



Semiannual Report

The complete Semiannual Report to Congress can be viewed at <http://oig.hhs.gov>

Office of Inspector General

April 1 - September 30, 2005

U.S. Department of
Health and Human Services



“*Working Together to Promote, Preserve & Protect the Nation’s Well-Being*”

This semiannual report
and other OIG publications and information
are on the Internet at <http://oig.hhs.gov>

Message from the Inspector General

This report, submitted pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG) for the 6-month reporting period that ended September 30, 2005.

OIG is dedicated to the mission of detecting fraud, waste, and abuse and promoting economy and efficiency in the programs of the Department of Health and Human Services (HHS). Oversight of the increasing costs associated with the Medicare and Medicaid programs, as well as the over 300 important discretionary programs administered by this Department, places significant responsibility on OIG to ensure that taxpayer dollars are spent wisely and appropriately. This charge expands with full implementation of the Medicare prescription drug program in January 2006.

Accountability for Medicaid funds and payment for Medicaid prescription drugs were focal points of OIG work during this reporting period. OIG continued its longstanding examination of State financing mechanisms used to maximize Medicaid payments. In addition, a series of three reports documented how the Medicaid program pays too much for prescription drugs compared with prices available in the marketplace. In June, OIG testified before the Senate Finance Committee on this Medicaid work. With the Federal share of Medicaid outlays expected to exceed \$192 billion in fiscal year 2006, OIG work on issues related to Medicaid spending will continue to grow in importance and impact.

The biggest immediate challenge for both OIG and the Department is the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In providing a new benefit to Medicare beneficiaries, this law creates the largest expansion of Medicare since its creation. Along with fulfilling its mandated MMA oversight responsibilities, OIG is diligently planning to ensure that we are fully prepared to prevent fraud, waste, and abuse in the new prescription drug program that will be operating in a dynamic marketplace. At the same time, expansion of health information technology and changes relating to how health care generally is delivered and paid for provide additional new oversight responsibilities and challenge OIG to stay current with rapid changes in program administration.

As the rollout of the new Medicare prescription drug program begins, OIG will work collaboratively with the Department, other Federal and State agencies, and the industry to ensure proper administration of this new benefit. In addition, OIG will continue to work closely with the Department to address the management challenges that lie ahead.

I want to express my appreciation to Congress, as well as to the senior management of the Department, for their support during my transition to the position of Inspector General at HHS. I am honored to be leading an organization of highly professional and talented employees who are committed to the mission of OIG and the important programs administered by the Department.



Daniel R. Levinson
Inspector General

Highlights

Summary of Accomplishments

For fiscal year (FY) 2005, the Office of Inspector General (OIG) reported savings and expected recoveries of nearly \$35.4 billion: \$32.6 billion in implemented recommendations and other actions to put funds to better use, \$1.2 billion in audit receivables, and \$1.6 billion in investigative receivables.

Also for this fiscal year, OIG reported exclusions of 3,806 individuals and entities for fraud or abuse of Federal health care programs and/or their beneficiaries; 537 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 250* civil actions, which include False Claims Act and unjust enrichment suits filed in district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters.

HealthSouth Corporation

The nation's largest provider of inpatient and outpatient rehabilitation services, HealthSouth Corporation, agreed to pay the Government \$325 million plus interest and entered a company-wide 5-year corporate integrity agreement with OIG. The settlement resolved allegations of Medicare Part A cost report fraud uncovered during the Government's investigation of the company's financial statements. The settlement also resolved allegations that the company submitted false claims to Medicare Part B for certain outpatient physical therapy services.

Medicaid Claims for School-Based Services

OIG published two audits of New York City's Medicaid claims for school-based services. One report found that 86 percent of sampled claims for speech services did not comply with Federal and State requirements. Deficiencies included no or inadequate documentation to support the claims, lack of proper referrals, and services rendered by unqualified providers. In the second report, none of the sampled claims for transportation services complied with all Federal and State requirements. Deficiencies included lack of documentation to support services rendered, failure to render other Medicaid-covered school health services when transportation was billed, and failure to document the need for services. OIG recommended that the State refund \$532 million to the Federal Government, resolve an additional \$12 million in set-aside claims, provide proper and timely guidance on Federal Medicaid criteria to New York City, improve its monitoring of claims, and instruct New York City to bill its Medicaid school-based claims properly and maintain appropriate documentation to support the claims.

Senate Testimony on Medicaid Financing Mechanisms

OIG testified before the Senate Finance Committee in late June regarding States' use of Medicaid financing mechanisms. Intergovernmental transfers (IGT), one such mechanism, are transfers of non-Federal public funds between local public Medicaid providers and State Medicaid agencies. Misuse of IGTs circumvents the Federal/State Medicaid partnership and increases Federal payments to States at

*In the original publication of this report, 12 civil actions successfully completed by OIG in a prior reporting period were mistakenly included in this figure. On April 7, 2006, this figure was adjusted to reflect the actual number of civil actions completed during the time period October 1, 2004, to September 30, 2005.

the expense of the intended beneficiaries. One example of IGTs involves upper-payment-limit (UPL) funds, which are intended to reimburse Medicaid providers but are often retained by the States. OIG audits identified several nursing homes whose quality of care was adversely affected because they were not allowed to retain enough UPL funds to provide adequate staffing.

Another program that can be abused is the Medicaid disproportionate share hospital (DSH) program, which provides Federal funds to compensate hospitals that care for large percentages of Medicaid beneficiaries and uninsured patients. OIG audits in two States found that hospitals were returning 80 to 90 percent of their DSH payments to the State, contrary to the program's purpose. OIG identified similar problems with Medicaid school-based health services.

OIG stated that current policies and practices severely limit the ability of Congress, HHS, and State and local governments to manage, account for, and assess the benefits of Medicaid dollars, including dollars manipulated in Medicaid financing mechanisms. OIG recommended that State Medicaid programs improve their oversight and accountability procedures.

Administrative Enforcement Actions

OIG has continued to increase administrative enforcement through the imposition of civil monetary penalties (CMPs) in a variety of circumstances. During this reporting period, OIG entered into several settlement agreements resolving CMP cases. These cases have included sanctions for alleged kickbacks, physician self-referral (the Stark statute) violations, and false claims. Cases have been settled with providers, suppliers, and individually with executive officers. Some of these settlements resulted from submissions by providers under the OIG self-disclosure protocol.

Medicaid Drug Price Comparisons

A series of three inspection reports found that statutorily defined prices for prescription drugs in the Medicaid and Medicare programs based on actual sales were substantially lower than published prices (average wholesale price) and wholesale acquisition costs. Overall Federal upper limit amounts for generic drug products were five times higher than the average manufacturer price for the same products in the third quarter of 2004. The results of these studies were presented before the Senate Committee on Finance in June 2005.

Outside Activities of Senior-Level National Institutes of Health Employees

Between 2001 and 2003, 40 percent of senior-level National Institutes of Health (NIH) employees received approval for 319 outside activities. About half of these outside activities involved teaching or consulting and most were compensated. An OIG evaluation identified several vulnerabilities that inhibit NIH's ability to effectively review outside activities, which can potentially create real or apparent conflicts of interest for employees. NIH concurred with the findings and recommendations and has already taken steps to address the concerns.

Table of Contents

Centers for Medicare & Medicaid Services	1
CMS-Related Reports	2
Hospital Compliance With Medicare’s Postacute Care Transfer Policy	2
Chiropractic Services in the Medicare Program: Payment Vulnerability Analysis	2
Managed Care Payments	2
Group Purchasing Organizations	3
Nurse Aide Registries: Long Term Care Facility Compliance and Practices	3
Medicare and Federal Employees Health Benefits Program Payment Rates for Home Oxygen Equipment	4
Consecutive Medicare Inpatient Stays	4
Partial Hospitalization Services	4
Medicare Graduate Medical Education Payments	5
Effectiveness of Revised Medicare Outlier Payment Regulations	6
Medicare Beneficiary Telephone Customer Service	6
Hospital Wage Data Used To Calculate Inpatient Prospective Payment System Wage Indexes	6
Outpatient Cardiac Rehabilitation	7
Medicare Contractor Administrative Costs	7
Organ Acquisition Costs	7
Self-Declaration of U.S. Citizenship for Medicaid	8
Self-Declaration of U.S. Citizenship for the State Children’s Health Insurance Program	8
Nursing Home Enforcement: The Use of Civil Monetary Penalties.....	8
Nursing Facility Performance in Assessing Residents in a Timely Manner and Submitting Required Data	9
Informal Dispute Resolution for Nursing Facilities	9
Medicaid Hospital Outlier Payments in Illinois.....	9
Medicaid Drug Rebate Program.....	10
Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices and Average Sales Price to Average Wholesale Price	10
Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Price	11
Children Enrolled in Separate State Children’s Health Insurance Programs and Medicaid Eligibility	11
New York City’s Claims for Medicaid Speech Services.....	11
New York City’s Claims for Medicaid Transportation Services.....	11
Iowa’s Adult Rehabilitation Services Program	12
Upper Payment Limits	12
Family Planning Service Costs.....	13
Hospital Patient Transfers Paid as Discharges Under Medicaid	13
Oklahoma’s Medicaid Administrative Costs.....	14
Medicaid Provider Overpayments.....	14
Medicaid Payments for Skilled Professional Medical Personnel	15
Medicaid Payments for Deceased Beneficiaries	15
Status of Rural Health Clinic Program	15
CMS Oversight of Short-Term Acute Care Nonaccredited Hospitals.....	16
Outreach	16
Advisory Opinions	16
Provider Self-Disclosure Protocol.....	16

Federal and State Partnership: Joint Audits of Medicaid	17
OIG Administrative Sanctions	17
Program Exclusions	17
Civil Monetary Penalties	18
Kickbacks	18
Patient Dumping	19
Criminal and Civil Enforcement	19
Hospitals	20
Home Health Agencies	20
Medicare Contractors	20
Durable Medical Equipment Suppliers	21
Prescription Drugs	21
Nursing Homes	21
Clinics	22
Practitioners	22
Medicaid Fraud Control Units	22
Public Health Agencies	23
Public Health Agency-Related Reports	24
Outside Activities of Senior-Level National Institutes of Health Employees	24
Credentialing and Privileging at Indian Health Service Hospitals	24
Federal Efforts to Address Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees	24
The Centers for Disease Control and Prevention’s Management of HIV/AIDS Grants	25
Hospital Bioterrorism Surge Capacity: Status of Early Implementation	25
Health Education Assistance Loan Defaults	25
Public Health-Related Investigations	26
Administration for Children and Families and Administration on Aging	29
Administration for Children and Families-Related Reports	30
Ability of Noncustodial Parents To Contribute Toward Medicaid Costs	30
Ability of Noncustodial Parents To Contribute Toward State Children’s Health Insurance Program Costs	30
Children’s Use of Health Care Services While in Foster Care: New York	30
Adoption Assistance Payments in Maine	31
Title IV-E Administrative and Training Costs in Delaware	31
Performance Data for Senior Medicare Patrol Projects	31
Undistributable Child Support Collections in Illinois	32
Child Support Enforcement	32
Task Forces	33
Task Force Table	33
Investigations	33

General Oversight	35
Non-Federal Audits	36
Resolving Recommendations	36
Table 1: Reports With Questioned Costs	37
Table 2: Funds Recommended To Be Put to Better Use.....	38
Legislative and Regulatory Review and Development	39
Regulatory Review Functions.....	39
Regulatory Development	39
Employee Fraud and Misconduct	40
Prosecutions	40
Appendixes	41
Appendix A: Savings Achieved Through Policy and Procedural Changes Resulting From Audits, Investigations, and Inspections April 1 Through September 30, 2005	43
Appendix B: Unimplemented Office of Inspector General Recommendations to Put Funds to Better Use	49
Appendix C: Unimplemented Office of Inspector General Program and Management Improvement Recommendations	57
Appendix D: Notes to Tables 1 and 2	67
Notes to Table 1	67
Notes to Table 2	76
Appendix E: Reporting Requirements of the Inspector General Act of 1978, as Amended	79
Appendix F: Status of Public Proposals for New and Modified Safe Harbors to the Anti-Kickback Statute Pursuant to Section 205 of the Health Insurance Portability and Accountability Act of 1996	81
Appendix G: Summary of Sanction Authorities	85
Program Exclusions	85
Patient Dumping	85
Civil Monetary Penalties Law	85
Summary of Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities.....	86

Please note: Numerical information in this report is rounded.

Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare and Medicaid programs. Financed by the Federal Hospital Insurance Trust Fund, Medicare Part A provides hospital and other institutional insurance for individuals 65 years old or older and for certain disabled persons. Medicare Part B (Supplementary Medical Insurance) is an optional program that covers most of the costs of medically necessary physician and other services and is financed by participants and general revenues.

The Medicaid program provides funding to States for medical care and other support and services for low-income individuals. State expenditures for medical assistance are matched by the Federal Government using a formula that compares per capita income in each State relative to the national average. The State Children's Health Insurance Program (SCHIP) expands health coverage to uninsured children whose families earn too much for Medicaid, but too little to afford private coverage.

The Office of Inspector General (OIG) devotes significant resources to investigating Medicare and Medicaid fraud, waste, and abuse and to monitoring these programs. These activities have helped ensure the cost-effective delivery of Medicare, Medicaid, and SCHIP services; safeguarded quality of care to beneficiaries of these programs; and reduced the potential for fraud, waste, and abuse. In addition, these efforts have led to criminal, civil, and/or administrative actions against perpetrators of fraud and abuse.

OIG also reports on audits of CMS financial statements, which currently account for more than 82 percent of Department of Health and Human Services (HHS) net costs. In addition to issuing an opinion on the statements, auditors assess compliance with Medicare laws and regulations and the adequacy of internal controls.

CMS-Related Reports

Hospital Compliance With Medicare's Postacute Care Transfer Policy

OIG examined whether acute care hospitals complied with Medicare's postacute care transfer policy during fiscal years (FY) 2001 and 2002. Of the 400 claims sampled, 381 were improperly coded as discharges to home rather than transfers to postacute care. Medicare reimburses differently depending on whether a patient is discharged to home or transferred to certain postacute care settings, such as a skilled nursing facility. Some hospitals did not have the necessary controls to ensure the accuracy of discharge status codes, and CMS lacked adequate payment system edits at the time of OIG's review. As a result, OIG estimated that Medicare overpaid hospitals approximately \$72.4 million in FYs 2001 and 2002.

OIG recommended that CMS instruct fiscal intermediaries to recover more than \$1 million in overpayments identified in the sample, instruct the intermediaries to review the remaining claims in the sampling universe and recover any additional overpayments, and monitor hospitals that have a high number of claims adjusted as a result of recently implemented system edits. CMS generally agreed with the recommendations. (A-04-04-03000)

Chiropractic Services in the Medicare Program: Payment Vulnerability Analysis

OIG found that approximately 67 percent of chiropractic services allowed by Medicare in 2001 did not meet Medicare coverage criteria and/or were miscoded or undocumented, potentially costing the program and its beneficiaries approximately \$285 million. Chiropractors who reviewed patient records determined that more than 90 percent of this amount represented services that were not medically necessary. Most of the medically unnecessary services were maintenance or preventive treatments, which are not Medicare-covered benefits.

Beneficiaries' use of chiropractic services continues to increase, making improper payments for these services a significant vulnerability for Medicare. OIG recommended that CMS ensure that chiropractic services comply with Medicare coverage criteria by establishing national frequency-based controls and funding service-specific reviews of chiropractic services. CMS should also require that its carriers educate chiropractors on Medicare Carriers Manual requirements for supporting documentation. CMS concurred with OIG's recommendations. (OEI-09-02-00530)

Managed Care Payments

Medicare+Choice organizations (MCO) are responsible for providing all Medicare-covered services, except hospice care, to enrollees in return for a predetermined capitation payment. MCOs with plans for which payment rates increased under the Benefits Improvement Protection Act (BIPA) of 2000 were required to use the additional amounts to reduce beneficiary premiums or cost-sharing, enhance benefits, contribute to a stabilization fund for benefits in future years, or stabilize or enhance beneficiary access to providers.

OIG issued reports on two MCOs' modifications to their 2001 adjusted community rate proposals under BIPA:

- An MCO in Texas submitted a revised proposal that reflected an increase of \$14.4 million in estimated direct medical care costs. About \$7.8 million of the \$14.4 million reflected an increase in Medicare capitation payments provided by BIPA, and \$6.6 million was not related to the BIPA

funding increase. Because \$5.2 million of the \$7.8 million BIPA capitation payment increase was not properly supported, OIG could not determine whether that part of the increase was used in a manner consistent with BIPA requirements. Also, \$5.3 million of the \$6.6 million increase not related to BIPA was unsupported.

OIG recommended that the MCO work with CMS to make appropriate cost adjustments and ensure that estimated costs in future proposals are properly supported. The MCO did not directly respond to the recommendations. (A-06-03-00027)

- An MCO in Oregon submitted a revised proposal that reflected a \$22.7 million increase in Medicare capitation payments. Approximately \$6.8 million of the increase was not adequately supported. Therefore, OIG could not determine whether that part of the increase was used in a manner consistent with BIPA requirements. Also, \$500,000 of the increase was supported but not used in a manner consistent with BIPA requirements.

