, a DME company, was sentenced to 7 years and 6 months’ incarceration and ordered to pay \$4,611,988 in joint and several restitution after pleading guilty to charges related to a scheme to defraud the Medicare program. From about December 2004 through July 2008, Kalu, along with Martin Iroegbu, the owner of another DME company, submitted claims for more expensive DME than was delivered to beneficiaries and for DME that was medically unnecessary or not delivered at all. Employees from both DME companies falsely represented during

presentations at Medicare beneficiaries' homes and churches that they could receive free medical equipment from the government. After the employees obtained beneficiaries' Medicare numbers, physicians' names, and their medical conditions, they completed fraudulent prescription forms for submission to Medicare. Iroegbu was previously sentenced to 2 years and 2 months' incarceration and ordered to pay \$575,430 in restitution for health care fraud.

Practitioners

- **Virginia** – Hematologist and oncologist Dr. Ronald Poulin was convicted following a jury trial, sentenced to 5 years and 3 months' incarceration, and ordered to pay \$790,641 in restitution for health care fraud, false statements relating to health care matters, and alteration of records to obstruct an investigation. Dr. Poulin defrauded Medicare and TRICARE by billing for more chemotherapy drugs than patients received and for submitting claims for office visits at a higher reimbursement level than what was rendered. He also directed his staff to alter and falsify patient record entries to support the false claims.
- **New York** – Podiatrists Ira Bell and Douglas Herzlich were the final two defendants sentenced out of 16 involved in a large-scale health care fraud scheme at Citywide podiatry clinics, which are in New York City. Bell and Herzlich, both of whom pleaded guilty in 2002, were ordered to pay restitution of \$275,139 and \$72,529, respectively, and Herzlich was sentenced to time served. The scheme, which dated to the 1980s, included soliciting patients for "free" treatments, billing for services not rendered, billing for medically unnecessary services, and/or billing for upcoded services in order to receive a higher reimbursement. The 16 defendants, including billing and administrative staff of Citywide, were convicted and ordered to pay over \$1.8 million in total restitution.
- **Pennsylvania** – Pursuant to his guilty plea, Dr. John Kristofic was sentenced to 12 months and 1 day in prison for health care fraud. Previously, Kristofic agreed to pay \$3,303,187 to resolve his liability under the FCA. The civil settlement resolved allegations that from January 2003 to August 2008, Dr. Kristofic submitted claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program for services not rendered to his patients either because Dr. Kristofic was not in the office or the patients were in hospitals under the care of other physicians on the dates claimed. Dr. Kristofic also regularly billed for treatments that his patients never received.

Transportation Companies

- **Indiana** – Randy Suddoth was sentenced to 2 years' incarceration and ordered to pay \$1,201,163 in restitution after pleading guilty to conspiracy to commit health care fraud. Suddoth owned Lane Medical Transportation (Lane Medical), a sham company that did not own or use any ambulances, but submitted false claims for non-existent ambulance trips and basic life support. Investigators interviewed beneficiaries whom Lane Medical claimed to have transported, but the beneficiaries had never heard of the company.

Prescription Drugs

- **Pennsylvania** – Pharmacist Craig Goldman was sentenced to 18 months in prison and ordered to pay \$576,000 in restitution after pleading guilty to charges of drug adulteration and misbranding, health care fraud, mail fraud, and aiding and abetting. Goldman, who owned and operated Bergman Pharmacy as a compounding pharmacy, replaced proprietary drugs with compounded versions without physician direction. Goldman then billed Medicare and private insurers as if the proprietary drugs were dispensed. The investigation also revealed that Goldman’s compounded drugs were contaminated with bacteria, and that he manufactured the compounded drugs without using medicinal quality water, wearing gloves, or wearing a mask. Additionally, in making a budesonide-based drug intended for asthma patients, Goldman used chemicals such as ethyl alcohol and Everclear (a pure grain alcohol), which are severe irritants to the respiratory system.
- **North Carolina** – Kathleen Giacobbe and Dr. Porfirio Orta-Rosario were found guilty in an unlawful prescription drug operation whereby they distributed powerful, addictive painkillers and anti-anxiety medications to thousands of customers nationwide. Giacobbe was sentenced to 6 years and 3 months in prison and Dr. Orta-Rosario was sentenced to 5 years in prison for conspiracy to distribute schedule III and schedule IV controlled substances, distribution of a schedule III controlled substance, and aiding and abetting the unlawful distribution of controlled substances. According to evidence presented at trial, Giacobbe and Dr. Orta-Rosario conspired with others to distribute prescription painkillers and anti-anxiety medications based on illegitimate prescriptions from Giacobbe’s online pharmacy. Individuals with no training or authority to write prescriptions conducted telephone interviews with customers, and then created drug orders bearing a doctor’s photocopied signature. The defendants faxed the drug orders to Woody Pharmacy because Giacobbe knew Woody Pharmacy would not question the legitimacy of the prescriptions. Trial testimony and evidence established that this operation resulted in the distribution of millions of dosage units of controlled substances from Woody Pharmacy, and the court found that this unlawful operation contributed to the deaths of three former customers. Previously, the owner of Woody Pharmacy, Dr. Alvin Woody, was sentenced to 3 years and 4 months in prison for charges related to this scheme.

Quality of Care

- **Pennsylvania** – Nine employees at MultiEthnic Behavioral Health Services, Inc., (MEBH) were sentenced for charges related to health care fraud and the death of an at-risk child who was under MEBH’s care. MEBH co-founders Mickal Kamuvaka and Mariam Coulibaly, supervisor Solomon Manamela, and employee Julius Murray were convicted of health care fraud, wire fraud, and conspiracy to obstruct a matter within the jurisdiction of a Federal agency. Coulibaly was also convicted of making false statements. Five other MEBH employees previously pleaded guilty to charges in connection with the fraud scheme. The nine defendants were sentenced to prison terms ranging from 15 months to 17 years and

6 months and were ordered to pay joint and several restitution ranging from \$316,000 to \$1,216,000.

MEBH, a contractor for the Philadelphia Department of Health Services, came under Federal and local investigation in 2006 after the death of a 14-year-old special-needs child with cerebral palsy who was supposed to be receiving services from MEBH. Murray was responsible for ensuring that the 14-year-old and other at-risk children received medical treatment, services for their disabilities, and schooling. Instead, the child was severely neglected to the point that she suffered severe bed sores and slowly starved, until she weighed only 42 pounds and died. After her death, Kamuvaka orchestrated a massive coverup, including the destruction of old records and the fabrication of new false records. The defendants' fraudulent activity also included creating false documentation for other patient visits that did not occur, forging guardian signatures, destroying records, fabricating documents, and other egregious activities intended to satisfy yearly audit requirements to maintain their contract with the State.

Other Criminal Enforcement

- **Louisiana** – Nikkie LaFleur was sentenced to 3 years and 1 month in prison and ordered to pay \$621,737 in restitution after pleading guilty to charges of health care fraud and criminal forfeiture. LaFleur was an account manager at Medical Provider Services, a billing service for physicians and other medical providers in Louisiana. According to court documents, LaFleur forged doctors' endorsements then billed Medicare and private insurance companies for services not rendered and upcoded diagnoses for higher reimbursement. LaFleur deposited both Medicare and private insurance companies' checks into her personal checking account and used the money to purchase items such as two jet skis, a tandem trailer, a 22-foot motorboat, a boat trailer, and a 13-foot travel trailer.

Medicaid Fraud

- **Idaho** – Vanessa Cattanea was sentenced to 20 months' incarceration and ordered to pay \$1,054,259 in restitution after she was found guilty of aiding and abetting health care fraud. Cattanea was the treatment director for Teton Family Services, a company owned by Ronald Hamilton that provided mental health services to children. Between August 2002 and March 2006, Hamilton and Cattanea knowingly and fraudulently billed Medicaid for services performed by unlicensed staff and for trips to Yellowstone National Park, Bear Lake, and Salt Lake City, which were not reimbursable Medicaid services. Hamilton, who was also found guilty of health care fraud, died in March 2010.

Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. In FY 2009, HHS awarded \$189.9 million in Federal grant funds to 50 State MFCUs (including Washington, DC), which employed a total of 1,835 individuals.

Collectively, in FY 2009, MFCUs reported 26,744 investigations, of which 17,090 were related to Medicaid fraud and 9,654 were related to patient abuse and neglect, including patient funds cases. The cases resulted in 1,539 individuals being indicted or criminally charged, including 960 for fraud and 579 for patient abuse and neglect, including patient funds cases. In total, 1,331 convictions were reported in FY 2009, of which 19 were related to Medicaid fraud and 512 were related to patient abuse and neglect, including patient funds cases.

Joint Investigations

- **Pennsylvania** – Pediatrician Dr. Saroj Parida was sentenced to 8 years' incarceration and ordered to pay \$7,116,423 in restitution after pleading guilty to charges of health care fraud, mail fraud, and forfeiture. From 2003 through 2009, Dr. Parida submitted fraudulent claims to Medicaid, TRICARE, and private insurance companies for services not rendered. The investigation involved OIG, the U.S. Postal Inspection Service, the Defense Criminal Investigative Service, the Pennsylvania Attorney General's MFCU and Insurance Fraud Section, the South Carolina Attorney General's MFCU and Insurance Fraud Division, and the Cumberland County, Pennsylvania, District Attorney's Office.
- **South Dakota** – Reed Hittle, physical therapist and owner of Precision Physical Therapy, Inc., was sentenced to 10 months' home confinement and ordered to pay \$119,260 in restitution for his guilty plea to charges of false statements relating to health care matters. Between January 2005 and July 2008, Hittle billed Medicare and Medicaid for physical therapy treatments on patients, documenting that he performed the treatments himself. However, many of the billed treatments were administered by an unlicensed and untrained assistant. The investigation involved OIG, the FBI, and the South Dakota MFCU.