OIG recommended that the MCO work with CMS to make appropriate cost adjustments and ensure that estimated costs in future proposals are properly supported and used in a manner consistent with BIPA. The MCO generally disagreed. (A-10-03-00011)

Group Purchasing Organizations

Group purchasing organizations (GPO) are buying consortiums designed to leverage the purchasing power of members, primarily hospitals and other health care providers, and to allow them to obtain discounts on medical supplies. In exchange for administrative services and the ability to sell through a GPO to its members, vendors pay administrative fees to GPOs.

In January 2005, OIG issued an audit on three GPOs (A-05-03-00074). The current report contains the results of a second audit focusing on how much revenue three additional GPOs received from vendors and the disposition of that revenue. OIG found that one health care system representing six member hospitals did not fully account for net revenue distributions on Medicare cost reports and did not distribute all of its administrative fees to its member hospitals to be offset on the respective hospitals' cost reports. As a result, administrative fees of about \$5 million were not offset on Medicare cost reports. In addition, one GPO did not distribute all rebates received to its members. That GPO withheld \$1.6 million of the total rebates.

OIG continued to recommend that CMS clarify instructions to hospitals on the proper Medicare cost report treatment of net revenue distributions. (A-05-04-00073)

Nurse Aide Registries: Long Term Care Facility Compliance and Practices

This report examined nursing homes' compliance with Federal requirements that they verify the State registry status of a nurse aide before employing that individual. OIG found that the long term care facility administrators reported checking their State nurse aide registries prior to hiring nurse aides and that the registry search results affected hiring decisions. However, 55 percent of administrators reported that they checked their own State's registry but not other State registries. Further, 17 percent of long term care facilities employed individuals as nurse aides without required registrations. Although 85 percent of administrators reported establishing additional screening procedures for nurse aides, some of these methods may not be fully effective.

OIG recommended that CMS utilize existing communication channels to emphasize that long term care facilities must comply with Federal regulations addressing consulting out-of-state registries and nurse aide registration requirements and encourage long term care facilities to use available resources to screen nurse aides. CMS concurred with the report's recommendations. (OEI-07-04-00140)

Medicare and Federal Employees Health Benefits Program Payment Rates for Home Oxygen Equipment

This report updates OIG's September 2004 report on Medicare payments for home oxygen equipment. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that CMS use Federal Employees Health Benefits (FEHB) plans' median payment rates to reduce Medicare fee schedule allowances for home oxygen equipment in 2005. Accordingly, OIG issued a report analyzing FEHB median payments for home oxygen equipment. Because questions were raised about the inclusion of oxygen contents for stationary and portable equipment in FEHB payment rates, OIG conducted additional work to clarify data in its earlier study. OIG found that plans' median payment rates were 12.4 percent lower for stationary equipment and 10.8 percent lower for portable equipment. The greatest difference between the median FEHB payment rate and the median Medicare fee schedule allowances was for oxygen concentrators. (OEI-09-03-00160, revised)

Consecutive Medicare Inpatient Stays

This inspection examined services to Medicare beneficiaries who had three or more inpatient stays, each within 1 day of discharge from the last facility. OIG found that the majority of such consecutive inpatient stays were appropriate. However, for 20 percent of the stays, medical records reviews showed that Medicare inpatient stays were associated with quality of care problems and/or unnecessary fragmentation of health care services across multiple inpatient stays. Medicare paid an estimated \$267 million for these sequences of stays in FY 2002. This inspection also found that 10 percent of individual stays within consecutive inpatient stay sequences were associated with poor quality of patient care.

OIG recommended that CMS direct quality improvement organizations and fiscal intermediaries, as appropriate, to monitor the quality, medical necessity, and appropriateness of inpatient services provided within the types of sequences of consecutive Medicare inpatient stays included in the review.

CMS concurred with OIG's findings, but stated that periodic reviews of sequences of consecutive inpatient stays were not warranted. (OEI-03-01-00430)

Partial Hospitalization Services

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients instead of inpatient psychiatric care. Providers of these services receive a per diem payment under the Medicare hospital outpatient prospective payment system. In extraordinary cases, additional Medicare payments, called outlier payments, may be made if the cost of care is high in relation to the average cost of treating comparable conditions or illnesses. OIG issued two reports on partial hospitalization services:

- At a community mental health center in Texas, medical reviewers determined that none of the services on 100 sampled claims met Medicare reimbursement requirements. For example, for 99 of the 100 claims, there was no evidence that the therapy sessions were active, intensive, and therapeutic. Based on its sample, OIG estimated that \$12.5 million in Medicare payments was

unallowable. OIG recommended that the center refund the overpayments and strengthen its procedures to ensure that future claims meet Medicare requirements. The center did not agree to make the refund but said that it would strengthen internal quality controls. (A-07-04-04034)

Another review noted that the fiscal intermediary did not always follow Medicare reimbursement requirements when calculating outlier payments to this center. Because the fiscal intermediary used an outdated cost-to-charge ratio, it overpaid the center \$8.8 million. This report provides an additional basis for recovering \$7.2 million of the \$12.5 million in unallowable payments noted above. OIG recommended that the intermediary recover the improper payments and ensure that future outlier payments are computed with the correct cost-to-charge ratio. The intermediary generally agreed. (A-07-04-04045)

- OIG found that the fiscal intermediary did not follow Medicare reimbursement requirements when calculating Medicare outlier payments to another community mental health center in Texas. In computing the outlier payments, the intermediary used an incorrect cost-to-charge ratio based on a short-period Medicare cost report. As a result, the intermediary overpaid the center approximately \$1.4 million.

OIG recommended that the intermediary recover the overpayment and ensure that the correct cost-to-charge ratios are used for future outlier payments. The intermediary partially agreed. (A-07-04-04035)

Medicare Graduate Medical Education Payments

Medicare pays teaching hospitals for both direct graduate medical education (GME) costs and indirect graduate medical education (IME) costs. Hospitals claim reimbursement for these costs on their annual Medicare cost reports based on formulas that use fixed base costs and the number of full-time equivalent (FTE) residents. For payment purposes, the number of FTE residents is the average of the actual FTE count for the current year and the preceding two cost reporting periods. This is often described as the rolling average.

OIG issued reports on two New York hospitals' FTE calculations:

- One hospital did not fully comply with Federal requirements and therefore overstated its GME and IME FTEs on the 1999 Medicare cost report. These overstatements resulted in excess GME reimbursement of more than \$1.25 million in 1999. Because Medicare reimburses hospitals based on a 3-year rolling average, the overstated FTEs on the 1999 cost report also resulted in excess GME and IME reimbursement totaling almost \$7.2 million in 2000 and 2001. Thus, the hospital overstated its claim by a total of \$8.4 million for the 3 years.

OIG recommended that the hospital refund the overpayments, reduce the FTE counts reported on its 1999 Medicare cost report, and strengthen its procedures. The hospital disagreed with some of OIG's findings. (A-02-02-01011)

- OIG noted similar problems at the second hospital that resulted in \$2.5 million in excess GME reimbursement in 1999. Because of the rolling average, the overstated FTEs on the 1999 cost report also resulted in almost \$2.4 million in excess GME and IME reimbursement in 2000 and 2001. The total overstatement was almost \$4.9 million for the 3 years.

OIG recommended that the hospital refund the overpayments, reduce the FTE counts reported on the 1999 Medicare cost report, and strengthen its procedures. The hospital generally disagreed. (A-02-02-01001)

Effectiveness of Revised Medicare Outlier Payment Regulations

To reimburse hospitals for treating extremely costly patients, Medicare makes additional payments called outlier payments. In 2003, CMS revised its regulations to stop excessive growth of these payments. OIG determined that the revisions had reduced collective outlier payments to the 362 hospitals reviewed; the average outlier payment per claim decreased by almost 43 percent. CMS estimated that the revised regulations would save Medicare at least \$9 billion over 5 years.

OIG recommended that CMS continue to monitor Medicare outlier payments to ensure that the payments comply with Medicare regulations. CMS agreed to do so. (A-07-04-04032)

Medicare Beneficiary Telephone Customer Service

This OIG study on telephone customer service found that, of the callers asked to rate satisfaction, 84 percent were satisfied overall with the customer service they received. However, 44 percent of all callers had difficulty accessing information from call centers, reporting at least one of the following experiences: (1) finding the interactive voice response (IVR) not easy to use, (2) not receiving an answer to their question or all the information they needed, or (3) not receiving an answer to their question as quickly as desired. Callers and call center managers both highly prioritized accuracy of answers, yet evidence suggests oversight of accuracy may be inadequate. Some call centers conducted quality assurance activities that exceeded CMS requirements, including activities that focused on accuracy.

OIG recommended that CMS: (1) strengthen current oversight to place greater emphasis on accuracy of answers given by customer service representatives, and (2) continue to seek ways to improve the national IVR system. The report noted that CMS is taking action to address issues raised in this report. (OEI-07-04-00030)

Hospital Wage Data Used To Calculate Inpatient Prospective Payment System Wage Indexes

Under the acute care hospital inpatient prospective payment system, the Medicare base rate paid to participating hospitals includes a labor-related share. To reflect labor cost variations among localities, CMS adjusts the labor-related share by the wage index applicable to the metropolitan statistical area in which the hospital is located. The wage index values are based on wage data that hospitals include on their Medicare cost reports.

This audit found that a hospital in Connecticut did not fully comply with Medicare requirements on the reporting of wage data. The hospital overstated its wage data by more than \$404,000 for the Medicare FY 2000 cost report period. As a result, the FY 2004 Connecticut statewide rural wage index was overstated by about 1 percent, and the average payments to the 2 hospitals in the statewide rural area and to 17 additional hospitals in 2 urban metropolitan statistical areas were overstated by about \$24 per hospital discharge. The hospital concurred with OIG's recommendation to strengthen financial reporting controls. (A-01-04-00511)

Outpatient Cardiac Rehabilitation

This report consolidates audits of Medicare outpatient cardiac rehabilitation provided by 34 hospitals, as requested by CMS. Cardiac rehabilitation is a physician-supervised exercise program that includes specific types of exercises individually prescribed for each patient. To be covered by Medicare, outpatient cardiac rehabilitation services must be provided under the direct supervision of a physician and “incident to” a physician’s professional services.

Among the hospitals reviewed, OIG found two very different sets of practices with respect to both the provision of direct physician supervision and the physician (referring or hospital) whose professional services the cardiac rehabilitation was provided “incident to.” OIG attributed this situation to inconsistent guidance in three Medicare manuals that provided national guidance to health care providers. Most hospital officials believed that the guidance in the various manuals was confusing.

OIG recommended that CMS clarify national Medicare cardiac rehabilitation coverage requirements and direct fiscal intermediaries to educate hospitals on the clarified national Medicare coverage policy. CMS agreed to develop and publish provider education materials to clarify the direct physician supervision and “incident to” provisions of the cardiac rehabilitation benefit. (A-05-03-00102)

Medicare Contractor Administrative Costs

This audit disclosed that a Medicare contractor claimed almost \$13 million in administrative costs that were not allowable for Medicare reimbursement, including excessive data costs, duplicate costs, and unallowable overhead. The contractor did not have adequate control procedures to ensure that only allowable costs were claimed.

OIG recommended that the contractor make a \$13 million cost adjustment. (OIG made no procedural recommendations because the contractor has terminated its Medicare contracts.) The contractor agreed with most, but not all, of the recommended cost adjustment. (A-01-02-00509)

Organ Acquisition Costs

Medicare reimburses certified transplant centers for their proportionate share of costs associated with the acquisition of organs for transplant to beneficiaries. Reviews of two transplant centers focused on their compliance with Medicare requirements for claiming organ acquisition costs on Medicare cost reports:

- A transplant center in Texas did not have systems to accumulate certain costs of organ acquisition separately from the costs of posttransplant and other hospital activities. Noting unallowable and unsupported costs on the 1997 through 2001 cost reports, OIG recommended that the Medicare intermediary recover a \$4.2 million overpayment, work with the transplant center to determine the allowable portion of \$13.6 million in unsupported costs, monitor the center’s future cost reports, and instruct the center to make procedural improvements. The Medicare intermediary agreed with all recommendations. (A-06-04-00017)
- OIG found similar problems in reviewing the 2000 cost report of a transplant center in Indiana. OIG recommended that the Medicare intermediary recover a \$270,000 overpayment, work with the transplant center to determine the allowable portion of \$2.5 million in unsupported costs, monitor the center’s future cost reports, and instruct the center to make procedural improvements. The

intermediary stated that it had reopened the 2000 cost report to make adjustments and would make necessary adjustments to subsequent cost reports. (A-05-04-00049)

Self-Declaration of U.S. Citizenship for Medicaid

In an effort to simplify Medicaid application procedures, in recent years CMS has encouraged the practice of allowing self-declaration of U.S. citizenship in the Medicaid program. However, CMS has also encouraged States to maintain program integrity by verifying the accuracy of citizenship statements with other, nonapplicant sources, such as State vital statistics databases and/or by conducting posteligibility-focused reviews. This OIG report found that 47 States allow self-declaration of U.S. citizenship for Medicaid, but that 44 of these States require documentary evidence of citizenship if statements seem questionable. Twenty-seven States do not verify any U.S. citizenship statements as part of their posteligibility quality control activities. Further, some States use types of evidence to document citizenship for Medicaid that are not accepted by CMS or the Social Security Administration. Finally, OIG found that other programs related to Medicaid, including Temporary Assistance to Needy Families, Supplemental Security Income, and foster care, were more likely to document citizenship.

OIG recommended that CMS strengthen posteligibility quality controls in States that allow self-declaration, issue a complete list of evidence that States may reference when determining eligibility, and explore allowing State Medicaid staff to use citizenship verifications from other Medicaid-related programs. CMS concurred. (OEI-02-03-00190)

Self-Declaration of U.S. Citizenship for the State Children's Health Insurance Program

OIG issued this memorandum in response to a CMS request for information about States' policies on self-declaration of U.S. citizenship for State Children's Health Insurance Program (SCHIP) benefits.

OIG found that 49 of 50 States and the District of Columbia currently allow self-declaration of U.S. citizenship for SCHIP benefits. State SCHIP directors in these States report accepting a signed declaration of U.S. citizenship from parents or guardians seeking SCHIP benefits for children. In addition, nine States have policies on self-declaration for SCHIP eligibility that differ from their policies for Medicaid. (OEI-02-03-00191)

Nursing Home Enforcement: The Use of Civil Monetary Penalties

This inspection report revealed that although CMS imposed \$81.7 million in civil monetary penalties (CMPs) during calendar years 2000 and 2001, only \$34.6 million (42 percent) of that amount was paid as of December 2002. The difference was primarily attributable to reductions stipulated in regulations and delays resulting from appeals and bankruptcies.

OIG recommended that CMS provide additional written guidance to its regional offices and to State agencies regarding appropriate dollar ranges for individual ratings of scope and severity with regard to CMPs. OIG also recommended that CMS clarify staff responsibilities with respect to past-due CMPs and conduct an internal process review that would enable CMS and States to streamline CMP processing. CMS concurred with these recommendations. (OEI-06-03-00420)

Nursing Facility Performance in Assessing Residents in a Timely Manner and Submitting Required Data

The objectives of this review were to determine the extent to which Medicare/Medicaid-certified nursing facilities meet Federal requirements to assess residents according to the required time schedule, submit records to the Minimum Data Set (MDS) Repository within the prescribed timeframe, and submit records for all residents in Medicare/Medicaid beds. Overall, OIG found a high degree of facility performance resulting in a national MDS Repository that is current and representative of its intended resident population. Facilities completed 95 percent of resident assessments on time and submitted 94 percent of records in a timely manner. OIG also found that facilities submitted records for 99.9 percent of residents in Medicare/Medicaid-certified beds, as required. However, a subgroup of facilities incorrectly coded records for an estimated 1,812 residents in beds not certified for Medicare/Medicaid. As a result, these records were inappropriately included in the national MDS Repository.

OIG recommended that CMS ensure that nursing facilities correctly code records of residents in noncertified beds so that no such records are included in the national MDS Repository. In response, CMS explained its plans to ensure that records for residents in noncertified units are not transmitted and stored in the MDS Repository. (OEI-06-02-00730)

Informal Dispute Resolution for Nursing Facilities

As part of its ongoing evaluation of the quality of care provided to nursing facility residents, OIG examined States' policies and practices for informal dispute resolution (IDR) of deficiencies in patient care discovered during State surveys. OIG found that States and nursing facilities substantially complied with requirements for IDR. Forty-eight of fifty States had written IDR policies, and all 14 States for which OIG reviewed case documentation largely followed proper procedures in conducting IDRs. In 45 percent of the cases reviewed, deficiencies cited were changed as a result of the reviews.

CMS concurred with our recommendations to ensure that all States had qualifying written policies and that States follow procedures for requesting IDRs and communicating their results. (OEI-06-02-00750)

Medicaid Hospital Outlier Payments in Illinois

Illinois makes outlier payments to hospitals if the cost of treating a Medicaid patient is extraordinarily high compared with the average cost of treating comparable conditions. OIG found that Illinois's method of computing inpatient hospital cost outlier payments did not result in reasonable payments. Illinois used an out-of-date factor to convert billed charges to costs and did not have adequate procedures to monitor cost outlier payments. As a result, cost outlier payments increased significantly and at a faster rate than other types of Medicaid payments. If Illinois had applied a more current factor to convert billed charges to costs, it could have saved approximately \$56.5 million between 1998 and 2002 for the three hospitals that OIG reviewed.