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

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

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

Public Health Reviews

Centers for Disease Control and Prevention

[Public Health](#) > [CDC](#) > [Vaccine](#) > [Schools](#)

2009 H1N1 School-Located Vaccination Program Implementation

Most selected localities in our review reported School-Located Vaccination (SLV) to be a useful method for vaccinating a large number of children in a short time, and localities reported challenges and lessons learned for future SLV programs.

SLV is any vaccination program that takes place on school grounds. Schools provide a convenient location with large spaces such as gymnasiums and cafeterias to host the event. Although the Centers for Disease Control (CDC) considers SLV to be a viable, large-scale vaccination method for children, it indicated in meetings with the Office of Inspector General (OIG) in late summer 2009 that onsite evaluations of the administration of H1N1 vaccine at SLV sites would be useful because data about local implementation of SLV programs have been limited, especially during influenza pandemics.

We found that, by locality, selected SLV sites vaccinated an average of 28 percent of enrolled students during their 1-day programs, ranging from 14 percent to 45 percent. This compares favorably to relevant State and national vaccination rates obtained over a longer period and through a variety of methods. For example, the average vaccination rate in the 6 corresponding States was 37 percent. However, this statewide percentage reflects the number of children vaccinated over about 3 months using multiple methods (e.g., private providers, commercial pharmacies, SLV) and for a wider age range.

We also found a number of challenges associated with implementing SLV programs. For example, we observed the majority of selected SLV sites used recommended vaccine storage containers but did not monitor and record vaccine storage temperature. All selected localities reported challenges obtaining sufficient SLV staff and distributing them effectively across staffing functions. Selected SLV sites reported experiencing challenges communicating a clear and consistent message to parents about potential vaccination adverse reactions and the need for a second vaccine dose. Most of the selected localities had not established a system to bill third-party payers for H1N1 vaccine administration.

The selected localities reported a number of things they would do differently in future SLV programs. These include simplifying the consent form and educational materials; standardizing the consent form review process; devoting more staff to registration, triage, and translation; streamlining staff communication and training; developing a centralized information-sharing system; and distributing information to parents and participating schools earlier.

Our data indicate that SLV can be a viable strategy for vaccinating a large number of students in a short period of time. However, SLV programs require a significant amount of planning and resources. To help mitigate challenges in future SLV programs, SLV planners will need specific, timely guidance and sufficient lead time for planning. This report contains no recommendations. ([OEI-04-10-00020](#))

Public Health > CDC > Vaccine > Prompt Payment Administration

Payments by the Centers for Disease Control and Prevention to Vaccine Manufacturers and Suppliers

CDC generally paid invoices for vaccines in a timely manner and calculated and paid required interest on late payments. Of the 179,129 invoices that CDC paid from April 2005 through August 2006, 172,566 (more than 96 percent) were paid within the required period. For the 6,563 remaining invoices, which were not paid within the required period, CDC paid appropriate interest or did not owe interest on 4,895 invoices but had not paid interest totaling approximately \$1 million on 1,668 invoices as of August 31, 2006. In the absence of other contractual provisions, an agency generally must pay a proper invoice within 30 days of the later of the receipt of the invoice or the receipt of the supplies. If an invoice is not paid on time, the agency incurs interest from the day after the payment was due until the payment is made. In addition, we determined that CDC had paid 46 invoices twice, resulting in duplicate payments totaling \$2 million.

We recommended that CDC (1) pay \$1.7 million in interest due one vendor; (2) recover \$687,000 in duplicate payments (net of interest due) from four vendors; and (3) consider reviewing all replacement paper invoices paid after August 31, 2006, to identify any unpaid interest or duplicate payments. CDC disagreed with our findings and recommendations. In response to CDC's comments, we reviewed additional documentation and found that CDC had recovered some of the duplicate payments noted in our draft report. We reduced the number and dollar value of duplicate payments reported in our final report accordingly. We maintain that our findings and recommendations, as revised, are valid. ([A-04-06-01042](#))

Public Health > CDC > Preparedness

Preparedness Program Funding in Louisiana

We found that for the period August 31, 2004, through August 30, 2006, Louisiana claimed some costs to CDC's preparedness program that were not allowable, allocable, and reasonable. Pursuant to the Public Health Service Act, CDC provides funds to State and major local health departments to improve preparedness and response capabilities for bioterrorism and other public health emergencies. From 1999 to 2005, CDC provided this funding through the Public Health Preparedness and Response for Bioterrorism Program. Since 2005, CDC has provided funding through the Public Health Emergency Preparedness Program. We refer to these two programs collectively as "the program." Our review found that Louisiana claimed \$11,000 in

unallowable program costs: \$7,000 for technical training that was paid for but not taken and \$4,000 related to payroll errors. These deficiencies occurred because the State (1) did not have controls in place to ensure that a prepaid technical training coupon package was fully used and (2) made clerical errors. In addition, we set aside \$1 million of contract costs because we were unable to determine whether the amount allocated to the program accurately reflected the relative benefits received. The remaining \$7.9 million in program expenditures that we reviewed was allowable, allocable, and reasonable.

We recommended that Louisiana (1) refund \$11,000 for costs that were improperly charged to the program, (2) work with CDC to determine what portion of the \$1 million in set-aside expenditures is allocable to the program and refund the unallowable portion to CDC, and (3) develop a policy for allocating contract costs and document its allocation methodology. The State generally concurred with our recommendations. ([A-06-08-00064](#))

Public Health > CDC > Audit Resolution

Centers for Disease Control and Prevention's Resolution of Audit Recommendations

CDC resolved 815 of the 1,167 audit recommendations that were outstanding during fiscal years (FY) 2007 through 2009. However, CDC did not resolve 274 of the 815 recommendations within the required 6-month period. As of September 30, 2009, CDC had not resolved 352 audit recommendations, of which 213 were past due for resolution. The dollar amount associated with the 213 recommendations is \$249.7 million. Office of Management and Budget (OMB) Circular A-50 requires that CDC resolve audit recommendations within 6 months after receipt of each audit report. Because CDC did not resolve all audit recommendations in a timely manner, it did not have reasonable assurance that it was exercising proper stewardship over Federal dollars.

We recommended that CDC (1) resolve all audit recommendations within the required 6-month audit resolution period and (2) resolve the 213 outstanding audit recommendations that were past due as of September 30, 2009. In response, CDC identified actions that it planned to take to meet the required resolution period in a responsible manner, consistent with laws, rules, and regulations. ([A-07-09-03131](#))

Food and Drug Administration

Public Health > FDA > Foreign Clinical Trials Inspections

Challenges to FDA's Ability To Monitor and Inspect Foreign Clinical Trials

We found that in FY 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. Eighty percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials. Over half of clinical trial subjects and sites were outside the United States. Although FDA inspected clinical

investigators at few clinical trial sites overall, FDA's inspections of foreign sites were at an even lower rate—less than 1 percent of foreign sites.

The Food, Drug, and Cosmetic Act (FDCA) requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products before approval for sale in the United States. The Food and Drug Administration (FDA) ensures the rights, safety, and well-being of subjects who participate in these trials and verifies that the clinical trial data collected are both accurate and reliable. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. However, critics have raised concerns about the increased prevalence of foreign clinical trials.

Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials. For example, if a sponsor has not submitted an Investigational New Drug (IND) application or consulted with FDA in some other way about its foreign clinical trials, FDA has no way of knowing whether and where such clinical trials are taking place and therefore cannot conduct inspections while the trials are underway. Further, despite guidelines, sponsors generally submitted data that were in non-standard formats, making it difficult to locate clinical trial information, particularly site locations and subject enrollment.

We recommended that FDA require standardized electronic clinical trial data and create an internal database of clinical trial data. FDA should also monitor trends in foreign clinical trials not conducted under INDs and, if necessary, take steps to encourage sponsors to file INDs. FDA should continue to explore ways to expand its oversight of foreign clinical trials. FDA agreed with all of our recommendations. ([OEI-01-08-00510](#))

Public Health > FDA > Food Facilities Inspections

FDA Inspections of Domestic Food Facilities

Our report identified significant weaknesses in FDA's inspections of food facilities. FDA inspects food facilities to ensure food safety and compliance with regulations. We found that from FYs 2004 through 2008, FDA inspects less than a quarter of food facilities each year. In addition, more than half of all food facilities have gone 5 or more years without an FDA inspection.

When FDA identifies violations that are significant enough to warrant an "official action indicated" (OAI) classification, some type of regulatory action should be recommended. This action could include issuing a warning letter, holding a regulatory meeting, or initiating an enforcement action such as a seizure or an injunction. In FY 2007, FDA took action against 46 percent of the facilities that initially received OAI classifications. FDA either lowered the classification or took no regulatory action for the remaining facilities. We also found that most of the facilities that received OAI classifications had a history of violations and that some facilities refused to grant FDA access to their records.

For 36 percent of the facilities that received OAI classifications, FDA took no additional steps to ensure that the violations were corrected. For the remaining facilities, FDA either reinspected

the facilities or reviewed some type of evidence from the facility that demonstrated that the facility had corrected violations.