OIG recommended that Illinois revise its method of computing cost outlier payments to ensure that payments are reasonable and that the State more closely monitor the payments. Although Illinois did not address the first recommendation, it outlined steps to strengthen its monitoring of outlier payments. (A-07-04-04031)

Medicaid Drug Rebate Program

The Medicaid drug rebate program allows Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs. Audits in 49 States and the District of Columbia found that only 4 States had no weaknesses in accountability and internal controls over their drug rebate programs. For the remaining 45 States and the District of Columbia, OIG identified weaknesses in the reliability of information submitted to CMS, accounting for interest on late rebate payments, rebate collection systems, and dispute resolution and collection processes.

OIG recommended that CMS reemphasize that States must submit accurate and reliable information to CMS and place a priority on their billing for and collection of drug rebates. CMS agreed with the recommendations. (A-06-03-00048)

Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices and Average Sales Price to Average Wholesale Price

During this reporting period, OIG released two companion reports on Medicaid prescription drug price comparisons. The reports found that statutorily defined prices for prescription drugs in the Medicaid and Medicare programs based on actual sales (average manufacturer price [AMP] and average sales price [ASP]) were substantially lower than published prices (average wholesale price [AWP]) and wholesale acquisition cost (WAC). Statutorily defined, sales-based prices were also lower than the States' estimated acquisition cost formulas, which are based on AWP and WAC. In addition, the differences between statutorily defined, sales-based prices and published prices were particularly large for generic drugs compared to brand-name drugs.

The first report, "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices," examined prices for Medicaid-reimbursed drugs (24,101 national drug codes). This report found that at the median, AMP was 59 percent lower than AWP. In comparison, the median AWP-based State estimated acquisition cost formula was AWP minus 12 percent. The difference between AMP and published prices was greatest for generic drugs. For generic drugs, AMP was 70 percent lower than AWP at the median. In comparison, AMP was 23 percent lower than AWP at the median for single-source brands and 28 percent lower for multisource brands. (OEI-05-05-00240)

The second report, "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price," examined prices for Medicare-covered drugs (2,077 national drug codes), which may also be covered by the Medicaid program. This report found that ASP was 49 percent lower than AWP. The difference between ASP and AWP was also greatest for generic drugs, similar to the companion report. For single-source brand codes, ASP was 26 percent below AWP at the median, and for multisource brand codes, ASP was 30 percent below AWP at the median. For generic national drug codes, ASP was 68 percent less than AWP at the median. OIG also found that the differences between AWP and other prices analyzed were similar for both reports. OIG found that the difference between AMP and AWP for generic drugs was 72 percent for Medicare-covered drugs. For single-source and multisource brand drugs, this report found that the differences between AMP and AWP for Medicare-covered drugs were 22 and 25 percent, respectively. (OEI-03-05-00200)

Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Price

In another report on Medicaid prescription drug pricing, OIG found that overall Federal upper limit amounts for generic drug products were five times higher than the average AMP amounts for the same products in the third quarter of 2004. During the same period, the Federal upper limit amount was, on average, 22 times higher than the lowest reported AMP. If Medicaid based Federal upper limit amounts on reported AMPs, the program could save hundreds of millions of dollars per year.

Although the purpose of the upper payment limit program was to ensure that the Federal Government acts as a prudent payer by taking advantage of market prices, Federal upper limit amounts are based on prices published in the national drug compendia. These published prices are often inflated and bear little or no resemblance to actual prices paid by providers. To correct this problem, OIG recommended that CMS work with Congress to set Federal upper limit amounts that more closely approximate acquisition costs. CMS concurred with OIG's recommendation. (OEI-03-05-00110)

Children Enrolled in Separate State Children's Health Insurance Programs and Medicaid Eligibility

This report fulfills the congressional mandate under the Balanced Budget Refinement Act of 1999 that OIG periodically determine the number of separate State Children's Health Insurance Program (SCHIP) enrollees who are also eligible for Medicaid and who, therefore, should have been enrolled in Medicaid rather than SCHIP. OIG found that only 1 percent of children enrolled in separate SCHIPs were eligible for Medicaid. However, inconsistent income calculations and lack of documentation create vulnerabilities that, if not addressed, could result in a greater number of children enrolled in separate SCHIPs who are required to be in Medicaid.

CMS concurred with OIG's findings and conclusions. It noted that current regulations support OIG's suggestion that CMS work closely with States to ensure that States maintain sufficient information in each applicant's record to support the eligibility determination. (OEI-07-03-00220)

New York City's Claims for Medicaid Speech Services

OIG found that New York City improperly claimed almost \$436 million in Federal Medicaid payments for speech services between September 1, 1993, and June 30, 2001. Of the 100 claims sampled, 86 did not comply with Federal and State requirements on, among other things, maintaining documentation to support services rendered, obtaining referrals from appropriate medical professionals, and meeting Federal standards on provider qualifications.

OIG recommended that the State refund the \$436 million, provide proper and timely guidance on Federal Medicaid criteria to New York City, improve its monitoring of speech claims, and instruct New York City to maintain appropriate documentation to support its claims. State officials disagreed with most aspects of the report. (A-02-02-01029)

New York City's Claims for Medicaid Transportation Services

OIG found that New York City improperly claimed more than \$96 million in Federal Medicaid payments for transportation services between September 1, 1993, and June 30, 2001. None of the 120 claims sampled complied with all Federal and State requirements. Deficiencies included lack of documentation to support services rendered, failure to render other Medicaid-covered school health services when transportation was billed, and failure to document the need for services.

OIG recommended that the State refund the \$96 million, work with CMS to resolve an additional \$12 million in set-aside claims, provide proper and timely guidance on Federal Medicaid criteria to New York City, improve its monitoring of transportation claims, and instruct New York City to bill its transportation claims properly and maintain appropriate documentation to support the claims. State officials disagreed with most aspects of the report. (A-02-03-01023)

Iowa's Adult Rehabilitation Services Program

Medicaid allows optional coverage of rehabilitation services. For FY 2002, Iowa claimed \$10.5 million in Federal Medicaid funds for adult rehabilitation services. Concerned about the allowability of claims and rising program costs, CMS requested that OIG review Iowa's program. Of the 100 claims sampled, 65 were unallowable under Federal and State requirements. The errors occurred because the State lacked adequate controls over the adult rehabilitation services program to ensure that services claimed for Medicaid reimbursement met applicable requirements.

OIG recommended that the State refund over \$6.2 million to the Federal Government and strengthen its policies and procedures. The State generally concurred with the recommendations.

(A-07-03-03041)

Upper Payment Limits

The upper payment limit (UPL) is an estimate of the amount that would be paid for Medicaid services under Medicare payment principles. The primary objective of the following reviews was to determine whether States calculated the UPLs for hospitals in accordance with Federal UPL regulations and the approved State plan amendments.

- **New Jersey** – New Jersey did not calculate the State FY 2003 inpatient and outpatient UPLs as required. The State continued to make payments for hospitals' inpatient services up to 150 percent of the UPL after the payment level had been reduced to 100 percent of the UPL, which resulted in unallowable Medicaid payments of \$17.6 million (\$8.8 million Federal share). The State also inadvertently applied an improper inflation factor in its outpatient UPL calculation, which resulted in unallowable Medicaid payments of \$3.8 million (\$1.9 million Federal share).

OIG recommended that New Jersey refund overpayments totaling almost \$10.7 million. New Jersey officials concurred with the recommendation. (A-02-03-01019)

- **North Carolina** – For State FY 2003, North Carolina's calculations of the UPLs for non-State government and private inpatient hospitals did not comply with its State plan amendment's requirement that the UPL be calculated based on costs incurred. As a result, the State made unallowable UPL payments of about \$42 million (\$26 million Federal share). The \$42 million is subject to adjustment during final cost settlement. Although the cost settlement process has been a State plan requirement since 1995, no final cost settlements have occurred since 1996. Also, contrary to Federal law and policy guidance, North Carolina did not include UPL payments in its calculation of State FY 2003 hospital-specific disproportionate share hospital (DSH) limits. Medicaid makes DSH payments to hospitals that serve disproportionate numbers of low-income patients with special needs. Although no DSH overpayment had occurred as of the end of OIG's audit period, the potential overpayment could have been at least \$42 million considering the excessive UPL payments cited above. Determining the actual DSH overpayment would require a final cost settlement.

OIG recommended that North Carolina revise its UPL and DSH calculations to comply with Federal and State requirements. OIG also recommended that the State resolve with CMS all outstanding issues affecting final cost settlements and, upon resolution, perform annual final cost settlements and refund the Federal share of any UPL and DSH overpayments. The State said that any action must await the conclusion of discussions with CMS. (A-04-03-02028)

Family Planning Service Costs

The Federal Government reimburses the costs of family planning services provided pursuant to Medicaid State plans at an enhanced 90-percent matching rate. These services are intended to prevent or delay pregnancy or to otherwise control family size. In three reviews, OIG found that States did not always comply with Federal requirements for claiming these costs to Medicaid.

- **Missouri** – Missouri retroactively claimed the \$11.1 million difference between the regular Federal matching rates and the enhanced 90-percent rate for prior family planning expenditures made since October 1995. The retroactive claim did not fully comply with Federal regulations, which generally limit reimbursement to claims filed within 2 years of the State expenditure. Of the \$11.1 million claimed, more than \$6.4 million did not meet this limitation and therefore was unallowable.

OIG recommended that Missouri refund the overpayment and ensure that future retroactive claims comply with Federal regulations. Missouri did not agree that its retroactive claim was subject to the 2-year rule. (A-07-04-01012)

- **New York** – New York State’s Medicaid Obstetrical Maternal Services (MOMS) program provides Medicaid-eligible pregnant women with improved access to maternity services. The MOMS services for which the State received Federal reimbursement at the enhanced 90-percent rate did not qualify as family planning services. As a result, the State improperly received almost \$1.6 million in Federal Medicaid funds for calendar years 2000 and 2003.

OIG recommended that the State refund the overpayment, issue to MOMS providers clear guidance that any procedures provided to pregnant women may not be claimed as family planning services, and strengthen its system edits to properly identify claims that are not related to family planning. The State generally concurred. (A-02-05-01001)

- **Virginia** – Between April 2001 and March 2004, Virginia overstated its claims for family planning service costs by \$3.7 million. Because the State claimed these costs at the enhanced family planning rate of 90 percent, rather than its regular Federal share of about 50 percent, Virginia received \$1.4 million in unallowable Federal reimbursement.

OIG recommended that Virginia refund the overpayment, apply an OIG-calculated factor to claims after March 2004, and refund the Federal share of any additional overpayments. Virginia concurred. (A-03-04-00209)

Hospital Patient Transfers Paid as Discharges Under Medicaid

This report summarized the results of audits in four States that had Medicaid payment provisions similar to the Medicare prospective payment system. OIG found \$6.4 million (\$3.6 million Federal share) in overpayments for hospital patient transfers incorrectly reported as discharges, as well as

potential overpayments of \$3.7 million (\$1.9 million Federal share) in these four States. In 25 other States and the District of Columbia, which prospectively pay for inpatient services and limit payments for transfers, OIG found that significant overpayments for transfers inappropriately billed as discharges could exist.

OIG recommended that CMS monitor the recovery of identified and potential overpayments described in the State-specific reports and encourage the 25 States and the District of Columbia to consider performing focused postpayment assessments of hospital discharges and to recover overpayments for transfers inappropriately billed as discharges. CMS agreed with the recommendations.

(A-05-03-00014)

Oklahoma's Medicaid Administrative Costs

At the request of CMS, OIG reviewed Medicaid administrative costs that Oklahoma claimed, as well as targeted case management costs claimed as administrative costs. OIG determined that almost \$3.6 million (\$1.8 million Federal share) in administrative costs claimed in one quarter and \$79.5 million (\$39.8 million Federal share) in targeted case management costs claimed over 5_ years were unallowable. The State should not have claimed targeted case management costs as administrative costs because they were separately reimbursed as a direct Medicaid service. Recognizing the error, the State made adjustments for most of the targeted case management costs; however, almost \$18.2 million (\$9.1 million Federal share) remained an overpayment at the end of the audit period.

OIG recommended that the State refund the remaining overpayments, improve its procedures for claiming administrative costs, and discontinue claiming targeted case management costs as administrative costs. The State did not agree with some of the findings. (A-06-03-00046)

Medicaid Provider Overpayments

Two reviews focused on the reporting of Medicaid provider overpayments to CMS. An overpayment is a payment to a provider in excess of the allowable amount.

- **District of Columbia** – In FY 2002, the District did not report overpayments totaling almost \$4 million (\$2.2 million Federal share) because the overpayments were under appeal and had not been collected. In addition, the District did not report overpayments totaling \$16.2 million (\$9.2 million Federal share) within the required timeframe because its practice was to report overpayments only after collecting them from providers. (A-03-03-00222)
- **West Virginia** – OIG noted similar problems in West Virginia for FY 2003. The State did not report over \$3.7 million in overpayments (\$2.9 million Federal share) because it was waiting to implement changes to its Medicaid Management Information System. The State also did not report over \$3.2 million (\$2.5 million Federal share) in overpayments within the required timeframe due to an oversight and because it did not use the correct date for “discovering” the overpayments.

OIG recommended that the District and West Virginia make financial adjustments, determine the value of overpayments identified after the audit period that have not been reported and report these as well, and ensure that future overpayments are reported within 60 days. The District concurred with the audit results and West Virginia partially concurred. (A-03-04-00207)

Medicaid Payments for Skilled Professional Medical Personnel

Federal regulations provide an enhanced rate of 75 percent for the compensation and training of skilled professional medical personnel and their supporting staff. OIG found that California improperly claimed about \$5.3 million in Federal Medicaid funding at the enhanced rate for FY 2003. The State's controls did not ensure that only eligible costs were claimed at the enhanced rate.

OIG recommended that the State refund the overpayments, strengthen controls to ensure that only eligible costs are claimed at the enhanced rate, and identify and refund costs improperly claimed at the enhanced rate after the audit period. The State did not comment on the recommended refund and partially agreed with the other recommendations. (A-09-04-00049)

Medicaid Payments for Deceased Beneficiaries

The Social Security Administration maintains a comprehensive file on all reported deaths of people who have Social Security numbers. This information is available to State and Federal agencies as a way to prevent payments for services rendered after a beneficiary's death. However, based on a statistical sample covering a 3-year period, OIG estimated that Florida paid \$11.6 million (\$6.5 million Federal share) for Medicaid services rendered after beneficiaries' deaths.

OIG recommended that the State review the sampling universe to identify and recover overpayments made on behalf of deceased beneficiaries and improve its procedures for identifying deceased beneficiaries to prevent future overpayments. The State agreed to implement the recommendations. (A-04-03-07029)

Status of Rural Health Clinic Program

In 1977, Congress created the Rural Health Clinic (RHC) Program to increase health services for Medicare and Medicaid beneficiaries living in rural underserved areas. To be eligible for RHC status, clinics must be located in areas that meet the RHC Act's definition of rural and underserved. Currently, 279 RHCs are located in areas that do not meet the rural and underserved criteria. Another 946 are located in shortage-designated areas that HRSA has not reviewed or updated within a 3-year period. Despite the identification of problems with the rural and underserved criteria in previous OIG and Government Accountability Office reports, the RHC Program continues to rely on them. Current rural and underservice criteria result in RHC participation in areas with existing health care systems. Because of its involvement in the RHC Program, OIG made recommendations to both HRSA and CMS.

OIG recommended that HRSA: (1) review shortage designations within the requisite 3-year period and (2) publish regulations to revise its shortage-designation criteria. OIG recommended that CMS: (1) issue regulations to ensure that only RHCs determined to be essential providers remain certified as RHCs, and (2) seek legislative authority or administratively require RHC applicants to document need and impact on access to health care in rural underserved areas. Both CMS and HRSA concurred with the recommendations. (OEI-05-03-00170)

CMS Oversight of Short-Term Acute Care Nonaccredited Hospitals

This report documents the extent to which the frequency of nonaccredited hospital surveys has changed since the 1999 OIG reports on the external review of hospital quality. Those reports found a large and growing number of short-term acute care nonaccredited hospitals that went 3 or more years without an oversight survey. In response, CMS committed to surveying nonaccredited hospitals every 3 years — the same frequency that the Joint Commission on Accreditation of Healthcare Organizations accredits hospitals. In this report, as in previous reports, we focused on short-term acute care nonaccredited hospitals, which now constitute 72 percent of all nonaccredited hospitals. OIG found that the percentage of short-term acute care nonaccredited hospitals surveyed within 3 years had improved from 50 percent to 79 percent between 1997 and 2003. However, the national annual survey rate is too low to sustain this progress. That rate for short-term acute care nonaccredited hospitals declined to 21 percent in 2003, from 28 percent in 2002, and 25 percent in 2001. Unless the national annual survey rate for short-term acute care nonaccredited hospitals increases, States will be unable to ensure that these hospitals are surveyed once every 3 years. The attention and resources that States can spend is limited by the number of nonaccredited hospitals converting to critical access hospitals, a growing number of complaint surveys, as well as demands to survey other facilities. OIG had no recommendations for CMS. (OEI-01-04-00020)

Outreach

As part of its ongoing effort to promote the highest level of ethical and lawful conduct by the health care industry, OIG has continued to issue advisory opinions, compliance guidance, and other guidance.