Based on the findings of this report, we recommended that FDA (1) increase the frequency of food facility inspections, with particular emphasis on high-risk facilities; (2) provide additional guidance about when it is appropriate to lower OAI classifications; (3) take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations; (4) ensure that violations are corrected for all facilities that receive OAI classifications; (5) consider seeking additional statutory authority that would allow FDA to impose civil penalties through administrative proceedings; and (6) seek statutory authority to allow FDA access to facilities' records during the inspection process.

FDA supported our two recommendations to seek additional statutory authority and agreed with our recommendation to provide additional guidance about when it is appropriate to lower OAI classifications. FDA noted several actions it has taken, or plans to take, to address the remaining three recommendations. ([OEI-02-08-00080](#))

Health Resources and Services Administration

Public Health > HRSA > HIV/AIDS

Ryan White Title II Funding in Florida

Florida did not always comply with Federal requirements in administering funds provided under Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act). From April 1, 2003, through March 31, 2006, Florida (1) did not fully comply with the requirement that Title II funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and (2) did not always use Title II funds for clients whose files contained the documentation needed to determine eligibility for the AIDS Drug Assistance Program (ADAP). Based on our sample results, we estimated that Florida claimed \$4.4 million in unallowable Federal funding. Title II grants fund the purchase of medications through ADAP and other health care and support services for people who have HIV/AIDS and who have no health insurance or are underinsured.

We recommended that Florida (1) refund \$4.4 million to the Federal Government; (2) follow its procedures for billing HIV/AIDS drugs to the Federal, State, or private health insurance plans with primary payment responsibility; and (3) follow its procedures for documenting clients' eligibility for ADAP funds. Florida said that refunding the money would have a devastating effect on ADAP clients but did not directly address our other recommendations. Florida did not provide any additional information that would cause us to modify our findings or recommendations. ([A-04-08-06002](#))

Indian Health Service

Public Health > IHS > Cost Administration

Fiscal Year 2005 Cost Statements

We reviewed the allowability of obligations included in the FY 2005 cost statements for 2 of the 12 Indian Health Service (IHS) area offices and found duplicate and unsupported costs, erroneous reporting, and costs on which we could not express an opinion.

The Social Security Act authorizes Medicare and Medicaid reimbursement to IHS providers. IHS providers use all-inclusive reimbursement rates to bill for certain Medicare and Medicaid services. These rates are developed from financial data reported in cost statements submitted by IHS and certain tribal hospitals. IHS Headquarters and area-office cost statements identify the portion of obligations from Headquarters and the area offices that is allowable under Medicare and allocable to IHS providers. Allowable Headquarters obligations are allocated to each area office.

The results of our reviews follow:

- Navajo area office. Of the \$29 million of obligations that was reported and that we reviewed, \$2.5 million pertaining to duplicate costs and erroneously reported depreciation was unallowable. The cost statement also included \$4.8 million for unsupported salaries, fringe benefits, and related obligations on which we could not express an opinion.

We recommended that IHS (1) adjust its next cost statement for the Navajo area office for \$2.5 million of unallowable costs; (2) review the Navajo area office's cost statements before and after FY 2005 and adjust its next cost statement for duplicated costs caused by contractor errors and for unallowable depreciation; (3) strengthen its policies and procedures to ensure that depreciation is not reported for items that are fully depreciated; (4) work with the Centers for Medicare & Medicaid Services (CMS) to determine how much of the \$4.8 million reported for salaries, fringe benefits, and related obligations was allowable and adjust its next cost statement for obligations that are determined to be unallowable; and (5) develop and implement policies and procedures to ensure that estimates used to allocate obligations in cost statements are supported with cost information that is current, accurate, and in sufficient detail. IHS concurred with all of our recommendations and described corrective actions that it planned to implement.

[\(A-07-08-02721\)](#)

- Oklahoma City area office. We found that the \$14.7 million of obligations reported included \$260,000 in duplicate obligations of the National Supply Service Center (which manages the purchase and distribution of drugs and other medical supplies in all 12 IHS areas) and \$430,000 for salaries, fringe benefits, and depreciation costs on which we could not express an opinion.

We recommended that IHS (1) adjust its next cost statement for the Oklahoma City area office to correct the \$260,000 of reported unallowable costs, (2) improve its oversight of cost statement preparation, (3) work with CMS to determine how much of the \$286,000 in reported salaries and fringe benefits was allocable and adjust its next cost statement for obligations determined to be unallocable, (4) develop and implement policies and procedures to ensure that obligations are allocated in a timely manner, (5) work with CMS to determine how much of the \$144,000 in reported depreciation costs was allowable and adjust its next cost statement for depreciation determined to be unallowable, (6) review the Oklahoma City area office's cost statements after FY 2005 and adjust its next cost statement for any unallowable depreciation costs, and (7) develop and implement policies and procedures to ensure that depreciation records contain the necessary information to properly support depreciation costs. IHS generally agreed with our recommendations. ([A-06-07-00080](#))

National Institutes of Health

[Public Health](#) > [NIH](#) > [Contract Administration](#)

Appropriations Funding for National Institutes of Health Contracts

From November 2008 through February 2009, a Department of Health & Human Services (HHS) internal review group assessed 176 HHS contracts, including 21 National Institutes of Health (NIH) contracts. Our reviews of 3 of the 21 NIH contracts assessed compliance with appropriations funding requirements and found that NIH funded the contracts in compliance with the purpose, time, and amount requirements specified in appropriations statutes. NIH had a bona fide need for the items and appropriately funded the contracts and their modifications from the pertinent appropriations year(s). These reports contain no recommendations.

- [Office of Research Facilities Development and Operations \(ORF\) contract HHSN292-03-D-0107, call order number NJE37991](#). ORF awarded this contract, totaling \$3.9 million, during FY 2005. Subsequently, ORF issued four change orders totaling approximately \$95,000 in FY 2006 and one change order for \$178,000 in FY 2007 for additional material and work. ([A-03-10-03101](#))
- [National Library of Medicine \(NLM\) contract HHSN276-2007-00186U](#). In FY 2007, NLM awarded this contract, which totaled \$464,000. ([A-03-10-03112](#))
- [NLM contract HHSN276-2007-00005U](#). NLM awarded this contract, totaling \$19.5 million, in FY 2007 and modified the contract in FYs 2008 and 2009 for \$19.5 million each year. ([A-03-10-03111](#))

Superfund Financial Activities at the National Institute of Environmental Health Sciences

In our review of Superfund financial transactions at the National Institute of Environmental Health Sciences (NIEHS) for FY 2009, we found that the transactions were allowable, allocable, and reasonable in accordance with applicable laws and regulations. NIEHS receives Superfund funding to train people who handle hazardous waste and manage hazardous waste facilities and to conduct research on the effects of hazardous substances on human health. We conducted this audit pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, which requires the inspector general of a Federal organization with Superfund responsibilities to audit all uses of the Superfund. Our report contained no recommendations. ([A-04-10-01076](#))

Public-Health-Related Legal Actions and Investigations

Health Education Assistance Loan Program

Under the Health Education Assistance Loan (HEAL) program, the Health Resources and Services Administration (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 HHS's 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 is responsible for excluding individuals who have defaulted on HEAL loans from participation in Federal health care programs.

During the semiannual period, we conducted evaluations of and excluded individuals from the HEAL program. Results of this work are below.

HEAL Exclusions

During the period covered by this report, 29 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, 2,292 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure

includes the 18 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 \$170.7 million. Of that amount, \$1.5 million is attributable to this reporting period.

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

- **Pennsylvania** – Dentist William Jakavick - \$110,545
- **California** – Chiropractor Mark Dankman - \$105,305
- **New York** – Dentist Joan Baisch-Ferraro - \$90,175
- **Idaho** – Chiropractor William Dennis - \$82,443
- **Virginia** – Dentist Ethel Miles - \$47,150

Human-Services-Related Reviews

Administration on Aging

[Human Services](#) > [AoA](#) > [Grantee Performance](#)

Senior Medicare Patrol Projects: May 2010 Performance Report

We found that total savings attributable to the Senior Medicare Patrol projects were over three times higher in 2009, compared to totals in 2008. The savings benefited Medicare, Medicaid, beneficiaries and others.

The Senior Medicare Patrol Projects receive grants from the Administration on Aging (AoA) to recruit retired professionals to serve as educators and resources in helping beneficiaries to detect and report fraud, waste, and abuse in the Medicare program. At least 1 project is in each of the 50 States, as well as in the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

In 2009, the 55 projects had a total of 4,444 active volunteers. These volunteers educated beneficiaries in 7,177 group education sessions and held 33,855 one-on-one counseling sessions. In addition, the projects conducted 311,377 media outreach activities and 5,684 community outreach education events. Medicare funds recovered attributable to the projects were \$76,176 and total savings to Medicare, Medicaid, beneficiaries, and others were \$214,060. The projects had 5 percent fewer active volunteers in 2009, compared to the number in 2008.

In December 2005, AoA asked that OIG continue to collect and report performance data for the Senior Medicare Patrol Projects to support AoA's efforts to evaluate and improve the performance of these projects. OIG agreed to collect performance data every 6 months but to report the data on an annual basis. We continue to emphasize that the number of beneficiaries

who have learned from the Senior Medicare Patrol Projects to detect fraud, waste, and abuse, and who subsequently call the OIG fraud hotline or other contacts, cannot be tracked. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track substantial savings derived from a sentinel effect whereby fraud and errors are reduced in light of Medicare beneficiaries' scrutiny of their bills. ([OEI-02-10-00100](#))

Administration for Children and Families

[Human Services](#) > [ACF](#) > [Head Start](#)

Health and Safety at Head Start Grantees

As described below, we found that Head Start grantees' failure to consistently comply with Federal and State requirements jeopardized the health and safety of children in their care.

As part of a series of reviews requested by the Administration for Children & Families' (ACF) Office of Head Start, we assessed various Head Start grantees' compliance with Federal and State requirements on ensuring the health and safety of children in their care. The major objectives of the Head Start program include promoting school readiness and enhancing the social and cognitive development of low-income children by providing health, educational, nutritional, and social services. In FY 2009, Congress appropriated \$7.1 billion to fund the Head Start program's regular operations. The American Recovery and Reinvestment Act of 2009 (Recovery Act) provides an additional \$2.1 billion for the program during FYs 2009 and 2010.

- [Grantee A in California](#). As of June 2009, the grantee had not obtained criminal record checks for 4 of its 35 employees. The grantee also did not obtain criminal record checks on six employees until after they were hired, and the files on four other employees did not contain the required documentation of criminal record clearances or a signed statement regarding criminal history. In addition, the grantee's four childcare facilities that we reviewed did not meet all Federal Head Start and State requirements for protecting children from unsafe materials and equipment. Furthermore, one of these facilities did not provide a fully secure environment for the children in its care. For example, kitchen doors were unlocked, allowing children access to stoves and other items that could pose a danger. We recommended that the grantee strengthen and consistently follow its existing procedures to ensure that (1) criminal record checks are obtained before hiring employees and all employee files contain documentation of criminal record clearances or exemptions and employee signed statements regarding criminal history and (2) all unsafe materials and equipment are stored in locked areas out of the reach of children, other unsafe conditions are addressed, and all facilities are secure. The grantee generally agreed with our findings and described actions taken to address the deficiencies. ([A-09-09-00089](#))

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- Grantee B in California. As of April 2010, the grantee had not obtained criminal record checks or signed statements regarding criminal history for 10 of its 159 employees. The grantee also did not obtain criminal record checks on six employees until after they were hired, and the files on four other employees did not contain the required documentation of criminal record clearances. In addition, the grantee's 13 childcare facilities did not meet all Federal Head Start and State requirements for protecting children from unsafe materials and equipment. Furthermore, two of these facilities did not provide a fully secure environment for the children in their care. For instance, a playground fence had a 10-inch gap. We recommended that the grantee strengthen and consistently follow its existing procedures to ensure that (1) criminal record checks are obtained before hiring employees and all employee files contain documentation of criminal record clearances or exemptions and employee-signed statements regarding criminal history and (2) all unsafe materials and equipment are stored in locked areas out of the reach of children, other unsafe conditions are addressed, and all facilities are secure. In response, the grantee described its completed and ongoing actions to address the deficiencies that we identified. ([A-09-10-01008](#))
 - Grantee A in Colorado. As of October 2009, employee files showed that 10 of the grantee's 52 employees were hired before their criminal background checks were completed. In addition, the grantee's four facilities did not meet all Federal Head Start and State health and safety regulations on protecting children from unsafe conditions. For example, some electrical outlets at three of the four facilities lacked protective safety plugs. We recommended that the grantee develop and consistently implement procedures to ensure that (1) employees are hired only after passing criminal background checks and (2) all unsafe conditions identified in this report are addressed in a timely manner. The grantee concurred with our recommendations but disagreed with our finding regarding the hiring of employees before their criminal background checks were completed. Nothing in the grantee's comments caused us to change our finding. ([A-07-09-02763](#))
 - Grantee B in Colorado. As of May 2009, the files on 9 of the grantee's 25 employees lacked documentation of criminal background checks, checks of the State child abuse and neglect system, or bus driver qualifications, and 1 employee's child abuse and neglect check was not completed within 10 days of employment as required. In addition, the grantee's two facilities did not meet all Federal Head Start and State health and safety regulations on protecting children from unsafe conditions. At both facilities, for instance, cleaning and other toxic materials were accessible to children. We recommended that the grantee develop and consistently implement procedures to ensure that (1) employees are hired only after passing criminal background checks, all employee files contain documentation of criminal background checks and checks of the child abuse and neglect system, and bus driver employee files contain documentation of background checks and other bus driver qualifications and (2) all unsafe conditions identified in this report are addressed in a timely manner. The grantee concurred with our findings and described its completed and ongoing actions to address the deficiencies that we identified. ([A-07-09-02761](#))

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- Grantee C in Colorado. As of September 2009, the grantee had not obtained criminal background checks on 5 employees or child abuse and neglect checks on 15 employees. Additionally, child abuse and neglect checks on 20 employees likely were not requested within the required timeframe. Furthermore, the grantee's five facilities did not meet all Federal Head Start and State health and safety regulations on protecting children from unsafe conditions. For example, flammable materials were stored near the water heaters at three facilities, and toothbrushes were kept next to the diaper-changing tables at one facility. We recommended that the grantee develop and consistently implement procedures to ensure that (1) employees are hired only after passing criminal background checks, all child abuse and neglect checks are requested within 10 days of employment, and all employee files contain documentation of criminal background and child abuse and neglect checks and (2) all unsafe conditions identified in this report are addressed in a timely manner. The grantee concurred with our findings and described its completed and ongoing actions to address the deficiencies that we identified. ([A-07-09-02764](#))
 - Grantee in Connecticut. As of December 2009, the files on 58 of the grantee's 59 Head Start employees lacked required documentation on fingerprint cards, child abuse and neglect registry checks, criminal record checks, and/or signed employee declarations. Further, the grantee did not meet all Federal Head Start and State requirements on protecting children from unsafe materials and equipment, and the grantee did not always provide a secure environment for the children in its care. Broken fencing between the playground and the parking lot and exposed wiring in an area accessible to children were among the hazards noted. We recommended that the grantee develop and consistently follow procedures to ensure that (1) all employee files contain evidence of completed fingerprint cards (for employees hired after September 1, 2000), evidence of a check of the State child abuse and neglect registry, documentation of a criminal background check, and an employee-signed declaration; (2) unsafe materials are stored in locked areas out of the reach of children and other unsafe conditions are addressed; and (3) all buildings are secure. The grantee generally agreed with our findings and described the actions it was taking. ([A-01-10-02500](#))
 - Grantee in the District of Columbia. As of June 2009, the files on all 19 of the grantee's Head Start employees lacked evidence of checks of the child protection register, evidence of completed background checks, or employee-signed declarations listing any relevant criminal convictions. Further, the grantee's two childcare facilities did not meet all Federal Head Start and State requirements on protecting children from unsafe materials and equipment, and one of the facilities did not provide a secure environment for the children in its care. Specifically, the facility's playground was not enclosed by a fence or natural barrier to prevent children from leaving the premises and entering a parking area. We recommended that the grantee develop and consistently implement procedures to ensure that (1) all employee files contain evidence of checks of the child protection register, evidence of completed background checks, and employee-signed declarations listing any relevant criminal convictions; (2) all unsafe materials and equipment are stored in locked

areas out of the reach of children and other unsafe conditions are addressed; and (3) all facilities are secure. The grantee concurred with our recommendations. ([A-03-09-00361](#))

- Grantee in Georgia. As of June 2009, the files on 21 of the grantee's 162 employees did not contain evidence of criminal record checks, and as of May 2009, 7 of the grantee's 8 childcare facilities did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. The lack of protective safety plugs on electrical outlets was the most common hazard noted. We recommended that the grantee consistently follow its existing procedures to ensure that (1) all employee criminal record checks are completed and employee files contain evidence of the checks and (2) all necessary repairs are completed and all unsafe conditions are addressed. In response, the grantee described its actions to address the deficiencies that we identified. ([A-04-09-03527](#))
- Grantee A in New York. As of July 2009, the grantee's files showed that the grantee had not obtained timely criminal background checks on 21 of its 36 Head Start employees. In addition, the grantee's childcare facility did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. For example, in one classroom, a bingo marker with a warning label that stated "KEEP AWAY FROM CHILDREN" was left in an area accessible to children. We recommended that the grantee develop and consistently follow procedures to ensure that (1) all employee files contain documentation of timely criminal background checks and (2) all unsanitary and unsafe conditions are corrected. The grantee concurred with our findings and described its completed and ongoing actions to address the deficiencies that we identified. ([A-02-09-02013](#))
- Grantee B in New York. As of October 2009, the grantee had not obtained criminal background checks, timely criminal background checks, and/or child abuse and maltreatment checks on 27 of its 92 Head Start employees. In addition, two of its five bus drivers did not have a timely tuberculosis screening or medical examination. Furthermore, 9 of the grantee's 10 childcare facilities did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. For example, at one facility, a rusty screw was protruding from a piece of playground equipment. We recommended that the grantee develop and consistently follow procedures to ensure that (1) all employee files contain documentation of timely criminal background checks and child abuse and maltreatment register checks, (2) all bus drivers have an initial health examination that includes screening for tuberculosis, and (3) all unsanitary and unsafe conditions are corrected in a timely manner. The grantee generally concurred with our findings and described its completed and ongoing actions to address deficiencies that we identified. ([A-02-10-02004](#))
- Grantee C in New York. As of June 2009, the files on 38 of the grantee's 110 Head Start employees and 1 of the 6 contracted bus drivers showed that the grantee had not obtained criminal background checks, timely criminal background checks, or child abuse and maltreatment checks, and none of the 6 contracted bus drivers had been screened for

tuberculosis. In addition, the grantee's nine childcare facilities that we reviewed did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. Finally, four of the nine childcare facilities that we reviewed did not provide a fully secure environment for the children in their care. At two facilities, for instance, cleaning materials and other toxic substances were accessible to children. We recommended that the grantee develop and consistently follow procedures to ensure that (1) all employee and contracted bus driver files contain documentation of timely criminal background checks and child abuse and maltreatment register checks, (2) all contracted bus drivers have an initial health examination that includes screening for tuberculosis, (3) all unsanitary and unsafe conditions are corrected in a timely manner, and (4) all facilities are secure. The grantee generally concurred with our findings and described its actions to address deficiencies that we identified. ([A-02-09-02018](#))