Advisory Opinions

In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, OIG, in consultation with the Department of Justice, may issue advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the Medicare and State health care programs. This authority allows OIG to provide case-specific formal guidance regarding the application of the anti-kickback statute and safe harbor provisions, and other OIG health care fraud and abuse sanctions. From the period April 1 through September 30, 2005, OIG received 29 advisory opinion requests and issued 4 advisory opinions.

Provider Self-Disclosure Protocol

In keeping with a longstanding commitment to assist providers and suppliers in detecting and preventing fraudulent and abusive practices, OIG established a set of comprehensive guidelines for voluntary self-disclosures, entitled “Provider Self-Disclosure Protocol,” available on the internet at <http://oig.hhs.gov> in the “Fraud Prevention & Detection” section.

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

To date, OIG has received 275 submissions. Self-disclosure cases have resulted in 55 recoveries and 55 settlements, totaling \$99.9 million collectively. For example:

- **Michigan** – After it self-disclosed conduct to OIG, St. Joseph Mercy-Oakland agreed to pay \$4 million to resolve its Civil Monetary Penalties Law (CMPL) liability for allegedly violating the Stark Law and anti-kickback statute. The hospital allegedly entered into improper financial arrangements with 14 different physicians and physician groups to induce patient referrals.

Federal and State Partnership: Joint Audits of Medicaid

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

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

OIG Administrative Sanctions

During this reporting period, OIG administered 2,135 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. A brief explanation of these sanction authorities can be found in Appendix G.

Program Exclusions

During this reporting period, OIG excluded 2,111 individuals and entities from participating in the Medicare and Medicaid programs and other federally sponsored health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of license revocation. Examples include the following:

- **Colorado** – A certified nurse aide was excluded for 25 years based on his conviction for sexual assault against a 77-year-old Alzheimer's nursing home patient. The man was sentenced to serve 15 years to life in prison.
- **Missouri** – Two individuals were excluded based on their multiple convictions for abuse that took place at a home for children with mental retardation. One individual was an emergency medical technician who was sentenced to 12 years in prison and excluded for 20 years. The other individual was a licensed practical nurse who was sentenced to 5 years in prison and excluded for 15 years.
- **New York** – A dentist's license was revoked by the New York State Education Department after he sexually assaulted numerous minor patients. Based on the action, OIG excluded the dentist for an indefinite period.

Civil Monetary Penalties

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties and assessments against a person or entity that, among other reasons, submits claims to a Federal health care program that the person or entity knows or should know are false or fraudulent. During this reporting period, OIG collected \$6.4 million in civil monetary penalties and assessments. For example:

- **District of Columbia** – MedStar Health Visiting Nurse Association, Inc., formerly known as The Visiting Nurse Association of Washington, D.C., and its home office, Visiting Nurse Association, Inc. (collectively, “MedStar VNA”), agreed to pay \$1.36 million and enter into a 5-year corporate integrity agreement to resolve their liability under the CMPL. OIG alleged that MedStar VNA submitted cost reports to the Medicare program for fiscal years ending in June 1998, 1999, and 2000 that contained claims that were false or fraudulent or that were not provided as claimed. In particular, OIG’s investigation focused on fraud allegations that MedStar VNA failed to disclose certain costs or provide documentation associated with related third parties in the relevant cost reports. The settlement agreement included the resolution of nonfraudulent adjustments that resulted in an outstanding Medicare overpayment for the fiscal year June 2000 cost report.
- **Virginia** – A practitioner agreed to pay \$46,000 to resolve his liability under the CMPL for allegedly violating the terms of his exclusion. OIG alleged that despite his exclusion, he sought and received employment with a nonprofit provider of community-based physical disability, mental health, and mental retardation services. The man allegedly served as the medical director for two of the facilities that received reimbursements for items and services furnished or prescribed by him. OIG learned of the alleged violation when the matter was self-disclosed by the practitioner’s employer.

Kickbacks

Individuals or entities that engage in unlawful referral or kickback schemes may be subject to criminal penalties under the Federal health care anti-kickback statute, civil monetary penalties under OIG’s CMPL authority, and/or program exclusion under OIG’s permissive exclusion authority. A description of these enforcement authorities can be found in Appendix G. The following are examples of kickback enforcement actions during this reporting period:

- **Pennsylvania** – Home Health Corporation of America (HHCA) agreed to pay \$300,000 and enter into a 5-year integrity agreement to resolve its liability under the CMPL provisions applicable to kickbacks. OIG alleged that from February 1997 through May 1998, HHCA made payments in the form of loans, consulting fees, and monthly space rental payments to six physicians located in Pennsylvania and Florida in exchange for their referral of Medicare beneficiaries requiring home health services and/or durable medical equipment provided by HHCA and paid for by the Medicare program.
- **Nebraska** – A former hospital chief executive officer (CEO) agreed to pay \$130,000 and to enter into a 3-year integrity agreement to resolve his liability under the CMP provisions applicable to kickbacks. OIG alleged that from September 1994 through October 1999, the former CEO provided financial assistance to a physician in the form of bank loan guarantees; payment of consultant fees; and the provision of discounted pharmaceuticals, biologicals, supplies, and medical equipment in exchange for her referral of Medicare beneficiaries requiring cardiology care to the hospital. As a result of the former CEO’s alleged conduct, he allegedly received annual bonuses that reflected, in

part, the referrals made by the physician to the hospital. The hospital previously entered into a False Claims Act settlement related to this conduct.

Patient Dumping

Of the total civil monetary penalties OIG collected between April 1 and September 30, 2005, \$213,000 represents collections from nine hospitals under the Emergency Medical Treatment and Labor Act, a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of settlements involving alleged violations of this statute:

- **Alabama** – Bessemer Carraway Medical Center - University of Alabama Medical West agreed to pay \$40,000 to resolve its CMP liability under the patient dumping statute. OIG alleged that Bessemer failed to provide a complete medical screening examination for a female patient who presented to Bessemer’s emergency department complaining of a fever and chills related to a kidney infection that had lasted for 4 days. The patient was allegedly seen by the triage nurse, who took the patient’s vital signs and allegedly concluded that the patient should be classified as nonurgent. The triage nurse allegedly instructed the patient to go to the registration desk to pay \$85. The patient allegedly left the hospital and went to another hospital where she was admitted and treated with IV antibiotics.
- **Louisiana** – St. James Psychiatric Hospital, Inc., agreed to pay \$30,000 to resolve its liability for CMPs under the patient dumping statute. OIG alleged that the hospital failed to accept appropriate transfers of two patients with psychiatric emergencies who needed the specialized capabilities of the hospital.

Criminal and Civil Enforcement

One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal health care programs involves the filing of false claims for reimbursement. False claims may be pursued under the civil False Claims Act and, in appropriate cases, under Federal and State criminal statutes. A description of these enforcement authorities can be found in Appendix G. The successful resolution of these matters often involves the combined investigative efforts and resources of OIG, Federal Bureau of Investigation, Medicaid Fraud Control Units (MFCUs), and a variety of other law enforcement agencies.

OIG has the responsibility to assist the Department of Justice in bringing and settling cases under the civil False Claims Act. Many providers elect to settle their cases prior to litigation. As part of their settlements, providers often agree to enter integrity agreements with OIG to avoid exclusions and to be permitted to continue participation in Medicare, Medicaid, and other Federal health care programs. These 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 activities.

In the fiscal year ending September 30, 2005, the Government negotiated \$1.4 billion in civil and administrative settlements related to Medicare, Medicaid, and other Federal health care programs. Some of these successful settlements, as well as notable criminal enforcement actions, are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

Hospitals

- **Alabama** – HealthSouth Corporation, the nation’s largest provider of inpatient and outpatient rehabilitation services, agreed to pay \$325 million plus interest to resolve allegations of fraud related to Medicare Parts A and B. The settlement resolved allegations of Medicare Part A cost report fraud involving false entries on HealthSouth’s home office cost statements and unallowable expenses on Medicare cost reports. The settlement also resolved allegations of Medicare Part B fraud concerning false claims for outpatient physical therapy services. HealthSouth allegedly billed the Medicare program for outpatient physical therapy services provided without a physician-certified plan of care, physical therapy services not performed by licensed providers, and one-on-one physical therapy when HealthSouth provided therapy services to more than one patient at a time.

In addition, HealthSouth entered into a 5-year corporate integrity agreement. Through a separate settlement with CMS, the company also resolved outstanding administrative issues relating to Medicare cost reports.

- **Pennsylvania** – Abington Memorial Hospital agreed to pay \$4.2 million and enter a 5-year corporate integrity agreement. Over a 9-year period, Abington allegedly submitted claims to Medicare for clinical laboratory services that were unbundled, upcoded, and/or double billed. In addition to the requirements of the corporate integrity agreement, the settlement agreement itself required the hospital to implement other specific compliance provisions, including the obligation to hire a new compliance team.

Home Health Agencies

- **Minnesota** – Intrepid USA Inc. agreed to pay \$8 million and enter a 5-year corporate integrity agreement to resolve its liability for allegedly submitting false claims to Medicare, Medicaid, TRICARE, and CHAMPUS between February 1997 and October 2004. Intrepid, a Minnesota-based corporation, owns and operates home health care and supplemental medical staffing businesses throughout the country. The Government alleged that Intrepid and certain affiliated entities submitted claims for home health services that were not provided by a qualified person, lacked physician orders and plans of care, lacked sufficient documentation of the patient’s homebound status, lacked an Outcome Assessment and Information Set evaluation, and/or were improperly coded. In addition, the Government alleged that during January 2002 through June 2003, Intrepid submitted claims to Medicaid for home health services that were not provided.
- **Louisiana** – A former owner of a home health agency was sentenced to 27 months in prison and ordered to pay \$2 million in restitution and a \$50,000 fine for defrauding the Medicare program. As part of the scheme, he diverted employees’ pension funds and bonuses paid by Medicare for his own personal use. Investigation revealed that Medicare funds were used to pay for lawn services at his home and for personal travel expenses.

Medicare Contractors

- **Pennsylvania** – United Healthcare Insurance Company agreed to pay \$3.5 million to resolve allegations that the contractor defrauded the Medicare program from 1996 to 2000. The Government alleged that United Healthcare’s telephone response unit mishandled beneficiary and provider phone inquiries and falsely reported its performance information to CMS while under contract with CMS as a regional carrier for durable medical equipment (DME) claims.

Durable Medical Equipment Suppliers

- **Texas** – The owner of a DME company was sentenced to 41 months imprisonment and ordered to pay \$2.2 million in restitution for health care fraud and money laundering. As part of the scheme, the man paid recruiters for locating Medicare patients and paid physicians for fraudulent certificates of medical necessity (CMNs) and prescriptions for wheelchairs. Though Medicare was billed for motorized wheelchairs, beneficiaries either never received wheelchairs at all or were provided with much less expensive scooters.
- **Oregon** – A DME supplier and its owner were sentenced for charges related to paying business associates to induce Medicare referrals. The company received reimbursements from Medicare for wheelchairs and accessories, hospital beds, and enteral nutrition that were not medically necessary. A \$2 million settlement agreement was previously reached, resolving their liability for DME that was allegedly either not provided or medically necessary and for allegedly using CMNs that were false, fraudulently obtained, or forged.

Prescription Drugs

- **Virginia** – A physician specializing in pain management was sentenced to 25 years imprisonment and ordered to pay a \$1 million fine for his conviction on illegal drug distribution charges. The physician was convicted following a 6-week jury trial on numerous charges of illegal drug distribution, including conspiracy to distribute controlled substances, and charges relating to drug trafficking that resulted in one death and serious bodily injury to others. The physician was also convicted for abusing a position of public and private trust and using a special skill in facilitating the commission and concealment of the offense. During the trial, the Government demonstrated that the physician knew his patients were selling and distributing the prescribed medications, including OxyContin. The physician performed perfunctory exams on patients then facilitated the patients' demand for excessive amounts of controlled substances. A narcotic drug approved for the treatment of moderate to severe pain, OxyContin is covered under the Virginia Medicaid program.

Nursing Homes

- **Connecticut** – Hillcrest Healthcare, Inc., agreed to pay \$750,000 to resolve its liability for the alleged failure to adequately oversee the management operations of the nursing home. The Government alleged that the nursing home submitted claims to Medicare and Medicaid from January 2002 through July 2004 for skilled nursing services provided to 22 beneficiaries that were not rendered in accordance with applicable laws, regulations, or rules, or were so inadequate as to constitute services that are not reimbursable under Medicare or Medicaid. Prior to the civil settlement, the State of Connecticut required Hillcrest to surrender its nursing home license, sell the facility, and pay a \$200,000 penalty. In addition, Hillcrest pled nolo contendere in January 2005 to second-degree manslaughter involving the death of a beneficiary and was ordered to pay a \$10,000 fine.
- **District of Columbia** – An owner of a nursing agency was sentenced to 15 months incarceration and ordered to pay \$74,000 in restitution for health care fraud. Beginning in January 2000, the woman engaged in a scheme to defraud Medicare and Medicaid by placing Certified Nurses Aides (CNAs) who she knew were not qualified or certified to work in various nursing facilities within the District of Columbia. The owner was able to accomplish her scheme by providing false and fictitious CNA registration cards.

Clinics

- **Washington** – Seattle Cancer Treatment and Wellness Center (SCTWC), an affiliate of Cancer Treatment Centers of America, agreed to pay \$478,000 and enter a 5-year corporate integrity agreement. SCTWC specializes in combining conventional oncology treatment with nonconventional medical treatments such as massage, acupuncture, and herbal medicine. The Government alleged that SCTWC submitted improper claims to Medicare and TRICARE for upcoded evaluation and management services and billed take-home oncology drugs as if they were physician administered.

Practitioners

- **Massachusetts** – An endocrinologist agreed to pay \$447,000 and enter a 5-year integrity agreement for allegedly submitting false claims to Medicare between January 1998 and December 2003. The Government alleged that the endocrinologist improperly billed cholesterol measurement services and also billed office visits as consultations and routine blood draws as critical care blood draws.
- **Tennessee** – A licensed social worker was sentenced to 6 months in jail and ordered to pay \$45,000 in restitution for health care fraud and false statements. The social worker administered a weekly program for a non-profit community mental health center. Though the program ended in 1999, the woman began to submit fraudulent claims to Medicare, Medicaid and TennCare for monthly and/or weekly individual psychotherapy services which were not provided for patients of the center. The center agreed to pay \$493,000 plus interest and enter a 5-year certification of compliance agreement to resolve its liability in the matter which it self-disclosed to OIG.

Medicaid Fraud Control Units

Currently, 48 States and the District of Columbia have Medicaid Fraud Control Units (MFCUs), which investigate and prosecute or refer for prosecution providers charged with defrauding the Medicaid program or abusing, neglecting, or financially exploiting beneficiaries in Medicaid-sponsored facilities. In FY 2004, OIG provided oversight for and administration of approximately \$131 million in Federal grant awards to the units. In FY 2005, OIG provided oversight for and administration of approximately \$149 million in Federal grant funds.

An example of a case worked jointly by OIG with the MFCU during this semiannual period follows:

- **South Dakota** – A retail pharmacy owner was ordered to pay \$83,000 in restitution for diverting pharmaceuticals from a nonprofit hospital. The owner used the illegally received pharmaceuticals to fill prescriptions for Medicaid patients. In November 2004, the pharmacy owner signed a stipulation and agreement with the South Dakota MFCU through which he agreed to pay \$9,000, the amount of unjust Medicaid reimbursements. This investigation involved OIG, the South Dakota MFCU, and the Food and Drug Administration.

Public Health Agencies

The activities conducted and supported by HHS public health agencies represent this country's primary defense against acute and chronic diseases and disabilities. These programs provide the foundation for the Nation's efforts in promoting and enhancing the continued good health of the American people.

- Public health agencies within the Department include:
- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention (CDC)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Agency for Healthcare Research and Quality (AHRQ)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

OIG continues to examine the policies and procedures of these agencies to determine whether appropriate controls are in place to guard against fraud, waste, and abuse. These activities include preaward and recipient capability audits and evaluations. This oversight work has provided valuable recommendations to program managers for strengthening the integrity of agency policies and procedures and improving program performance.

Public Health Agency-Related Reports

Outside Activities of Senior-Level National Institutes of Health Employees

OIG identified several vulnerabilities that inhibit National Institutes of Health's (NIH) ability to effectively review outside activities of senior-level employees. Departmental employees are allowed, with approval, to work privately with non-Federal entities on their personal time through outside activities. However, these activities must not conflict with employees' official duties. Although outside activities can offer many benefits, they can potentially create real or apparent conflicts of interest for employees. Between 2001 and 2003, 40 percent of NIH senior-level employees received approval for 319 outside activities. About half of these outside activities involved teaching or consulting and most were compensated. Vulnerabilities noted by OIG include the finding that employees submitted limited information regarding their outside activities. There are also several problems in the review process itself, such as approvals after the start date, limited use of written recusals, and inadequate followup of ongoing outside activities. To address these vulnerabilities, OIG recommended that NIH improve the quality and extent of information it receives about outside activities, and address inadequacies in the review process for outside activities. NIH concurred with the findings and recommendations. (OEI-01-04-00150)

Credentialing and Privileging at Indian Health Service Hospitals

Industry-wide standards and Indian Health Service (IHS) policy require credentialing and privileging reviews of medical practitioners, and the Indian Child Protection and Family Violence Prevention Act requires background investigations of all IHS employees and contractors. Concluding a series of reviews requested by IHS, OIG issued reports on two IHS-operated hospitals in Montana:

- One hospital did not verify the credentials of three-quarters of the sampled practitioners before they provided patient care, did not issue current privileges for 20 percent, and did not have information indicating that it had requested background investigations for 55 percent of practitioners. (A-07-03-00159)
- Another hospital did not verify the credentials of 55 percent of the sampled practitioners before they provided patient care, did not issue current privileges for 6 percent, and did not have information indicating that it had requested background investigations for 52 percent of practitioners. (A-07-03-00152)

OIG recommended that IHS direct both hospitals to complete credentialing and privileging reviews in a timely manner and to initiate the required background investigations for their practitioners. IHS stated that all recommended corrective actions had been taken.