- Grantee A in Texas. As of December 2009, although the files on the grantee's 85 employees and contractors contained evidence of the required background checks, the grantee did not always request these checks when they were due. In addition, four of the six grantee childcare facilities that we visited did not meet all Federal Head Start and State requirements on protecting children from unsafe materials and equipment. Finally, two of the six grantee childcare facilities that we visited did not provide a fully secure environment for the children in their care. At two facilities, for example, exterior doors were unlocked, allowing unrestricted access into the facilities. We recommended that the grantee develop and consistently follow procedures to ensure that (1) required background checks are completed when due, (2) all unsafe conditions are corrected and all necessary repairs are addressed in a timely manner, and (3) all facilities are secure. In response, the grantee described actions that it had taken or planned to take to address the deficiencies that we identified. ([A-06-09-00081](#))
- Grantee B in Texas. As of February 2010, the files on 28 of the grantee's 130 employees did not contain evidence of all required background checks. Although the files on the 102 remaining employees contained evidence of the required background checks, the grantee did not always request these checks when they were due. In addition, 13 of the grantee's 15 childcare facilities that we visited did not meet all Federal Head Start and State requirements on protecting children from unsafe materials and equipment. Finally, 7 of the grantee's 15 childcare facilities that we visited did not provide a fully secure environment for the children in their care. For example, a hammer was left unattended on a handrail leading to a building entrance. We recommended that the grantee share this report with Community Development Institute (CDI), which currently operates the grantee's Head Start program, to ensure that (1) required background checks are completed when due, (2) all unsafe conditions are corrected and all necessary repairs are addressed in a timely manner, and (3) all facilities are secure. The grantee stated that it had no staff to verify whether the deficiencies noted in the report had been corrected because ACF had suspended financial assistance to the grantee's Head Start program. The grantee added that CDI, ACF's national interim management contractor, would operate the Head Start program during the

suspension. We revised our recommendations to reflect CDI's role during the grant suspension period. ([A-06-10-00060](#))

- Grantee C in Texas. As of January 2010, the files on 6 of the grantee's 75 employees and contractors did not contain evidence of all required background checks. The files on the 69 remaining employees and contractors contained evidence of the required background checks, but the checks were not always requested when they were due. In addition, the grantee's 11 childcare facilities did not meet all Federal Head Start and State requirements on protecting children from unsafe materials and equipment. Finally, three of the grantee's childcare facilities did not provide a fully secure environment for the children in their care. For instance, the chain-link fence around one facility's playground had barbed wire tangled between its links. We recommended that the grantee develop and consistently follow procedures to ensure that (1) required background checks are completed when due, (2) all unsafe conditions are corrected and all necessary repairs are addressed in a timely manner, and (3) all facilities are secure. The grantee agreed with most of our findings and described actions that it had taken or planned to take to address most of the deficiencies that we identified. ([A-06-10-00053](#))
- Grantee A in Wisconsin. As of May 2009, the grantee could not provide any evidence that its two contracted bus drivers had received driving record checks, preemployment medical examinations, or required training. In addition, the grantee's three childcare facilities did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment and providing a secure environment for children. For example, at one facility, the door to the faculty lounge was unlocked, allowing children access to a gas stove. We recommended that the grantee develop and consistently follow procedures to ensure that (1) if it resumes transportation services, all Federal requirements related to bus driver qualifications and training are met and documented and (2) 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, and all facilities are secure. The grantee agreed with our recommendations and with most of our findings. ([A-05-09-00079](#))
- Grantee B in Wisconsin. As of December 2009, employee files showed that the grantee had not obtained a criminal record check on 1 of its 94 employees before employment. In addition, 13 of the grantee's 15 bus drivers did not meet all Federal bus driver qualification requirements before employment, and the grantee's files contained no evidence that it had provided classroom and behind-the-wheel instruction to any bus drivers before they transported children. Finally, three of the grantee's five childcare facilities did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. At one facility, for instance, a movable rack of folding chairs obstructed an exit. We recommended that the grantee develop and consistently follow procedures to ensure that (1) employees are hired only after passing criminal background checks, (2) all Federal requirements related to bus driver qualifications and training are met and documented, and (3) all unsafe conditions are addressed. The grantee generally agreed with

our findings and described the actions that it had taken or planned to take to address them. ([A-05-10-00022](#))

- Grantee C in Wisconsin. As of February 2010, the grantee's files provided no evidence that the paint coatings at any of its 15 childcare facilities were free from hazardous quantities of lead. In addition, 10 of the grantee's 12 childcare facilities that we visited did not meet other Federal Head Start and State regulations on protecting children from unsafe materials and equipment. For example, at nine facilities, trash cans in classrooms and other areas accessible to children were uncovered. We recommended that the grantee develop and consistently follow procedures to ensure that all unsafe conditions are addressed in a timely manner. In response, the grantee described actions that it had taken or planned to take to address most of our findings. ([A-05-10-00040](#))

Human Services > ACF > Foster Care > Federal Share

Foster Care Costs Claimed on Behalf of Delinquent Children in Georgia

We found that Georgia's Title IV-E foster care claims on behalf of delinquent children did not meet all Federal requirements for child eligibility and allowable costs. Title IV-E of the Social Security Act authorizes Federal funds for State foster care programs and establishes eligibility requirements, such as age, income, and specified judicial determinations. At the Federal level, ACF administers the program.

Based on our sample results, we estimated that the State claimed unallowable Title IV-E costs for FYs 2005 and 2006 totaling \$596,000 (Federal share), including \$60,000 in maintenance payments and \$536,000 in associated administrative costs. We were unable to determine the allowability of the remaining maintenance payments totaling \$664,000 and associated administrative costs totaling \$6 million because the State was unable to demonstrate that the daily maintenance rates for Title IV-E eligible children did not contain unallowable costs. The State's claims met Federal requirements for childcare institution eligibility.

We recommended that the State (1) refund to the Federal Government \$596,000 for unallowable costs, (2) ensure that permanency hearings are held within the specified timeframe and that appropriate documentation is maintained, (3) ensure that the daily maintenance rates for Title IV-E children include only allowable costs, and (4) work with ACF to resolve the allowability of maintenance payments totaling \$664,000 and associated administrative costs totaling \$6 million. The State said that it would work to settle the unallowable costs and resolve the administrative costs. The State did not specifically address our second and third recommendations.

([A-04-07-03519](#))

Adoption Assistance Subsidies in New Jersey

New Jersey claimed Federal reimbursement twice for the same \$9.6 million (\$4.8 million Federal share) in adoption assistance subsidies identified as a result of its contingency-fee contract with a private company. This error occurred because the State's procedures for reporting adoption assistance subsidies on its quarterly expenditure reports were inadequate. Pursuant to Title IV-E of the Social Security Act, ACF administers the adoption assistance program. The adoption assistance program provides Federal funds to States to facilitate the timely placement of children whose special needs or circumstances would otherwise make them difficult to place with adoptive families. We recommended that the State refund \$4.8 million to the Federal Government. The State concurred with our recommendation. ([A-02-09-02019](#))

Child Support Enforcement

Child Support Intergovernmental Collaboration

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); 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 28 convictions and court-ordered restitution and settlements of \$2.5 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

-
- **Maine** – David Carlson, convicted after a 4-day trial, was sentenced to 12 months and 1 day in prison and ordered to pay \$43,728 in restitution for failure to pay child support. Evidence presented at trial showed that, prior to his divorce, Carlson had withdrawn over \$120,000 from investment accounts, yet failed to make a single voluntary child support payment from the time he was ordered to pay in January 2004 until his arrest in September 2008. The Government was able to demonstrate that Carlson, an industrial engineer, elected not to work rather than pay child support, claiming that physical ailments prevented him from obtaining employment. However, Carlson found a job and was physically able to work after being ordered to obtain employment as part of his pretrial release.
 - **Tennessee** – Shaun Martin was sentenced to 42 consecutive weekends in prison and ordered to pay \$128,854 in restitution for failure to pay child support. Investigators found that Martin, who was living and working in Tennessee, willfully failed to pay child support to his child’s custodian who was living in Indiana. As part of the sentencing, Martin was ordered to spend 100 hours of community service speaking about the importance of paying child support.

Highlights of recent enforcement actions to which OIG has contributed are posted to OIG’s Web site at: <http://www.oig.hhs.gov/fraud/enforcement/criminal/>.

Departmentwide Issues

Non-Federal Audits

OMB Circular A-133 establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under this circular, covered entities must conduct annual organizationwide “single audits” of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities’ management of Federal funds. In this semiannual period, OIG’s National External Audit Review Center reviewed 1,422 reports that covered \$2.2 trillion in audited costs. Federal dollars covered by these audits totaled \$798 billion, about \$325 billion of which was HHS money.