Federal Efforts to Address Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees

Prompted by a congressional request, OIG studied whether and how the Office of Population Affairs (OPA) informs its Title X Family Planning program grantees of their obligations under State laws requiring the reporting of child abuse, child molestation, sexual abuse, rape (including statutory rape), and incest for Title X grantees. OIG also reviewed how OPA monitors its grantees regarding these requirements.

OIG found that OPA informed and periodically reminded Title X grantees of their responsibilities regarding State child abuse and sexual abuse reporting requirements. Furthermore, OPA included State reporting requirements in its reviews and site visits of grantees. (OEI-02-03-00530)

The Centers for Disease Control and Prevention's Management of HIV/AIDS Grants

The Centers for Disease Control and Prevention's (CDC) management of HIV/AIDS prevention grants during FYs 1999 through 2003 did not always comply with Federal requirements. OIG's review of CDC records on 15 grants — including 5 grants to State agencies and 10 grants to community-based organizations — identified deficiencies in the preaward, award, and postaward phases of grants management. The deficiencies existed because CDC management had not provided appropriate guidance to employees; the guidance in CDC's grants manual was not always consistent with laws, regulations, and departmental policies.

Given the extent of deficiencies identified, OIG concluded that CDC could not ensure that its grants management operations provided appropriate direction to and oversight of HIV/AIDS prevention grantees. Following the audit fieldwork, CDC rescinded the agency's grants manual and adopted an HHS-wide policy manual. (A-04-03-08011)

Hospital Bioterrorism Surge Capacity: Status of Early Implementation

In response to the fall 2001 terrorist attacks, Health Resources and Services Administration (HRSA) established the National Bioterrorism Hospital Preparedness Program Cooperative Agreement. The agreement includes critical benchmarks to increase hospital surge capacity in the event of another attack. As of spring 2004, OIG measured State achievement of surge capacity critical benchmarks based on State program officials' self-assessments gathered during site visits and telephone interviews. Of the 50 States, the District of Columbia, and the 3 municipalities OIG reviewed, 50 reported shortcomings in meeting the critical benchmarks. OIG also concluded that the failure to meet even one critical benchmark could undermine a hospital's ability to achieve overall surge capacity. To the extent that the barriers identified in this report still exist, HRSA can assist States in achieving hospital surge capacities by appropriately focusing future years' Cooperative Agreement guidance on those barriers. In addition, this report could help HRSA project officers better assist States by understanding the barriers individual States face in developing surge capacities. (OEI-04-03-00500)

Health Education Assistance Loan Defaults

Through the Health Education Assistance Loan (HEAL) program, HRSA guarantees commercial loans to students seeking education in health-related fields of study. The students are allowed to defer repayment of these loans until after they have graduated and begun to earn an income. Although the Department's Program Support Center (PSC) takes all steps it can to ensure repayment, there are loan recipients who ignore their indebtedness.

After PSC has exhausted efforts to secure repayment of a debt, it declares the individual in default. Thereafter, the Social Security Act permits, and in some instances mandates, exclusion from Medicare, Medicaid, and all Federal health care programs for nonpayment of these loans. Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered. During the period covered by this report, 26 individuals and related entities were excluded as a result of PSC referral of their cases to OIG.

Individuals who have been excluded as a result of default may enter into settlement agreements, whereby the exclusion is stayed while they pay specified amounts each month to satisfy the debt. If they default on these settlement agreements, the individuals can then be excluded until the entire debt is repaid and cannot appeal these exclusions. Some health professionals, upon being notified of their exclusion, immediately repay their HEAL debts.

After being excluded for nonpayment of their HEAL debts, a total of 1,939 individuals have taken advantage of the opportunity to enter into settlement agreements or completely repay their debts. This figure includes the 47 individuals who have entered into such a settlement agreement or completely repaid their debts during this reporting period. The amount of money being repaid through settlement agreements or through complete repayment totals \$139.9 million. Of that amount, \$3.2 million is attributable to this reporting period.

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

- A California chiropractor – \$224,000
- A Colorado dentist – \$155,000
- A Florida chiropractor – \$110,000

Public Health-Related Investigations

OIG also investigates allegations involving improper use of HHS grant funds. The following are examples of cases resolved during this reporting period:

- **Maryland** – Harlan Sprague Dawley, Inc. (HSD), agreed to pay \$7.2 million plus interest to resolve its liability for allegedly supplying researchers with genetically nonconforming lab mice. HSD, an Indiana-based supplier of laboratory rodents, was under two contracts with the National Institute on Aging, an institute within the National Institutes of Health, to supply rodents with certain genetic characteristics for use in age related research. The Government alleged that the C57 breeder mice HSD provided did not conform to the known C57 genetic profile. This called into question the genetic integrity of mice used for the two contracts and, in some cases, the validity of the age-related studies performed by researchers.
- **Alabama** – The University of Alabama at Birmingham (UAB) and its related parties agreed to pay \$3.4 million to resolve allegations concerning an NIH grant. The Government alleged that UAB misrepresented the amount of time to be spent by researchers on grant work and that UAB double-billed Medicare for medical services that were also paid through the grant. The agreement also requires UAB to submit a detailed compliance certification to OIG for a term of 3 years.

- **Pennsylvania** – The University of Pennsylvania (Penn), Children’s National Medical Center (CNMC), and three physician researchers entered into settlement agreements to resolve their liability for allegedly engaging in grant fraud in the course of conducting NIH- and FDA-funded clinical research on an investigational drug to treat a certain enzyme deficiency. As part of these settlements, Penn and CNMC agreed to pay \$517,000 and \$515,000, respectively. The three physician researchers agreed to substantial compliance obligations including training and the appointment of a medical monitor. Among other allegations, the Government contended that adverse reactions of patients were not reported, that the study continued when it should have been terminated, and that one patient died during the course of the research.
- **Massachusetts** – A former medical student was sentenced to 364 days in prison and ordered to pay \$304,000 in restitution on charges of loan and scholarship fraud. Originally in the United States on a student visa that later expired, the man used a false identity to obtain a bachelor’s degree and a medical degree using federally guaranteed loans and scholarships including a scholarship from the HHS’s Scholarships for Disadvantaged Students (SDS) program. SDS provides scholarships to full-time, financially needy students from disadvantaged backgrounds who are enrolled in health professions and nursing programs.

Administration for Children and Families and Administration on Aging

The Administration for Children and Families (ACF) provides direction and funding for programs designed to promote stability, economic security, responsibility, and self-support for the Nation's families. Some of the major programs include Temporary Assistance for Needy Families (TANF), Child Support Enforcement, Foster Care, Family Preservation and Support, Head Start, and the Child Care and Development Block Grant. OIG reviews of these programs focus on ways to increase the efficient use of program dollars; to more effectively implement programs; to better coordinate programs among the Federal, State, and local governments; and to strengthen States' financial management practices.

The Administration on Aging (AoA) awards grants to States for establishing comprehensive community-based systems that assist the elderly in maintaining their independence and in remaining in their homes as long as possible. Socially and economically disadvantaged elderly and low-income minority elderly are targeted for assistance, including supportive and nutrition services, education and training, low-cost transportation, and health promotion. OIG has reported opportunities for program improvements to target the neediest for services, expand available financial resources, upgrade data collection and reporting, and enhance program oversight.

Administration for Children and Families-Related Reports

Ability of Noncustodial Parents To Contribute Toward Medicaid Costs

This eight-State review found that States could reduce State and Federal Medicaid costs by increasing the number of noncustodial parents who provide medical support for their children pursuant to Title IV-D. For the 1-year period tested, 27 percent of Title IV-D children who were enrolled in Medicaid had noncustodial parents who were financially able to contribute toward their children's Medicaid costs. These noncustodial parents could contribute an estimated \$99 million of the Medicaid costs for the Title IV-D children reviewed in the eight States.

OIG recommended that ACF and CMS (1) provide specific guidance to States on collecting Medicaid costs from noncustodial parents who have the financial ability to pay and who do not have affordable employer-sponsored health coverage available, (2) clarify third-party liability regulations to assist State Medicaid agencies in coordinating with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders, and (3) seek legislation that would allow States to accumulate medical support payments to offset Medicaid fee-for-service costs for a reasonable period. The agencies generally agreed, though CMS believed that existing regulations and guidance provided sufficient authority for State Medicaid agencies to coordinate with State Title IV-D agencies. (A-01-03-02501)

Ability of Noncustodial Parents To Contribute Toward State Children's Health Insurance Program Costs

In this eight-State review, OIG estimated that 425,752 uninsured children whose noncustodial parents were unable to provide court-ordered medical support would have been eligible to receive State Children's Health Insurance Program (SCHIP) benefits during the audit period if no other health insurance had been available. An estimated 228,907 of these children had noncustodial parents who could have contributed \$130 million toward the \$214 million in costs that would have been incurred if the children had been enrolled. OIG also determined that 120,356 Title IV-D children received SCHIP benefits during the audit period. An estimated 34,066 of these children had noncustodial parents who could have contributed \$14 million toward the \$22 million in SCHIP premiums paid on behalf of their children.

OIG recommended that CMS issue program guidance to advise States of their authorities under Federal law to collect SCHIP costs from noncustodial parents and determine whether additional Federal funds are needed to assist States in interfacing their Title IV-D and SCHIP databases and in implementing a process to collect SCHIP costs from noncustodial parents and, as appropriate, provide such funds. CMS did not believe that formal guidance was necessary but agreed to informally alert States of their authority to collect SCHIP costs. CMS also commented that States already have the ability, under their 10-percent administrative SCHIP cap, to build the necessary infrastructure. (A-01-03-02502)

Children's Use of Health Care Services While in Foster Care: New York

OIG assessed whether sampled New York children in foster care have Medicaid coverage and are receiving health care services. OIG found that all 50 children in the sample have Medicaid coverage and access to health care services. However, many foster caregivers said they are not taught how to navigate the Medicaid system, in that they are not given an explanation of covered services or a schedule of

necessary doctors' appointments. As examples, 21 caregivers had not heard of Medicaid's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program, which requires each State to make preventive and follow-up care available to children receiving Medicaid, and 28 caregivers reported that they did not receive important information about their children's medical history.

OIG recommended that ACF and CMS work with New York to further promote access by addressing the caregivers' limited knowledge of Medicaid and the EPSDT. CMS concurred. OIG also recommended that ACF help the State ensure that the most complete medical histories are shared with the children's caregivers. ACF noted that New York's Program Improvement Plan contains action steps that address the gathering of medical information and the physical and mental health needs of children served by New York's child welfare system. (OEI-02-00-00362)

Adoption Assistance Payments in Maine

The adoption assistance program helps States to encourage the adoption of hard-to-place children. The Federal Government shares in the cost of adoption assistance maintenance payments for children who meet Federal eligibility requirements. The maintenance payments are based on a daily rate that varies depending on whether a child has special needs.

Maine did not consistently comply with Federal eligibility requirements in claiming adoption assistance maintenance payments during State FYs 2001 through 2003. For example, the State did not, in all cases, meet program income eligibility requirements or satisfy judicial determination requirements demonstrating that continuation in the home would be contrary to the child's welfare. As a result, the State claimed \$4.2 million (Federal share) in unallowable payments.

OIG recommended that the State make financial adjustments and claim future adoption assistance payments only for children meeting Federal eligibility requirements. The State concurred with the recommendations. (A-01-04-02503)

Title IV-E Administrative and Training Costs in Delaware

Title IV-E of the Social Security Act, as amended, authorizes Federal funds for States to provide foster care and adoption assistance for children. ACF provides funding at a 50-percent rate for State administrative expenditures and at an enhanced 75-percent rate for certain State training expenditures.

In this report, OIG expressed concerns about the allowability of \$6.2 million in Federal funding that Delaware claimed for administrative and training costs. The State allocated to the Title IV-E program a disproportionate share of costs for case management of Title IV-E candidates and used incorrect salaries to allocate costs to the claim. Also, contrary to Federal regulations, the State claimed indirect costs at the enhanced 75-percent Federal funding rate rather than the allowable 50-percent rate.

OIG recommended that the State make financial adjustments, improve its cost allocation plan, and strengthen its procedures. The State concurred with the recommendations. (A-03-03-00562)

Performance Data for Senior Medicare Patrol Projects

Senior Medicare Patrol Projects receive grants from AoA to recruit retired professionals to serve as educators and resources in assisting Medicare beneficiaries to detect and report fraud, waste, and abuse in the Medicare program. This report aimed to track performance data, perform comparative

data analysis, and verify documentation of overpayments recovered as a result of these projects. From July through December 2004, the 57 projects in operation educated over 179,600 beneficiaries in over 79,700 group training sessions and one-on-one sessions. As a result of these educational efforts, the projects received over 6,300 complaints, of which 559 were referred to Medicare contractors for followup. A total of 328 complaints resulted in money recouped to Medicare or other action taken, for a total of over \$27,200 recouped to the program. In addition, OIG documented savings of over \$149,100 to individuals, \$17,100 to Medicaid, and \$9,300 to beneficiaries. (OEI-02-04-00361)

Undistributable Child Support Collections in Illinois

ACF's Office of Child Support Enforcement (OCSE) requires States to offset Child Support Enforcement program costs by recognizing and reporting program income from undistributable child support collections and interest earned on program funds. OIG found that Illinois did not report program income for almost \$1.7 million in undistributable child support collections for the quarters ended December 1998 through December 2003. Illinois stated that it did not report this income because it was unaware of the reporting requirement. In addition, OIG was unable to determine the Federal program income portion of more than \$1.7 million in outstanding Cook County child support checks because data on the check register were insufficient to link checks to child support cases.

OIG recommended that Illinois make financial adjustments, work with OCSE to negotiate the Federal share of program income for the outstanding child support checks, and improve its procedures. Illinois agreed with most of the recommendations. (A-05-04-00039)

Child Support Enforcement

The detection, investigation, and prosecution of noncustodial parents who fail to pay court-ordered child support is a priority for OIG. Working with the OCSE, the Department of Justice, U.S. Attorneys' Offices, U.S. Marshals Service, and other Federal, State, and local partners, OIG develops ways to expedite the collection of child support. Since 1995, OIG has opened 2,986 investigations of child support cases nationwide, which have resulted in 1,106 convictions and court-ordered restitution and settlements of \$57 million.

Task Forces

In 1998, OIG and OCSE initiated "Project Save Our Children," a child support initiative made up of multiagency, multijurisdictional investigative task forces for child support enforcement. The task forces are designed to identify, investigate, and prosecute egregious criminal nonsupport cases on both the Federal and State levels by coordinating law enforcement, criminal justice, and child support office resources. See the child support task forces table below.

Task Force Table

Task Force Regions	Task Force Headquarters	Task Force States
Great Plains	Topeka, Kansas	Iowa, Kansas, Missouri, Nebraska, North Dakota, South Dakota
Mid-Atlantic	Baltimore, Maryland	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia
Midwest	Columbus, Ohio	Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
New England	Boston, Massachusetts	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Northeast	New York, New York	New Jersey, New York, Puerto Rico, Virgin Islands
Pacific North	Olympia, Washington	Alaska, Idaho, Oregon, Washington
Rocky Mountains	Denver, Colorado	Colorado, Montana, Utah, Wyoming
Southeast	Atlanta, Georgia	Alabama, Florida, Georgia, Kentucky, North Carolina, South Carolina, Tennessee
Southwest	Dallas, Texas	Arkansas, Louisiana, Mississippi, New Mexico, Oklahoma, Texas
West Coast	Sacramento, California	Arizona, California, Hawaii, Nevada

Central to the task forces are the screening units located in each task force region and staffed by investigative analysts from OIG and OCSE. The units receive child support cases from the States, conduct preinvestigative analyses of these cases through the use of databases, and then 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.

At this point, the task force units have received over 9,030 cases from the States. As a result of the work of the task forces, 550 Federal arrests have been executed and 529 individuals sentenced. The total ordered amount of restitution related to Federal investigations is \$25.4 million. There have been 366 arrests at the State level and 343 convictions or civil adjudications to date, resulting in \$18.2 million in restitution being ordered.

Investigations

OIG investigations of child support cases, nationwide, resulted in 63 convictions and court-ordered restitution and settlements of \$3.6 million during this semiannual period. Examples of the Federal arrests, convictions, and sentences for failure to pay child support include the following:

- **New Jersey** – A man was sentenced to 24 months' incarceration, 1 year of probation and ordered to pay \$145,000 in restitution for failure to pay child support. The man, who holds a master's degree in electrical engineering, was found guilty at the conclusion of his jury trial.

- **Ohio** – A man was sentenced to 5 years' probation and ordered to pay \$52,000 in restitution for failure to pay child support. In 1988, the man was ordered to pay support for his three children. He made sporadic payments until May 1997 at which time he stopped paying completely. As part of his probation, he was ordered to participate in a drug treatment program for 3 years.
- **Florida** – A man was sentenced to 5 years' probation and ordered to pay \$47,000 in restitution for failure to pay child support. Since 1986, the man made only two support payments for his two children who are now emancipated. A fugitive from justice for years, the man was arrested in Tennessee and extradited back to Florida in 2004. As part of his sentence, the man was ordered to enroll in an alcohol treatment program.
- **South Dakota** – A man was sentenced to 5 years' probation and ordered to pay \$6,000 for failure to pay child support; prior to sentencing, he paid \$19,000. The man used numerous alias names, Social Security numbers, and dates of birth to avoid paying child support. In a bankruptcy proceeding, which was revealed during the investigation, the man listed himself as the owner of a California-based company with assets of over \$15 million.

General Oversight

The Office of the Assistant Secretary for Budget, Technology and Finance (ASBTF) is responsible for developing and executing the Department of Health and Human Services (HHS) budget; ensuring that HHS performance measurement and reporting are in compliance with the Government Performance and Results Act; establishing and monitoring departmental policy for financial management (including debt collection, audit resolution, cost policy, and financial reporting); and developing and monitoring HHS information technology policy (including information technology security). The Assistant Secretary is the Department's Chief Financial Officer and oversees the Department's Chief Information Officer. The Department also has the responsibility, by virtue of the magnitude of its funding, to negotiate the payment rates and methods that many outside entities, such as State and local governments, charge for administering HHS and other Federal programs.

The Office of the Assistant Secretary for Administration and Management (ASAM) is responsible for HHS policies regarding human resources, grants, and acquisition management. This office also oversees the Program Support Center, which provides a range of administrative services, such as human resources, financial management, and administrative operations.

OIG has general oversight responsibility for these activities. A related major responsibility derives from Office of Management and Budget Circular A-133, under which HHS is the cognizant agency to audit the majority of Federal funds awarded to major research schools and State and local government cost allocation plans. OIG also oversees the work of non-Federal auditors of Federal money at some 6,700 entities, such as community health centers and Head Start grantees, as well as at State and local governments, colleges and universities, and other nonprofit organizations. OIG also is responsible for auditing the Department's financial statements.

OIG reviews audits, inspections, and studies performed by others, such as the Office of Management and Budget's Program Assessment and Rating Tool and reports of the Government Accountability Office. It takes these studies into account when planning its own work and examines management actions designed to correct the deficiencies cited in these prior studies.

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 are required to have an annual organization-wide audit of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entity's management of Federal funds. In the second half of FY 2005, OIG's National External Audit Review Center reviewed 977 reports that covered \$1.2 trillion in audited costs. Federal dollars covered by these audits totaled \$423.4 billion, about \$189.9 billion of which was HHS money.

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

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

Reports issued:	
Without changes or with minor changes	829
With major changes	110
With significant inadequacies	<u>38</u>
Total:	977

The 977 reports included recommendations for HHS program officials to take action on cost recoveries totaling \$1.3 billion, as well as 4,049 recommendations for improving management operations. In addition, these audit reports provided information for 84 special memorandums that identified concerns for increased monitoring by departmental management.

Resolving Recommendations

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

Table 1: Reports with Questioned Costs*

Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
For which no management decision had been made by the beginning of the reporting period ¹	729	\$2,289,132,000	\$299,806,000
Issued during the reporting period	66	\$733,742,000	\$85,379,000
Total Section 1	795	\$3,022,874,000	\$385,185,000
Section 2			
For which a management decision was made during the reporting period ^{2,3}			
Disallowed costs	430	\$952,435,000	\$122,888,000
Costs not disallowed	63	\$30,477,000	\$128,000
Total Section 2	493	\$982,912,000	\$123,016,000
Section 3			
For which no management decision had been made by the end of the reporting period			
Total Section 1 minus Total Section 2	302	\$2,039,962,000	\$262,169,000
Section 4			
For which no management decision was made within 6 months of issuance ⁴	230	\$1,312,335,000	\$131,233,500

* Details concerning footnotes can be found in Appendix D.

Table 2: Funds Recommended to be Put to Better Use*

Reports	Number of Reports	Dollar Value
Section 1		
For which no management decision had been made by the beginning of the reporting period ¹	59	\$7,331,320,000
Issued during the reporting period	6	\$72,665,000
Total Section 1	65	\$7,403,985,000
Section 2		
For which a management decision was made during the reporting period		
Value of recommendations that were agreed to by management		
Based on proposed management action	23	\$6,439,478,000
Based on proposed legislative action		
Value of recommendations that were not agreed to by management	3	\$14,357,000
Total Section 2	26	\$6,453,835,000
Section 3		
For which no management decision had been made by the end of the reporting period ²		
Total Section 1 minus Total Section 2	39	\$950,150,000

* Details concerning footnotes can be found in Appendix D.

Legislative and Regulatory Review and Development

Regulatory Review Functions

Section 4(a) of the Inspector General Act of 1978 requires that the Inspector General review existing and proposed legislation and regulations and make recommendations in this report concerning the impact on the economy and efficiency of the administration of the Department's programs and on the prevention of fraud and abuse. In reviewing regulations and legislative proposals, OIG uses as the primary basis for its comments the audits, inspections, investigations, and other activities highlighted in this and previous semiannual reports.

During the fiscal year 2005 reporting period, OIG was involved in the review and clearance of the implementing regulations resulting from the various Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions. OIG took part in the multiple review and submittal of substantial comments and recommendations relating to potential fraud and abuse issues in conjunction with implementation of the regulations for the Medicare Part D Prescription Drug Benefit, establishment of the Medicare Advantage program, and e-prescribing standards for the prescription drug program. OIG's general concerns have been with reviewing vulnerabilities and ensuring OIG's ability to conduct effective oversight.

Regulatory Development

OIG is responsible for the development and publication of a variety of sanction regulations addressing civil money penalty and program exclusion authorities administered by the Inspector General, as well as regulations promulgating safe harbors related to the anti-kickback statute. During this semiannual reporting period, OIG:

- Published final regulations addressing OIG's authority to impose civil money penalties against endorsed sponsors under the Medicare prescription drug discount card program that knowingly engage in false or misleading marketing practices, overcharge program enrollees, or misuse transitional assistance funds.
- Finalized and published revised Healthcare Integrity and Protection Data Bank regulations addressing data collection reporting requirements. The rule specifically clarified the types of personal numeric identifiers that may be reported to the data bank in connection with adverse actions.
- Developed and published proposed rulemaking in accordance with section 431 of MMA establishing regulatory standards for a new safe harbor under the Federal anti-kickback statute for certain goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act.
- In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published revised final regulations addressing OIG's authority to impose civil money penalties against any individual or other person involved in the possession, use, and transfer of prohibited select agents and toxins as set forth in 42 CFR part 73.

- Prepared and published a corrections amendment to the Healthcare Integrity and Protection Data Bank regulations in 45 CFR part 61 to clarify the existing definition for the term “any other negative action or finding.”

In addition, during fiscal year 2005, OIG continued to develop and publish a number of Federal Register notices that serve to reflect OIG policy and procedures with regard to compliance program guidance and other OIG administrative matters. During this semiannual period, OIG:

- Developed and published final Supplemental Compliance Program Guidance for Hospitals that provided voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.
- In accordance with section 205 of the Health Insurance Portability and Accountability Act, published the OIG annual notice soliciting proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.
- Developed and published a Federal Register notice setting forth specific revisions to Part A, Chapter AF of OIG’s Statement of Organization, Functions, and Delegations of Authority. The revised organizational statement reflects a recent realignment of certain functions for carrying out the statutory requirements for operating OIG.

Employee Fraud and Misconduct

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

- **Arizona** – A former Indian Health Service employee was sentenced to concurrent terms of 5 years in prison for theft and 3 years in prison for forgery and ordered to pay \$770,000 in restitution. During a 5-year period, the long-time Federal employee deposited State Medicaid program insurance checks made payable to IHS into his personal bank account.

Prosecutions

During this semiannual reporting period, OIG investigations resulted in 279 successful criminal actions. Also during this semiannual period, 780 cases were presented for criminal prosecution to the Department of Justice and, in some instances, to State and local prosecutors. Criminal charges were brought by prosecutors against 350 individuals and entities.

In addition to terms of imprisonment and probation imposed in the judicial processes, \$522 million was ordered to be returned or returned as a result of OIG investigations during this reporting period. Civil settlements from investigations resulting from audit findings are included in this figure.

Appendixes

Appendix A

Savings Achieved Through Policy and Procedural Changes Resulting From Audits, Investigations, and Inspections April 1 Through September 30, 2005

The following schedule highlights savings resulting from Office of Inspector General (OIG) efforts to prevent unnecessary obligations for expenditures of Federal funds or to improve agency systems and operations. These achievements depend greatly on the contributions of others, such as partners within the Department. The amounts shown represent funds or resources that will be available for better use as a result of documented measures taken by Congress or by management in response to OIG audits, investigations, and inspections, including actual reductions in unnecessary budget outlays; deobligations of funds; reductions in costs incurred or preaward grant reductions from agency programs or operations; and reduction and/or withdrawal of the Federal portion of interest subsidy costs on loans or loan guarantees, insurance, or bonds.

Legislative savings are annualized amounts based on Congressional Budget Office (CBO) fiscal year estimates for the related legislation. OIG calculates annualized administrative savings based on departmental figures, where available, for the year in which the change is effected or for multiple years, if applicable. The savings listed on the table below represent approximately one-half of the annualized savings.

Total savings from these sources were nearly \$16.686 billion (\$16,685,700,000) for this semiannual period.

OIG Recommendation	Implementing Action	Savings (millions)
CENTERS FOR MEDICARE & MEDICAID SERVICES		
<p>Medicare Home Health Payments: CMS should restructure the payment system for home health care to eliminate inappropriate incentives that unnecessarily increase cost and utilization; prevent unscrupulous providers from gaining entry into the program; and improve program controls, such as eligibility determinations and approval of plans of care and services. (OEI-04-93-00260 OEI-09-96-00110, A-04-96-02121)</p>	<p>Chapter 1 of Subtitle G of the Balanced Budget Act of 1997 (BBA) (as amended by the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1998), which pertains to home health benefits, addresses OIG's concerns regarding the need to restructure and control the payment system for these services. For example, it mandates that a prospective payment system be developed and that the total payments in fiscal year (FY) 2000 be equal to the amount that would have been paid under the prior system if cost limits were reduced by 15 percent. It also eliminates periodic interim payments to home health agencies.</p>	\$6,630

OIG Recommendation	Implementing Action	Savings (millions)
<p>Medicare Indirect Medical Education: CMS should base the indirect medical education adjustment factor on the level support by CMS's empirical data. (A-07-88-00111)</p>	<p>Section 4621 of the BBA (as amended by the Balanced Budget Refinement Act of 1999) reduced the indirect teaching adjustment factor from 7.7 percent in FY 1997 to 7.0 percent in FY 1998, 6.5 percent in FY 1999, 6.0 percent in FY 2000, and 5.5 percent in FY 2001 and thereafter.</p>	<p>\$2,440</p>
<p>Medicaid Enhanced Payments to Local Providers: CMS should 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. (A-03-00-00216)</p>	<p>On January 18, 2002, 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 on May 15, 2002.</p>	<p>\$2,400</p>
<p>Payment Reform for Part B Drugs and Biologicals: CMS should reexamine drug reimbursement methodologies based on average wholesale price (AWP) with the goal of reducing payments in both Medicare and Medicaid. (Multiple reports and testimony, including OEI-03-96-00420, OEI-03-97-00290, OEI-03-00-00310, OEI-03-97-293, A-06-00-00023, A-06-01-00053, A-06-02-00041)</p>	<p>Sections 303-305 of the MMA revised the current payment methodology for Part B covered drugs and biologicals that were not paid on a cost or prospective payment basis. Under the MMA, most drugs were to be paid at 85 percent of the April 1, 2003, AWP effective January 1, 2004, unless they fell under certain exceptions. CBO specifically attributed the FY 2004 savings to sections 304 and 305. After 2004, most drug prices are to be based on the average sales price or competitive acquisition instead of AWP.</p>	<p>\$800</p>
<p>Medicare Secondary Payer: CMS should ensure sufficient resources and contractor training for retroactively examining paid claims to identify other payer sources and initiating recovery action on all related overpayments. (Multiple reports and testimonies, including A-02-98-01036, A-04-92-02057, A-09-89-00162, A-10-86-62005)</p>	<p>Section 301 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) clarifies, retroactively, the Secretary's authority to make certain reimbursable conditional payments and take recovery actions against all responsible entities, including collection of damages, under Medicare's secondary payer provisions. This action builds on other program improvements related to OIG's work that were implemented by the BBA of 1997, OBRA 1993, OBRA 1990, and OBRA 1989.</p>	<p>\$600</p>
<p>Graduate Medical Education Payments: CMS should reevaluate Medicare's policy of paying graduate medical education (GME) costs for all physician specialties and consider backing legislation to reduce Medicare's investment in GME for a more accurate and representative sharing of GME costs. (A-06-92-00020)</p>	<p>Sections 4623 and 4626 of the BBA provided for limits in the number of residents counted for purposes of Medicare GME payments and offered payments for voluntary reductions in the number of residents to limit Medicare's share of GME costs.</p>	<p>\$590</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Payment for Durable Medical Equipment: CMS should take steps to reduce payments for a variety of DME and related supplies. (Multiple reports including OEI-03-01-00680, OEI-03-02-00700, OEI-07-96-00221, OEI-03-96-00230, OEI-03-94-0021, OEI-06-92-00861, OEI-06-92-00866)</p>	<p>Section 302 of the MMA froze payments for certain DME items, including prosthetic devices, prosthetics, and orthotics, effective January 1, 2004.</p>	<p>\$400</p>
<p>Medicare Home Health Payments: The home health agency update factor should be reduced to account for the high error rate found in OIG's review. The annual update was defined as the home health market basket percentage increase. (A-04-99-01194)</p>	<p>Section 701 of the MMA changes the updates of home health rates from fiscal year to calendar year beginning in 2004, with the update for the last 3 quarters of 2004 equal to the market basket increase minus 0.8 percent.</p>	<p>\$300</p>
<p>Clinical Diagnostic Laboratory Tests: CMS should seek legislation to allow across-the-board adjustments in Medicare laboratory fee schedules, bringing them in line with the prices that laboratories charge physicians in a competitive marketplace and periodically evaluate the national fee schedule levels. (A-09-89-00031, A-09-93-00056)</p>	<p>Sections 628 of the MMA froze annual updates for FY 2004 through FY 2008. This action builds on prior legislative actions in the BBA of 1997, 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>\$200</p>
<p>Payment for Services Furnished in Ambulatory Surgical Centers: CMS should set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and establish parity among Ambulatory Surgery Centers (ASC) and outpatient departments. (OEI-05-00-00340, OEI-09-88-01003, A-14-98-00400, A-14-89-00221)</p>	<p>Section 626 of the MMA limited the ASC update starting April 1, 2004, then freezes updates for a period beginning the last quarter of FY 2005.</p>	<p>\$200</p>
<p>Hospice Certification: CMS should restructure hospice benefit policies to curb inappropriate growth in the program, particularly with regard to the fourth benefit period. (OEI-05-95-00250, A-05-96-00023)</p>	<p>Sections 4441-4449 of the BBA contained provisions to control hospice payments and practices, such as replacing the current unlimited fourth benefit period with an unlimited number of 60-day benefit periods (each requiring recertification).</p>	<p>\$80</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Fraud and Abuse Provisions of the Balanced Budget Act: CMS should require durable medical equipment (DME) suppliers and home health agencies to provide Social Security numbers and employee identification numbers (OEI-04-96-00240, OEI-09-96-00110); refuse to enter into provider agreement with any home health agency whose owners or principals have prior criminal records or are the relatives of owners of a provider that had defrauded Medicare (OEI-09-96-00110); apply “inherent reasonableness” provisions when assessing the appropriateness of Medicare payments (OEI-03-94-00392); and authorize competitive bidding as a means of providing Medicare services (OEI-03-94-00021, OEI-06-92-00866, OEI-03-96-00230). Also, CMS should clarify which general and administrative and fringe benefit costs at hospitals and home health agencies are related to patient care; specifically, distinguish between employee benefits and/or prerequisites to entertainment and patient care, and specify that the cost of entertainment, goods or services for personal use, alcohol, all fines and penalties and associated interest, dues, and membership costs associated with civic and community organizations are not allowable. (A-03-92-00017, A-04-93-02067)</p>	<p>Subtitle D of the BBA contained a number of provisions that corresponded to and were supported by OIG work. For example, the BBA authorized the Secretary to collect Social Security numbers and employer identification numbers from entities under Medicare, Medicaid, and Title V; authorized the Secretary to refuse to enter into contracts with physicians or suppliers that have been convicted of felonies; authorized the exclusion of entities owned or controlled by the family or household members of excluded individuals; authorized CMS to make inherent reasonableness adjustments up to 15 percent to all Part B services except physician services; authorized up to five demonstration projects to be completed by December 31, 2002 (one must be oxygen and oxygen equipment) which can have multiple sites to allow competitive bidding; and prohibited “reasonable cost” payments for items such as entertainment, gifts and donations, education expenses, and personal use of automobiles.</p>	<p>\$80</p>
<p>Rural Health Clinics: The oversight and functioning of the current cost reimbursement system should be improved by implementing caps on provider-based rural health clinics and allowing States to do so, or finding other ways to make reimbursement between provider-based and independent clinics more equitable. In addition, the certification process should be modified to increase State involvement and ensure more strategic placement of rural health clinics. Recertification should be required within a specific time limit (for example, 5 years), applying new criteria to document the need and impact on access. (OEI-05-94-00040)</p>	<p>Section 4205 of the BBA extended the per-visit payment limits to provider-based clinics and stipulated that the shortage area requirements designation be reviewed triennially.</p>	<p>\$80</p>
<p>Hospital Sales: CMS should eliminate the requirement that Medicare adjust for gains and losses when hospitals undergo changes of ownership. (OEI-03-96-00170)</p>	<p>Section 4404 of the BBA eliminated the requirement that Medicare make adjustments by setting the Medicare capital asset sales price equal to the net book value.</p>	<p>\$60</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Payments for Ambulance Services: CMS should seek legislative authority to develop a fee schedule for ambulance transportation and examine the inherent reasonableness of current allowable charges. (OEI-05-95-00300)</p>	<p>Section 4531 of the BBA of 1997 made interim reductions in ambulance payments by limiting the allowed rate of increase and mandated the establishment of a fee schedule by January 1, 2000. Such fee schedule is to be set so that aggregate payments are reduced by 1 percent.</p>	<p>\$20</p>
<p>ADMINISTRATION FOR CHILDREN AND FAMILIES</p>		
<p>Availability of Health Insurance for Title IV-D Children: Connecticut should either implement policies and procedures to require noncustodial parents to pay all or part of the Medicaid costs for their dependent children or establish a statewide health insurance plan that provides reasonably priced, comprehensive coverage for children, with costs paid by noncustodial parents. (A-01-97-02506)</p>	<p>The BBA of 1997 established Title XXI of the Social Security Act, known as the State Children's Health Insurance Program (SCHIP), to enhance Medicaid coverage provided to children and allow States to create insurance options for families who exceed Medicaid resource and income limits. Connecticut received CMS approval in April 1998 to initiate a child health program. Under Connecticut law, applicants include noncustodial parents under court orders to provide health insurance.</p>	<p>\$5.7</p>
<p>PRIOR SEMIANNUAL REPORTING PERIOD CORRECTION</p>		
<p>Medicare Outlier Payments: To prevent future inappropriate outlier payments, CMS should focus its attention on (1) determining how to limit, if not eliminate, the policy which allows for the use of the statewide rate in place of a hospital-specific rate, (2) dramatically reducing the time lag between the payment of outliers and the actual closing of a specific hospital's cost report, particularly for the hospitals that the fiscal intermediary identify as having significantly increased their charges, and (3) eliminating the hospitals' ability to construct and manipulate charges to determine whether an outlier payment is warranted in a specific medical case without regard to the actual costs involved in that case. (A-07-02-04007)</p>	<p>CMS issued new regulations on June 9, 2003. As a result of the new regulations, the Medicare program is estimated to save at least \$9 billion from 2004 to 2008.</p> <p>Note: This item of savings was unintentionally omitted from the spring 2005 Semiannual Report. It is included here to correct that omission.</p>	<p>\$1,800</p>