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

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

Reviews of Non-Federal Audits

Reports issued:	
Without changes or with minor changes	1,307
With major changes	106
With significant inadequacies	9
Total	1,422

The 1,422 reports included 4,175 recommendations for improving management operations. In addition, these audit reports provided information for 45 special memorandums that identified concerns for increased monitoring by management.

Other Departmentwide Reports

[Departmentwide Issues](#) > [Recovery Act](#) > [Data Quality](#)

Data-Quality Reviews of Information Reported by Recipients of Recovery Act Funds

For the first and second reporting periods (February 17 through September 30, 2009, and October 1 through December 31, 2009), we found that HHS's limited data-quality reviews of recipient-reported Recovery Act information identified material omissions and significant errors.

Section 1512 of the Recovery Act requires recipients of certain Recovery Act funds to report to the applicable Federal agency, not later than 10 days after the end of each calendar quarter, (1) the total amount of Recovery Act funds received and the amount that was expended or obligated, (2) a detailed list of all projects for which Recovery Act funds were expended or obligated, and (3) detailed information on payments to subrecipients and vendors. Federal agencies are required to conduct limited data-quality reviews intended to identify material omissions and/or significant errors in the recipients' reported information. HHS took several steps to minimize material omissions and significant errors. Consequently, this report contains no recommendations. ([A-09-10-01001](#))

Resolving Recommendations

In accordance with the IG Act, § 5, 5 U.S.C. App., tables indicating the dollar value of actions taken on OIG's recommendations in this semiannual period have been developed and are provided in Appendix B.

Appendixes

- Appendix A: Savings Achieved Through Implementation of Recommendations
- Appendix B: Recommendations for Questioned Costs and Funds To Be Put to Better Use
- Appendix C: Reporting Requirements of the Inspector General Act of 1978, as Amended
- Appendix D: Public Proposals for New and Modified Safe Harbors
- Appendix E: Summary of Sanction Authorities
- Appendix F: Peer Review Results
- Appendix G: Acronyms and Abbreviations

Appendix A: Savings Achieved Through Implementation of Recommendations

After laws involving the Department of Health and Human Services (HHS) programs have been enacted, the Office of Inspector General (OIG) analyzes them to identify provisions that were supported by recommendations arising from OIG work. A similar process occurs with respect to administrative changes by HHS management through regulations or other directives.

For administrative changes, the savings estimates are developed by the pertinent HHS operating or staff division or by OIG. For legislative savings, we use estimates prepared by the Congressional Budget Office (CBO). As part of the process of informing Congress of the potential impact of legislation under consideration, CBO projects the annual Federal costs and savings that are expected to result from enacting legislation.

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

Total savings attributed to fiscal year (FY) 2010 as a result of legislative and administrative actions supported by OIG recommendations totaled \$21,014 million (\$21 billion).

OIG Recommendation	Implementing Action	Savings (millions)
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)		
State-Enhanced Payments Under Medicaid Upper Payment Limit Requirements. The Centers for Medicare & Medicaid Services (CMS) should move as quickly as possible to issue regulatory changes to the upper payment limit (UPL) rules governing enhanced payments to local government providers. The recommendation related to findings in OIG report number A-03-00-00216.	On January 12, 2001, CMS issued revisions to the UPL regulations that, among other things, created new payment limits for local-government-owned providers. This final rule significantly affects a State's ability to reap windfall revenues by reducing the available funding pool from which to make enhanced payments to local-government-owned providers.	\$8,000

OIG Recommendation	Implementing Action	Savings (millions)
<p>Medicaid Enhanced Payments to Local Providers. Reconsider capping the aggregate upper payment limit (UPL) at 100 percent for all facilities, rather than the 150-percent allowance for non-State-owned Government hospitals. The recommendation relates to findings in OIG report number A-03-00-00216.</p>	<p>CMS issued a final rule that modified the Medicaid UPL provisions to remove the 150-percent UPL for services furnished by non-State-owned or -operated hospitals. The rule became effective in the spring of 2002.</p>	<p>\$3,200</p>
<p>Medicare Advantage Payments. Modify payment rates to a level fully supported by empirical data considering the effects of the multiple elements that impact total payments. The recommendation that MA payment rates should be fully supported by empirical data mirrors a body of past and continuing OIG work. The source report for this recommendation was A-14-00-00212.</p>	<p>Section 5301 of the DRA amended the Social Security Act, § 1853(k), to phase out risk adjustment budget neutrality in determining the amount of payments to Medicare Advantage (MA) organizations. The DRA defined the applicable amount in calculating benchmark amounts; codified the phase-out schedule for the budget neutrality adjustment; and identified the adjustments to be made to the budget neutrality calculation during the phase-out years. CBO scored the provision to save about \$6.5 billion through FY 2010 with \$2.9 billion attributed to FY 2010.</p>	<p>\$2,900</p>
<p>Payment Reform for Part B Drugs and Biologicals. Reexamine drug reimbursement methodologies based on average wholesale price (AWP) with the goal of reducing payments in both Medicare and Medicaid. The recommendation relates to findings in the following OIG reports. OEI-03-96-00420 OEI-03-97-00290 OEI-03-00-00310 OEI-03-97-00293 A-06-00-00023 A-06-01-00053 A-06-02-00041</p>	<p>Sections 303 through 305 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the current payment methodology for Part B-covered drugs and biologicals that were not paid on a cost or prospective payment basis. Under the MMA, most drugs were to be paid at 85 percent of the April 1, 2003, AWP effective January 1, 2004, through December 31, 2004, unless they met certain exceptions. Since January 1, 2005, most drug prices have been based on the average sales price or competitive acquisition instead of AWP.</p>	<p>\$1,900</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Medicare Secondary Payer. Ensure sufficient resources and contractor training for retroactively examining paid claims to identify other payer sources and initiating recovery action on all related overpayments. The recommendation related to findings in the following OIG reports. A-02-98-01036 A-04-92-02057 A-09-89-00162 A-10-86-62005</p>	<p>Section 301 of the MMA clarifies the Secretary’s authority to make certain reimbursable conditional payments and to take recovery actions against all responsible entities, including collection of damages, under Medicare Secondary Payer provisions. This section builds on other program improvements related to OIG’s work that were implemented by the Balanced Budget Act (BBA), Omnibus Budget Reconciliation Act (OBRA) 1993, OBRA 1990, and OBRA 1989.</p>	<p>\$1,000</p>
<p>Clinical Diagnostic Laboratory Tests. Seek legislation to allow across-the-board adjustments in Medicare laboratory fee schedules, bringing them in line with the prices that laboratories charge physicians in a competitive marketplace, and periodically evaluate the national fee schedule levels. The recommendation related to findings in the following OIG reports. A-09-89-00031 A-09-93-00056</p>	<p>Section 628 of the MMA froze annual updates for FY 2004 through FY 2008. This action builds on prior legislative actions in the BBA, OBRA 1993, OBRA 1990, and legislation in 1984 that were also responsive to OIG’s recommendations to curb excessive clinical laboratory test reimbursements by Medicare.</p>	<p>\$1,000</p>
<p>Payments for Durable Medical Equipment. Take steps to reduce payments for a variety of durable medical equipment (DME) and related supplies. The recommendation related to findings in the following OIG reports: OEI-03-01-00680 OEI-03-02-00700 OEI-07-96-00221 OEI-03-96-00230 OEI-03-94-0021 OEI-06-92-00861 OEI-06-92-00866</p>	<p>Section 302 of the MMA froze payments for certain DME items, including prosthetics and orthotics, effective January 1, 2004.</p>	<p>\$900</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Medicare Home Health Payments. Reduce the Home Health Agency (HHA) update factor to account for the high error rate found in OIG's review. The annual update was defined as the home health market basket percentage increase. The recommendation related to findings in report number A-04-99-01194.</p>	<p>Section 701 of the MMA changed the updates of home health rates from fiscal year to calendar year beginning in 2004, with the update for the last three quarters of 2004 equal to the market basket increase minus 0.8 percent.</p>	<p>\$800</p>
<p>Payment for Services Furnished in Ambulatory Surgical Centers. Set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and establish parity among ambulatory surgical centers (ASC) and outpatient departments. The recommendation related to findings in the following OIG reports. OEI-05-00-00340 OEI-09-88-01003 A-14-98-00400 A-14-89-00221</p>	<p>Section 626 of the MMA limited the ASC update starting April 1, 2004, then froze updates for a period beginning the last quarter of FY 2005, effectively reducing the payment advantage to ASCs for those procedure codes that are more highly paid in the surgical center compared to outpatient departments. Section 626 also mandated that CMS implement a new payment system that takes into account disparities in the costs of procedures performed in ASCs and the costs of procedures performed in hospital outpatient departments, which CMS implemented by regulation effective January 1, 2008.</p>	<p>\$400</p>
<p>Capped Rental Durable Medical Equipment. Eliminate the semiannual maintenance payment allowed for capped rental DME, pay only for repairs when needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13th month. The recommendation related to findings in report number OEI-03-00-00410.</p>	<p>Section 5101 of the Deficit Reduction Act of 2005 (DRA) revised the payment rules for capped rental DME to require that ownership of the item transfer to the beneficiary after the 13th month and that Medicare pay for maintenance services on a cost-reimbursement basis.</p>	<p>\$200</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Part B Drugs Average Sales Price. Adopt an alternate calculation of volume-weighted average sales price that is consistent with the results set forth in section 1847A(b)(3) of the Social Security Act. The recommendation related to findings in report number OEI-03-05-00310.</p>	<p>Section 112 of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised calculation method for calculating volume weighted average sales prices for Medicare Part B drugs that comports with OIG’s recommendation.</p>	<p>\$200</p>
<p>Medicaid Third Party Liability. Determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition of a third party, require third parties to match their eligibility files with Medicaid’s eligibility files, and allow Medicaid up to 3 years to recover payments from liable third parties. The recommendation related to findings in report number OEI-03-00-00030.</p>	<p>Section 6035 of the DRA made several changes to strengthen Medicaid’s third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also includes requiring States to ensure that health insurers, as a condition of doing business in the State, provide requested coverage data; accept the State’s right of recovery; and agree, conditionally, not to deny a claim solely on the basis of date of submission of the claim when the claim is submitted by the State within a 3-year period beginning on the date on which the item or service was furnished.</p>	<p>\$190</p>
<p>Medicare Secondary Payer. Implement stronger follow-up procedures for employers who fail to respond to data requests, exercise civil monetary penalty authority, and seek necessary legislative authority for mandatory data reporting. A-02-98-01036; A-02-02-01037; A-02-02-01038; A-04-01-07002; A-09-89-00100.</p>	<p>Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 amended the Medicare secondary payer provisions of the Social Security Act, § 1862(b), to provide for mandatory reporting for various categories. CBO estimated that this provision would result in savings of \$1.1 billion over 10 years, with \$100 million attributed to FY 2010.</p>	<p>\$100</p>
<p>Additional Rebates for Brand-Name Drugs With Multiple Versions. OIG recommended that CMS continue to seek legislative authority to modify the rebate formula calculation to ensure that manufacturers cannot circumvent additional rebates by bringing new</p>	<p>Section 2501(d) of the Patient Protection and Affordable Care Act, as amended by section 1206(a) of the Health Care and Education Reconciliation Act of 2010, addresses this issue. CBO estimated savings of \$100 million attributed to the effect of the amendment in FY 2010.</p>	<p>\$100</p>