Appendix B

Unimplemented Office of Inspector General Recommendations to Put Funds to Better Use

This schedule represents potential annual savings or one-time recoveries that could be realized if OIG recommendations were enacted by Congress or the Department through legislation, regulation, or management action. In some cases, these recommendations are beyond the direct authority of the departmental operating division. Congress develops savings over a 5- or 10-year budget cycle that result in far greater dollar impact than the annual estimates shown in the table below. The same can be said for regulations issued and management actions taken by the Department. Savings are based on preliminary OIG estimates and reflect economic assumptions that are subject to change. The magnitude of the savings may increase or decrease because of interactive effects if changes are enacted together.

More detailed information may be found in OIG’s “Red Book.” (See <http://oig.hhs.gov>.)

OIG Recommendation	Status	Savings (millions)
CENTERS FOR MEDICARE & MEDICAID SERVICES		
<p>Clinical Laboratory Tests: CMS should develop a methodology and legislative proposal to pay for tests ordered as custom panels at substantially less than the full price for individual tests and study reinstating the beneficiary coinsurance and deductible provisions for laboratory services as a means of controlling utilization. (A-09-89-00031, A-09-93-00056)</p>	<p>CMS initially agreed with the first recommendation but not the second. The BBA required the Secretary to request that the Institute of Medicine (IOM) study Part B laboratory test payments. As a result of IOM’s recommendations, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that CMS conduct a demonstration that applies competitive bidding for clinical laboratory services. The initial report to Congress is due by December 31, 2005.</p>	\$1,130*
<p>Outpatient Surgery Rates: CMS should seek authority to set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and remove the procedure codes that meet its criteria for removal from the Ambulatory Surgery Center (ASC) list of covered procedures. (A-14-89-00221, A-14-98-00400, OEI-05-00-00340)</p>	<p>CMS agreed to consider seeking authority to set rates that are consistent across sites as it develops its legislative program. CMS also issued a notice of proposed rulemaking, which has not been finalized, that would remove certain procedure codes from the ASC list of covered procedures.</p>	\$1,100

*This savings estimate would result from the copayment; the savings estimate for panels has yet to be determined.

OIG Recommendation	Status	Savings (millions)
<p>Medicaid Reimbursement for Brand-Name Drugs: CMS should encourage States to bring pharmacy reimbursement more in line with pharmacies' actual acquisition cost of brand-name drugs. OIG recommended a four-tier approach to reimbursement: single-source innovator drugs, all drugs without Federal upper payment limits (UPL), multiple-source drugs without Federal UPLs, and multiple-source drugs with Federal upper limits. (A-06-00-00023, A-06-02-00041)</p>	<p>CMS concurred with OIG's recommendation and is working with States to review their estimates of acquisition costs in light of OIG's findings. In addition, the President's FY 2006 budget proposed a legislative change that would limit the Federal reimbursement to States for Medicaid pharmacy payments to the amount that the State would have paid, in the aggregate, for covered outpatient drugs based on the manufacturer's average sales price.</p>	<p>\$1,080</p>
<p>Medicare Payments for Mental Health Services: CMS should ensure that mental health services are medically necessary, reasonable, accurately billed, and ordered by an authorized practitioner by using a comprehensive program of targeted medical reviews, provider education, improved documentation requirements, and increased surveillance of mental health services. (OEI-02-99-00140, OEI-03-99-00130, A-04-98-02145, A-01-99-00507, A-01-99-00530)</p>	<p>CMS concurred and has initiated some efforts, particularly regarding community mental health centers. OIG is reviewing this area to determine if substantial errors are still present.</p>	<p>\$676</p>
<p>Medicaid Reimbursement for Generic Drugs: CMS should encourage States to bring pharmacy reimbursement more in line with pharmacies' actual acquisition cost of generic drugs. OIG recommended a four-tier approach to reimbursement: single-source innovator drugs, all drugs without Federal UPLs, multiple-source drugs without Federal UPLs, and multiple-source drugs with Federal upper limits. (A-06-01-00053, A-06-02-00041)</p>	<p>CMS concurred with OIG's recommendation. The agency is working with States to strongly encourage them to review their estimates of acquisition costs and will follow up to ensure that they take OIG's findings into account. In addition, the President's FY 2006 budget proposed a legislative change that would limit the Federal reimbursement to States for Medicaid pharmacy payments to the amount that the States would have paid, in aggregate, for covered outpatient drugs based on the manufacturer's average sales price. OIG will continue to monitor the pricing of Medicaid reimbursements for generic drugs.</p>	<p>\$470</p>
<p>Payment Policy for Medicare Bad Debts: OIG presented four options for CMS to consider, including the elimination of a separate payment for bad debts, the offset of Medicare bad debts against beneficiary Social Security payments, the limitation of bad debt payments to prospective payment system hospitals that are profitable, and the inclusion of a bad debt factor in the diagnosis-related group rates. CMS should seek legislative authority to further modify bad debt policies. (A-14-90-00339)</p>	<p>The Balanced Budget Act of 1997 (BBA) provided for some reduction of bad debt payments to providers. The Benefits Improvement Protection Act of 2000 subsequently adjusted upwards the percentage of total hospital bad debt that would be reimbursed. However, additional legislative changes are needed to implement the modifications that OIG recommended.</p>	<p>\$340</p>

OIG Recommendation	Status	Savings (millions)
<p>Cost Effectiveness of “Pay and Chase” Methods for Medicaid Pharmacy Third-Party Liability Recoveries:</p> <p>CMS should determine whether States’ cost-avoidance waivers for pharmacy claims are meeting the cost-effectiveness criterion. CMS can ascertain cost-effectiveness by requiring States to track dollars that they pay and chase and the amounts that they recover. CMS should also review States’ policies to determine if they are paying and chasing pharmacy claims without waivers. (OEI-03-00-00030)</p>	<p>CMS agreed that States’ cost-avoidance waivers should be reexamined and has made a concerted effort to track States’ pay-and-chase activities. The concept of cost avoidance involves returning a claim to the provider so that the provider can seek recovery from a liable third party. The CMS central office asked the regional offices to identify any waivers that have been granted, any pending waiver requests, and situations in which a State is using pay-and-chase without an approved waiver. CMS is also working with States that cost-avoid pharmacy claims (and with the National Association of Chain Drug Stores in developing guidance to assist States in implementing cost avoidance.</p>	<p>\$185</p>
<p>Graduate Medical Education:</p> <p>CMS should revise the regulations to remove from a hospital’s allowable graduate medical education (GME) base-year costs any cost center with little or no Medicare utilization and submit a legislative proposal to compute Medicare’s percentage of participation under the former, more comprehensive system. (A-06-92-00020)</p>	<p>CMS did not concur with the recommendations. Although the BBA of 1997 and the Balanced Budget Refinement Act of 1999 contained provisions to slow the growth in Medicare spending on GME, OIG believes that its recommendations should be implemented and that further savings can be achieved.</p>	<p>\$157.3</p>
<p>Medicaid Drug Rebate Program:</p> <p>The best-price calculation in the Medicaid drug rebate program should be indexed to the consumer price index-urban. (A-06-94-00039)</p>	<p>CMS continues to disagree with the recommendation. OIG continues to monitor the drug rebate program; audits will continue to focus on enhancing the collection of rebates and providing potential savings to the rebate program.</p>	<p>\$123</p>
<p>Inappropriate Payments for Nail Debridement:</p> <p>CMS should require Medicare carriers to recoup the overpayments found in OIG’s sample and to carefully scrutinize payments for nail debridement services through medical reviews, require podiatrists to adequately document the medical necessity of all nail debridement services, and require CMS regional offices and carriers to educate podiatrists on Medicare payment policies for nail debridement claims. (OEI-04-99-00460)</p>	<p>CMS concurred; the agency plans to continue to maximize the effectiveness of its medical review strategy, collect the overpayments identified in OIG’s sample, and educate podiatrists on Medicare policy for paying nail debridement claims.</p>	<p>\$96.8</p>

OIG Recommendation	Status	Savings (millions)
<p>Medical Equipment/Supply Claims Lacking Valid, Active Unique Physician Identification Numbers: CMS should create edits to identify medical equipment and supply claims that do not have a valid and active unique physician identification number (UPIN) listed for the ordering physician. (OEI-03-01-00110)</p>	<p>CMS concurred and implemented an edit to reject claims listing a deceased physician's UPIN beginning in April 2002. CMS decided not to implement edits for inactive and invalid UPINs. Instead, the agency initiated provider education efforts and issued two program memorandums.</p>	<p>\$91</p>
<p>Expansion of the Diagnosis Related Group Payment Window: CMS should propose legislation to expand the diagnosis related group (DRG) payment window to at least 7 days immediately before the day of admission. (A-01-02-00503)</p>	<p>CMS did not concur with the recommendation and has not pursued a legislative proposal.</p>	<p>\$37</p>
<p>End-Stage Renal Disease Payment Rates: CMS should reduce the payment rates for outpatient dialysis treatments to reflect current efficiencies and economies in the marketplace. (A-14-90-00215)</p>	<p>CMS agreed, and the Benefits Improvement Protection Act of 2000 (BIPA) required the Secretary to develop a composite rate that includes, to the extent feasible, payment for laboratory tests and drugs that are routinely used in dialysis treatments but are now separately billable. MMA requires the Secretary to establish a case-mix adjusted composite rate for 2005 and to conduct a demonstration of a bundled case-mix adjusted prospective payment system. The Act also directs CMS to use the results of an OIG study on separately billable end-stage renal disease (ESRD) drug payments and costs to set the 2005 composite payment rate.</p>	<p>\$22**</p>
<p>Respiratory Assist Devices With a Backup Rate: CMS should reclassify bilevel respiratory assist devices with a backup rate from the "frequent and substantial servicing" category to the "capped rental" category under the durable medical device benefit. (OEI-07-99-00440)</p>	<p>CMS concurred and published a proposed rule in August 2003 clarifying that bilevel respiratory assist devices with a backup rate be paid as capped rental items.</p>	<p>\$11.5</p>

** This estimate represents annual program savings of \$22 million for each dollar reduction in the composite rate given the population of ESRD beneficiaries at the time of OIG's review.

OIG Recommendation	Status	Savings (millions)
<p>Indirect Medical Education: CMS should reduce the indirect medical education (IME) adjustment factor to the level supported by CMS's empirical data and initiate further studies to determine whether different adjustment factors are warranted for different types of teaching hospitals. (A-07-88-00111)</p>	<p>CMS agreed with the recommendation. The BBA of 1997, as amended by the Balanced Budget Refinement Act of 1999, reduced the IME adjustment to 5.5 percent in 2002 and thereafter. OIG believes that the factor should be further reduced to eliminate overlap with the disproportionate share adjustment.</p>	<p>TBD***</p>
<p>Medicare Secondary Payer—End-Stage Renal Disease Time Limit: CMS should extend the Medicare secondary payer (MSP) provisions to include ESRD beneficiaries without a time limitation. (A-10-86-62016)</p>	<p>CMS was concerned that an indefinite MSP provision might encourage insurers to drop uneconomical services, namely facility dialysis and transplantation. OIG continues to advocate that when Medicare eligibility is due solely to ESRD, the group health plan should remain primary until the beneficiary becomes entitled to Medicare based on age or disability. At that point, Medicare would become the primary payer.</p>	<p>TBD</p>
<p>Inpatient Psychiatric Care Limits: CMS should develop new limits to deal with the high cost and changing utilization patterns of inpatient psychiatric services and apply a 60-day annual and a 190-day lifetime limit to all psychiatric care regardless of the place of service. (A-06-86-62045)</p>	<p>CMS agreed with OIG's findings but stated that further analysis would be required before any legislative changes could be supported.</p>	<p>TBD</p>
<p>Hospital Capital Costs: CMS should determine the extent that capital reductions are needed to fully account for hospitals' excess bed capacity and report the percentage to Congress. (A-09-91-00070, A-14-93-00380)</p>	<p>CMS did not agree with the recommendation. Although the BBA of 1997 reduced capital payments, it did not include the effect of excess bed capacity and other elements included in the base-year historical costs.</p>	<p>TBD</p>
<p>Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement: CMS should seek legislation that would require participating manufacturers to pay Medicaid drug rebates based on average wholesale price (AWP) or study other viable alternatives to the current program of using average manufacturer price to calculate the rebates. This legislation would have resulted in about \$1.15 billion in additional rebates for 100 brand-name drugs with the highest total Medicaid reimbursements in calendar years 1994-1996. (A-06-97-00052)</p>	<p>CMS agreed to pursue a change in the rebate program similar to that recommended. The President's FY 2003 budget proposed a legislative change that would base the drug rebate on the difference between the AWP and the best price for a drug. That legislative change was ultimately dropped and none of the subsequent Presidential budgets included a similar proposal.</p>	<p>TBD</p>