OIG Recommendation	Implementing Action	Savings (millions)
versions of existing brand-name drugs to market. A-06-09-00033.		
<p>Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations.</p> <p>Require drug manufacturers that excluded sales to health maintenance organizations (HMO) from their best price calculations to repay the rebates and evaluate the policy guidance relating to exclusion of sales to other (non-HMO) repackagers from best price determinations. Medicaid rebates were lost because sales to HMOs were improperly excluded from drug manufacturers’ best price determinations in FYs 1998 and 1999. The recommendation related to findings in report number A-06-00-00056.</p>	<p>CMS issued Medicaid Drug Rebate Program Release #47 in July 2000, reiterating that section 1927(c) of the Social Security Act requires that manufacturers include in the best price the lowest price available to, among other entities, any wholesaler, retailer, provider, and HMO. The release specifically stated that this includes sales to organized health care settings, such as HMOs.</p>	\$81
<p>Rebates for Physician-Administered Drugs.</p> <p>Encourage States to take actions to collect rebates on physician-administered drugs, especially single-source drugs. States should either use National Drug Codes (NDC) instead of procedure codes or link procedure codes to NDCs for single source drugs. The recommendation related to findings in report number OEI-03-02-00660.</p>	<p>Section 6002 of the DRA requires States to provide for the collection and submission of utilization data needed to secure rebates for physician-administered drugs and provide that the utilization data for single source and specified multiple-source physician-administered drugs be submitted using NDC numbers (unless the Secretary specifies an alternative coding system).</p>	\$20

ADMINISTRATION FOR CHILDREN AND FAMILIES		
OIG Recommendation	Implementing Action	Savings (millions)
<p>Triennial Reviews of Child Support Orders and Medical Support by Parents. Ensure that more periodic reviews are initiated and take action to increase medical support by parents. OIG reviewed the effects of 1996 legislation that no longer required States to conduct periodic reviews and adjustments of child support orders (unless requested by a State agency or parent) and found that many States had, in effect, discontinued the reviews. The recommendations related to findings in report number OEI-05-98-00100.</p>	<p>Section 7302 of the DRA implemented our recommendation to increase periodic reviews by requiring States to adjust child support orders of families on the Temporary Assistance for Needy Families program every 3 years. CBO estimated net savings resulting from section 7302 as \$20 million in 2010. Section 7307 of the DRA requires, for court orders that are issued or amended after enactment, that all States assess the ability of either or both parents to provide medical support for their children. CBO estimated savings from section 7307 as \$3 million in FY 2010.</p>	<p>\$23</p>

Appendix B: Recommendations for 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.

Audit Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decision had been made by the beginning of the reporting period ¹	155	\$1,096,110,000	\$46,084,000
Reports issued during the reporting period	123	\$171,342,000	\$56,899,000
Total Section 1	278	\$1,267,452,000	\$102,983,000
Section 2			
Reports for which a management decision was made during the reporting period ^{2,3,4}			
Disallowed costs	138	\$438,576,000	0
Costs not disallowed	8	\$19,314,000	\$13,831,000
Total Section 2	146	\$457,890,000	\$13,831,000
Section 3			
Reports for which no management decision had been made by the end of the reporting period			
Total Section 1 Minus Total Section 2	132	\$809,562,000	\$89,152,000

Continued			
Section 4			
Reports for which no management decision was made within 6 months of issuance ⁵	64	\$672,497,000	\$32,253,000

Table 2: Funds Recommended To Be Put to Better Use (Audit Reports)

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 Appendix A.

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	12	\$3,956,885,000
Reports issued during the reporting period	10	\$362,735,000
Total Section 1	22	\$4,319,620,000
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	1	\$39,206,000
Based on proposed legislative action		
Value of recommendations not agreed to by management		\$0
Total Section 2	1	\$39,206,000
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	21	\$4,280,414,000

End Notes to Tables 1 and 2

Table 1 End Notes

¹ The opening balance was adjusted upward by \$340.6 million primarily because of a reevaluation of previously issued non-Federal audit recommendations.

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

- A-01-02-00516, *Review of Potentially Excessive Medicare Payments-United Government Services*. CMS subsequently determined that several high-dollar claims were allowable and reversed its original management decision to disallow \$1,382,206.
- A-07-05-04048, *Followup Audit of the Medicaid Drug Rebate Program in Colorado*. CMS originally agreed with the recommended refund of \$1,925,367. Subsequently CMS determined that the net refund due from the State was \$102,725.
- A-09-03-00042, *Review of Payments Made by United Government Services for Home Health Services Preceded by a Hospital Discharge*. CMS subsequently increased its original disallowance to reflect \$1,445,138 in additional overpayments.

Not detailed are net reductions to previously reported disallowed costs totaling \$84,229.

³ Included are management decisions to disallow \$353.7 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 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, MANUFACTURER A, MAR 2008, \$268,000,000
CIN: A-06-07-00039	REVIEW OF AMP CALCULATION, MANUFACTURER C, MAR 2008, \$101,000,000
CIN: A-03-07-00560	PENNSYLVANIA 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-09-02-00054	AUDIT OF STATE OF CALIFORNIA DSH PROGRAM FOR FY 1998, MAY 2003, \$33,318,976
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL BASED HEALTH SERVICES, CONNECTICUT, MAY 2003, \$32,780,146
CIN: A-06-07-00040	REVIEW OF AMP CALCULATION, MANUFACTURER B, MAR 2008, \$27,700,000
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 PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENTS, CASTILLE SAMPLE, SEP 2007, \$11,611,822
CIN: A-01-07-00013	REVIEW OF MEDICAID SUPPLEMENTAL PAYMENT TO UMASS MEMORIAL HEALTH CARE, INC., DEC 2009, \$8,531,218
CIN: A-06-02-00034	COST REPORTS AND MEDICARE FEE-FOR-SERVICE PAYMENTS, SCOTT & WHITE, MAY 2003, \$8,229,574
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 TENNESSEE 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-04-04-02003	MEDICARE OUTLIER PAYMENTS TO COMMUNITY MENTAL HEALTH CENTERS, APR 2006, \$4,762,036
CIN: A-04-08-03523	REVIEW OF TITLE IV-E ADOPTION ASSISTANCE MAINTENANCE PAYMENTS IN FLORIDA FOR THE PERIOD OCTOBER 1, 2004 THROUGH SEPTEMBER 30, 2007, MAY 2009, \$4,413,264
CIN: A-09-01-00085	AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR STATE FY 1998, SEP 2002, \$3,776,054
CIN: A-06-04-00076	MEDICAL REVIEW OF SYNERGY'S PARTIAL HOSPITALIZATION SERVICES CLAIMS, MAR 2006, \$3,098,296
CIN: A-10-96-00001	REVIEW OF GROUP HEALTH'S GHCPs REPORTING OF ESRD, APR 1997, \$2,763,498
CIN: A-07-08-03114	REVIEW OF MISSOURI ACF TRAINING COSTS, AUG 2009, \$2,556,099
CIN: A-03-08-00553	AUDIT OF PENNSYLVANIA TITLE IV-E FOSTER CARE CHILDREN OVER 19 YEARS OLD, NOV 2009, \$1,641,903
CIN: A-04-06-01042	PAYMENTS TO VACCINE SUPPLIERS, MAR 2010, \$962,998
CIN: A-07-09-03119	MISSOURI CLAIM FOR TITLE IV-E TRAINING COSTS FOR SALARIES AND BENEFITS, JUL 2009, \$741,872
CIN: A-07-09-03121	MISSOURI 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, INDIANA, 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-04-04-02010	REVIEW OF COMPREHENSIVE OUTPATIENT REHABILITATION THERAPY SERVICES PROVIDED BY ABSOLUTE THERAPY INC., NOV 2006, \$414,712

CIN: A-06-06-00072	REVIEW OF COST FOR TEXAS MEDICAL FOUNDATION AUDITEE, MAY 2008, \$403,581
CIN: A-05-01-00096	PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355
CIN: A-07-09-03120	MISSOURI CLAIM FOR TITLE IV-E 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, MICHIGAN, 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-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 THROUGH 2008, JUL 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, AUG 2009, \$116,728
CIN: A-05-05-00044	DUPLICATE MEDICARE PAYMENTS TO COST-BASED HEALTH MAINTENANCE ORGANIZATION PLAN, ARNETT HEALTH PLANS, INC. FOR FISCAL YEARS 2000 THROUGH 2003, SEP 2005, \$111,862
CIN: A-05-97-00017	FHP, INC. HMO INSTITUTIONAL STATUS PROJECT, JUN 1998, \$109,114
CIN: A-05-01-00079	PAYMENTS TO BLUE CARE MID-MICHIGAN FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$100,692
CIN: A-05-02-00067	REVIEW OF MEDICARE FEE-FOR-SERVICE PAYMENTS AND COST REPORTS, WELBORN, JUN 2003, \$97,623
CIN: A-05-01-00090	PAYMENTS TO AETNA U.S. HEALTHCARE PENNSYLVANIA FOR 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, NEW YORK, MAR 2008, \$77,358
CIN: A-05-01-00089	ADDITIONAL BENEFITS REVIEW ON MANAGED CARE ORGANIZATION, OCT 2002, \$77,000
CIN: A-09-06-00039	MEDICARE INTEGRITY, AUDIT OF QUALITY IMPROVEMENT ORGANIZATION, WASHINGTON STATE, FEB 2008, \$73,636
CIN: A-04-05-02000	AUDIT OF HHA THERAPY BILLINGS, SEP 2005, \$63,425
CIN: A-05-01-00086	PAYMENTS TO HMO OF NE PENNSYLVANIA FOR INSTITUTIONAL 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 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, ARIZONA - FOR INSTITUTIONAL BENEFICIARIES, APR 2002, \$21,233
CIN: A-08-04-76779	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003, \$18,925
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR INSTITUTIONALIZED BENEFICIARIES, MAY 2002, \$18,842
CIN: A-05-01-00095	PAYMENTS TO HUMANA OF ARIZONA FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$18,645
CIN: A-07-03-00151	REVIEW OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, JUN 2003, \$18,400
CIN: A-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
Total CINs:	64
Total Amount:	\$672,497,323

Table 2 End Notes (Audits)

¹ The opening balance was adjusted downward by \$1.6 million.

² Because of administrative delays, some of which were beyond management control, resolution of the following 10 audits was not completed within 6 months of issuance of the report. The OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period:

CIN: A-06-09-00033	REVIEW OF ADDITIONAL REBATES OF NEW BRAND NAME DRUGS, MAR 2010, \$2,500,000,000
CIN: A-06-07-00042	INDEXING THE REBATE FOR GENERIC DRUGS, OCT 2007, \$966,000,000
CIN: A-02-07-02000	OPEN AND INACTIVE GRANTS ON THE PAYMENT MANAGEMENT SYSTEM, ACF, FEB 2009, \$472,155,156
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
CIN: A-05-06-00038	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, INDIANA, MAR 2007, \$871,677
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, MINNESOTA, SEP 2006, \$28,240
CIN: A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 THROUGH 2008, JUL 2009, \$17,764
TOTAL CINS:	10
TOTAL AMOUNT:	\$3,955,450,106

Appendix C: Reporting Requirements of 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	Highlights section.
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 <i>Compendium of Unimplemented Office of Inspector General Recommendations</i> : 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
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	Appendix B

Section of the Act	Requirement	Location
(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	To be reported annually in the spring <i>Semiannual Report</i> .
(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 F

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

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

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

In response to the 2009 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
<p>Create a Health Center Patient Incentive Safe Harbor that would protect incentives connected to a patient's condition or treatment plan that Federally Qualified Health Centers (FQHCs) or FQHC look-alikes would like to offer to encourage patients to either obtain medically necessary treatment, reward compliance with a treatment program, or reward achievement of treatment-related goals.</p>	<p>OIG is considering this suggestion.</p>
<p>Either clarify that free continuing medical education (CME) programs offered by hospitals do not violate the anti-kickback statute or establish a safe harbor to protect hospital CME programs.</p>	<p>OIG is not adopting the suggestion to establish a safe harbor for this purpose. The concept of "free programs" could vary greatly and should be addressed on a case-by-case basis, such as under the advisory opinion procedures.</p>

Proposal	OIG Response
Establish a safe harbor for shared savings and gain-sharing arrangements.	OIG is considering this suggestion.
Establish a safe harbor for arrangements that support health care clinical innovation and/or payment reform models (e.g., pilot accountable care organizations, medical home, and joint ventures that support integration and care coordination).	OIG is considering this suggestion.

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

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) 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 CMPL, “should know” is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The CMPL and its implementing regulations also authorize actions for a variety of other violations, including submission of claims for items or services furnished by an excluded person; requests for payment in violation of an assignment agreement; violations of rules regarding the possession, use, and transfer of biological agents and toxins; and payment or receipt of remuneration in violation of the anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

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 CMP under OIG's CMPL 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 F: 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 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 complied with to provide DoD OIG with reasonable assurance of performing and reporting in

Date	Reviewing Office	Office Reviewed	Findings
			<p>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.</p> <p>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 at December 2009.</p>

Office of Investigations Peer Review Results

During this semiannual reporting period, no peer reviews were conducted by HHS OIG's Office of Investigations (OI) and OI did not conduct a peer review of other OIGs. Listed below is information concerning OI's peer review activities during prior reporting periods.

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

Date	Reviewing Office	Office Reviewed	Findings
January 2010	HHS OIG, OI	U.S. Department of Justice 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.

Appendix G: Acronyms and Abbreviations

Following are selected acronyms and abbreviations used in this publication.

Terms, Titles, and Organizations

ACF	Administration for Children & Families
ADAP	AIDS Drug Assistance Program
AIDS	acquired immunodeficiency syndrome
AMP	average manufacturer price
AoA	Administration on Aging
ASP	average sales price
BLS	Bureau of Labor Statistics
CCA	certification of compliance agreement
CDC	Centers for Disease Control and Prevention
CERT	Comprehensive Error Rate Testing (program)
CHIP	Children's Health Insurance Program
CIA	corporate integrity agreement
CLAS	Culturally and Linguistically Appropriate Services in Health Care
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
CWF	Common Working File
CY	calendar year
DEA	Drug Enforcement Administration
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
DPNA	denial of payment for new admissions
DSH	disproportionate share hospital
EBNHC	East Boston Neighborhood Health Center
ENT	enteral nutrition therapy
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
ESPNS	Elder Service Plan of the North Shore
ESRD	end stage renal disease
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FFP	Federal financial participation
FFS	fee for service
FHH	Fort Hamilton Hospital
FI	fiscal intermediary

FISS	Fiscal Intermediary Shared System
FMAP	Federal medical assistance percentage
FUL	Federal upper limit
FY	fiscal year
HCPCS	Healthcare Common Procedure Coding System
HEAL	Health Education Assistance Loan
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HHA	home health agency
HHS	Department of Health & Human Services
HIPDB	Health Care Integrity and Protection Data Bank
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
ICD	implantable cardioverter defibrillator
IHS	Indian Health Service
IMD	institutions for mental disease
IPF	inpatient psychiatric facility
IRF	inpatient rehabilitation facility
LCD	local coverage determination
LEP	limited English proficiency
MAC	Medicare administrative contractor
MEBH	MultiEthnic Behavioral Health Services, Inc.
MFCU	Medicaid Fraud Control Unit
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NLM	National Library of Medicine
NPI	national provider identifier
OAI	official action indicated
OCSE	Office of Child Support Enforcement
OIG	Office of Inspector General
OCR	Office for Civil Rights
OMB	Office of Management and Budget
OMH	Office of Minority Health
ORF	Office of Research Facilities Development and Operations
PDE	prescription drug event
P.L.	Public Law
PERM	Payment Error Rate Measurement (program)
PPI	Producer Price Index
PPS	prospective payment system
PSC	program safeguard contractor
PSC	Program Support Center
SLV	School-Located Vaccination (program)
SNF	skilled nursing facility

THA	The Health Alliance of Greater Cincinnati
TUH	The University Hospital
UCCP	uncompensated care pool
UIMA	University Internal Medicine Associates
UPIN	unique physician identifier number
U.S.C.	United States Code
ZPIC	Zone Program Integrity Contractor

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, Public Law (P.L.) No. 101-381
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980, P.L. No. 96-510
DRA	Deficit Reduction Act of 2005, P.L. No. 109-171
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
FDCA	Federal Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191
IDEA	Individuals with Disabilities Education Act of 2004, P.L. No. 108-446
IG Act	Inspector General Act of 1978 (IG Act), as amended by P.L. No. 111-25, 5 U.S.C. App.
IPIA	Improper Payment Information Act of 2002, P.L. No. 107-300
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173
Recovery Act	American Recovery and Reinvestment Act of 2009, P.L. No. 111-5



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