*** To be determined.

OIG Recommendation	Status	Savings (millions)
<p>Home Health Agencies: CMS should revise Medicare regulations to require the physician to examine the patient before ordering home health services. (OEI-04-93-00262, OEI-04-93-0026, OEI-12-94-00180, OEI-02-94-00170, A-04-95-01103, A-04-95-01104, A-04-94-02087, A-04-94-02078, A-04-96-02121, A-04-97-01169, A-04-97-01166, A-04-97-01170, A-04-99-01195)</p>	<p>Although the BBA of 1997 included provisions to restructure home health benefits, CMS still needs to revise Medicare regulations to require that physicians examine Medicare patients before ordering home health services. Subsequent to the BBA, OIG's four-State review found that unallowable services continued to be provided because of inadequate physician involvement. CMS agreed in principle, stating that it recognized the need for physician involvement in home health care planning and was considering new approaches to fostering the coordination of home health care across disciplines in the Medicare home health conditions of participation. CMS also provided additional payments for physician care plan oversight and education for physicians and beneficiaries.</p>	TBD
<p>Payments Returned by Public Providers: CMS should propose legislation to require that Medicaid payments that public providers return to States be declared a refund to be used to offset or credit the Federal financial participation that the original payment generated. (A-03-00-00216)</p>	<p>In April 2004, CMS testified before the House Energy and Commerce Committee and indicated that it supports declaring returned funds as credits or refunds to offset the original State payment. The Federal share would then be calculated based on the net Medicaid payment that the provider retained. In addition, the President's FY 2006 budget proposed a legislative change that would disallow State Medicaid payments not retained by public providers.</p>	TBD
<p>Definitive Guidance on Calculating Upper Payment Limits and Use of Facility-Specific Limits Based on Actual Costs: CMS should provide States with definitive guidance on calculating upper payment limits (UPL) so that a uniform standard is applied to all States. This guidance could be provided through a letter to the Medicaid Directors. OIG also believes that States should use facility-specific UPLs that are based on actual cost report data. (A-03-00-00216)</p>	<p>CMS partially concurred with OIG's recommendations. CMS agreed that it should provide more guidance on calculating the UPL. In addition, the President's FY 2006 budget proposed a legislative change that would limit reimbursement levels to government providers to no more than the cost of providing services.</p>	TBD

OIG Recommendation	Status	Savings (millions)
<p>Excessive Medicaid Disproportionate Share Hospital Payments: CMS should ensure that the monetary recommendations made to individual States have been resolved regarding Disproportionate Share Hospital (DSH) payments that exceeded the hospital-specific limits. CMS should also establish regulations requiring States to</p> <p>(1) implement procedures to ensure that future DSH payments are adjusted to actual incurred costs, (2) incorporate the procedures into their approved State plans, and (3) include only allowable costs as uncompensated care costs in their DSH calculations. Finally, CMS should strengthen its review and approval of State plans to ensure consistency with Federal requirements and use the results of audits conducted under MMA as part of its review process. (Various audit reports)</p>	<p>CMS has begun taking action in individual States to recover overpayments. It is currently developing a regulation on the Medicaid DSH program.</p>	<p>TBD</p>
<p>Compliance With Requirements for Medicaid School-Based Health Services: CMS should recover the overpayments identified during OIG’s individual State audits of school-based health claims. In addition, States should disseminate CMS guidance and other information to local education agencies in a timely manner, monitor local education agencies to ensure compliance with Federal and State requirements, and assist local education agencies in developing written policies and procedures that require service providers to document all health services and to retain those records for review. (Various audit reports)</p>	<p>CMS has begun taking action in individual States to recover overpayments. OIG will provide CMS with a summary report on its work in this area with additional recommendations involving school-based health services.</p>	<p>TBD</p>
<p>Eliminate or Reduce Transition Periods for Compliance With Revised Medicaid Upper Payment Limits: CMS should seek authority to eliminate or reduce the 8-year transition period included in the revised UPL regulation. (A-03-00-00216)</p>	<p>CMS did not concur with OIG’s recommendation. According to CMS, the transition periods were established pursuant to either notice-and-comment rulemaking or legislation, and offering new proposals at this time would undermine the consensus reached through those processes. CMS anticipates no further action on OIG’s recommendation.</p>	<p>TBD</p>

OIG Recommendation	Status	Savings (millions)
VARIOUS OPERATING DIVISIONS		
<p>Recharge Center Costs: The Assistant Secretary for Administration and Management should propose changes to OMB Circular A-21 to improve guidance on the financial management of recharge centers. The revision should include criteria for establishing, monitoring, and adjusting billing rates to eliminate accumulated surpluses and deficits; preventing the use of recharge funds for unrelated purposes and excluding unallowable costs from the calculation of recharge rates; ensuring that Federal projects are billed equitably; and excluding recharge costs from the recalculation of facilities and administrative cost rates. (A-09-96-04003)</p>	<p>The Department concurred and has worked with OMB on a revision to A-21. The proposed revision, which was published in the Federal Register in August 2002, would require that adjustments to a recharge center's billing rate take into account overrecoveries and/or underrecoveries from previous periods. Rate adjustments would be required at least every 2 years. The final circular was issued in May 2004.</p>	\$1

Appendix C

Unimplemented Office of Inspector General Program and Management Improvement Recommendations

This schedule represents Office of Inspector General (OIG) findings and recommendations that, if implemented, would result in substantial benefits. The benefits relate primarily to effectiveness rather than cost-efficiency.

More detailed information can be found in OIG’s “Orange Book,” which is available on the Internet at <http://oig.hhs.gov>.

OIG Recommendation	Status
CENTERS FOR MEDICARE & MEDICAID SERVICES	
<p>Accountability Over Billing and Collection of Medicaid Drug Rebates: The Centers for Medicare and Medicaid Services (CMS) should ensure that States implement accounting and internal control systems in accordance with Federal regulations for the Medicaid drug rebate program. Such systems must provide for accurate, current, and complete disclosure of drug rebate transactions and provide CMS with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program. (A-06-92-00029, A-06-03-00048)</p>	<p>CMS concurred with the recommendation and set up a reporting mechanism to capture rebate information. The agency still needs to ensure that States establish adequate accounting and internal control systems to obtain reliable information. Current audit results have shown that this remains a problem in most States.</p>
<p>Fairly Presenting the Medicare Accounts Receivable Balance: CMS should require Medicare contractors to implement or improve internal controls and systems to ensure that reported accounts receivable are valid and documented. (A-17-95-00096, A-17-97-00097, A-17-98-00098, A-17-00-00500, A-17-00-02001, A-17-01-02001, A-17-02-02002, A-17-03-03003)</p>	<p>CMS hired consultants to assist in validating accounts receivable reported by Medicare contractors and provided comprehensive instructions to contractors. For the long term, CMS is developing an integrated general ledger system as the cornerstone of its financial management controls.</p>

OIG Recommendation	Status
<p>Guidance to Drug Manufacturers To Better Implement the Medicaid Drug Rebate Program: CMS should survey manufacturers to identify the various calculation methods used to determine average manufacturer price (AMP). CMS should also develop a more specific policy for calculating this price that would protect the interests of the Government and that would be equitable to the manufacturers. (A-06-91-00092)</p>	<p>CMS did not concur, stating that the drug law and the rebate agreements already established a methodology for computing AMP. OIG disagrees because the rebate law and agreements defined AMP but did not provide specific written methodology for computing it.</p>
<p>Accuracy of Carrier Payment Data: CMS should conduct a review of carriers' claims processing data to examine the scheduled date of payment entered on claims sent to the Common Working File (CWF). If there is no correlation between the claims payment date variable and the actual date of payment, CMS should define what data should be entered into this field and how it should be calculated, and/or revise the current variable definition to clarify for National Claims History data users that the scheduled date of payment is not an accurate reflection of the actual claim payment date. CMS should also review the carriers' claims processing data to determine the accuracy of the information contained in the Contractor Reporting of Operational and Workload Data system. (OEI-03-00-00350)</p>	<p>CMS stated that a review is under way to compare data contained in the National Claims History File with data at the carrier level. CMS has also approved two new edits, which will enforce the payment floor standards on claims sent to the CWF.</p>
<p>Resident Assessment Instruments: CMS should more clearly define minimum data set (MDS) elements and work with States to train nursing home staff. OIG recommended that CMS establish an audit trail to validate the 108 MDS elements that impact facility reimbursement by Medicare. (OEI-02-99-00040, OEI-02-99-0041)</p>	<p>CMS generally concurred with OIG's recommendations for improved data definitions and training, but did not concur with the recommendation to establish an audit trail. In 1998, CMS devoted significant resources to the development of an accuracy improvement program by letting a contract develop MDS accuracy review protocols. Once the protocols were developed, CMS funded a program safeguard contractor in September 2001, known as the data assessment and verification system (DAVE), to audit and verify MDS data. In January 2004, CMS developed and implemented the DAVE project onsite and offsite audit process of the MDS in long term care facilities to assess the accuracy and reliability of assessment data submitted.</p>

OIG Recommendation	Status
<p>Assessments of Mental Illness: CMS should work with States to improve the assessment of persons with serious mental illness and use survey and certification to monitor compliance. OIG also recommended that CMS define specialized services that are to be provided by the State to nursing home residents with mental illness. (OEI-05-99-00700)</p>	<p>CMS concurred with most of OIG’s recommendations and has made revisions to its training curriculum for nursing home surveyors. In addition, CMS offered several national satellite broadcasts in 2001 and 2004 to increase surveyor knowledge and ability to recognize mental illness, to educate surveyors on Pre-Admission Screening and Resident Review (PASRR) implementation and oversight, and to improve surveyors’ abilities to determine facility compliance with assessment and care requirements. CMS has also held several training conferences for Resident Assessment Instrument (RAI) coordinators to improve the identification of mental illness symptoms in patients in nursing facilities. CMS will convene an expert panel of PASRR in 2005 to assess the PASRR program and determine what opportunities may exist through guidance or interpretation of statute and regulations to help States. CMS is also exploring the role State surveyors may have in identifying compliance with PASRR Level II assessment requirements.</p>
<p>Nursing Home Residents With Serious Mental Illness: CMS should improve the quality and usefulness of its data sources by requiring the use of a unique provider number across systems, requiring reporting of resident data by age and diagnosis, and encouraging States to use these data in demonstrating their progress in placing disabled persons in the most integrated settings. OIG also recommended training to improve data collection and accurate coding. (OEI-05-99-00701)</p>	<p>CMS concurred with most of OIG’s recommendations, except for reporting the MDS records by primary, secondary, and tertiary diagnoses. In February 2005, CMS issued a letter to State Medicaid directors indicating that it will begin to release MDS data to States with Americans with Disabilities Act compliance activities. CMS will also require States to evaluate the PASRR outcomes, further obligating States to develop accurate data systems useful for identifying serious mental illness in nursing facility residents. In addition, CMS is planning to implement the use of a unique provider number on or before May 2007.</p>
<p>Payments for Mental Health Services: CMS should promote provider awareness of documentation and medical necessity requirements, develop a comprehensive list of psychological testing tools that can be correctly billed, target problematic services for prepayment edits or postpayment medical review, and encourage carriers to take advantage of the MDS, especially for its assessment of patient cognitive level. (OEI-03-99-00130, OEI-02-99-00140)</p>	<p>CMS generally concurred with OIG’s recommendations. It plans to explore a variety of educational efforts and will refer the reports to the carrier clinical workgroup on psychiatric services. Carriers will conduct data analysis of psychological testing and psychotherapy claims and will conduct medical reviews, if indicated. CMS provided training for providers concerning Medicare payments for Part B mental health services via Medlearn in April 2003.</p>

OIG Recommendation	Status
<p>Organ Donation: CMS should revise the Medicare conditions for coverage for organ procurement organizations (OPOs) to make them more accountable for implementing the new donation rule and require OPOs to provide hospital-specific data on referrals and on organ recovery. HRSA should require that OPOs submit hospital-specific data on referrals and on organ recovery and support demonstration projects on how to effectively train and make use of designated requestors. (OEI-01-99-00020)</p>	<p>CMS concurred with the recommendations and indicated that it will explore ways in which additional data can be used to assess OPO effectiveness and hospital compliance with the donation rule. CMS published a Notice of Proposed Rule-Making on February 4, 2005, establishing new conditions of coverage regarding OPOs. That proposed regulation requires OPOs to report hospital-specific organ donation, including organ donor potential and the number of actual donors, at least annually to the public. The Health Resources and Services Administration, through its contract for operation of the Organ Procurement and Transplantation Network, requires OPOs to submit hospital-specific data on organ recovery.</p>
<p>Outpatient Surgery Rates: CMS should (1) seek authority to set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and (2) remove the procedure codes that meet its criteria for removal from the Ambulatory Surgery Center (ASC) list of covered procedures. (OEI-05-00-00340)</p>	<p>Section 626 of Public Law 108-173 mandates that the Government Accountability Office conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments. The report will include recommendations that advise CMS regarding payments to ambulatory surgical centers and CMS will implement a new payment system for ambulatory surgical centers beginning on or after January 1, 2006, and not later than January 1, 2008. CMS issued a proposed rule on November 26, 2004, to update the list of Medicare-approved ambulatory surgical centers procedures in 2005. CMS proposed to remove from the ambulatory surgical centers list a number of the codes recommended for deletion by OIG. Nearly 500 comments were submitted timely and CMS is reviewing those comments and preparing a final rule for implementation in the summer of 2005.</p>
<p>Medicare-Approved Heart Transplant Centers: CMS should develop standards for continuing approved centers as well as guidelines for what levels of performance trigger specific responses from CMS. In the short term, OIG also recommends that CMS improve its oversight of centers by entering into an arrangement with the HRSA for the regular exchange of volume and survival rate data. (OEI-01-02-00520)</p>	<p>On February 4, 2005, CMS published proposed rule (70 FR 6140), "Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplant." The notice of proposed rulemaking established the requirements for approval and reapproval of transplant centers to perform organ transplants. The approval requirements include data submission, outcome measures, and process requirements. CMS expects to publish the final rule within 1 to 1.5 years. HRSA has partnered with CMS in developing outcome measures for the proposed rule and will continue to act as a liaison between CMS and the Scientific Registry of Transplant Recipients to provide assistance to review data on transplant center(s) performance.</p>

OIG Recommendation	Status
<p>Quality Improvement Processes in Dialysis Facilities: We recommended that CMS revise the Conditions of Coverage, examine ways to foster the commitment of attending physicians to performance measures, develop more effective intervention strategies for facilities, and work with the corporations to share experiences and minimize reporting burdens on dialysis facilities. (OEI-01-99-00052)</p>	<p>CMS concurred with most of OIG’s recommendations. The Conditions of Coverage proposed rule was published in February 2005 and has a 90-day public comment period. The proposed conditions would require a facility-level data driven Quality Assessment and Performance Improvement program (QAPI), increased participation of attending physicians in patient care and in supporting the facility QAPI program, increased medical director role, and electronic clinical measure reporting.</p>
<p>End-Stage Renal Disease Data Management: OIG recommends that CMS develop a strategic plan for addressing End-Stage Renal Disease (ESRD) data management, including creating short- and long-term remedies for current data problems, reassessing the data needs of users, improving the efficiency of data distribution, improving ongoing communication with users and data contributors, and better coordinating with the Social Security Administration. (OEI-07-01-00250)</p>	<p>CMS concurred with OIG’s recommendations. As of February 15, 2005, CMS along with the ESRD networks, its contractors, and the renal community worked together to consolidate its three ESRD systems now referred to as the Consolidated Renal Operations in a Web-enabled Network (CROWN). The three systems include: (1) the Renal Management Information System (REMIS), (2) the Standard Information Management System (SIMS), and (3) the Vital Information System to Improve Outcomes in Nephrology (VISION). SIMS went into production on January 1, 2000, and REMIS went into production on July 13, 2003. The REMIS application directly addresses concerns raised by OIG. The CROWN is the automated system that combines all of CMS’s electronic data on ESRD benefits and utilization. The CROWN provides for the collection, validation, and storage of information about the national ESRD program, its beneficiaries, and the services provided to them.</p>
<p>Accuracy of Nursing Home Compare: OIG recommends that CMS require State agencies to verify that the most recent inspection results are in CMS databases and establish a single point of contact for reporting discrepancies on the Web site. (OEI-01-03-00130)</p>	<p>CMS agreed with the first recommendation. CMS will consider adding regional office contact information to the Nursing Home Compare to facilitate corrections to the Web site. CMS is currently working with the Web site designers and the regional offices to develop the most efficient means of providing CMS oversight over State survey agency data entry.</p>
<p>Variation in State Medicaid Drug Prices: OIG recommends that CMS share more accurate drug pricing information with States, conduct further research on the factors that affect States’ drug prices, and annually review States’ reimbursement data to target technical assistance to higher paying States. (OEI-05-02-00681)</p>	<p>CMS plans to follow up with States that paid higher relative drug prices, particularly States with prices above the UPL.</p>

OIG Recommendation	Status
<p>CMS Oversight of Cost-Avoidance Waivers: OIG recommends that CMS approve only waivers that meet the criteria for cost-effectiveness as set forth by Federal regulations, strengthen oversight activities through improved document retention, and collect information from States regarding recovery rates from pay-and-chase activities. Cost avoidance involves returning claims to providers so that the providers can bill the liable third parties. (OEI-03-00-00031)</p>	<p>CMS concurred with OIG’s recommendation that it approve only cost-effective waivers. CMS continues to address the oversight of and/or need for cost-avoidance waivers. CMS central and regional offices continue to work closely with States to identify circumstances for which cost-avoidance waivers are not necessary (i.e., Medicaid services not covered by third parties or benefits not directly available to the provider). CMS has also worked with States to diminish the need for waivers by frequently encouraging States to eliminate paying and chasing of claims and relying instead on cost-avoidance. CMS has made substantial progress on Medicaid pharmacy claims. In August 2001, OIG reported that only 17 States were cost-avoiding (in part or whole) pharmacy claims. A recent CMS survey indicated that 40 States currently meet that description and an additional 4 States are planning systems conversions. CMS plans to follow up with remaining States to consider what further assistance should be offered. Where waivers continue to be necessary, CMS will continue to emphasize cost-effectiveness and proper document retention.</p>
<p>Uninsured Children Through State Children’s Health Insurance Programs: CMS should resolve the inconsistency between the requirement that States report on changes in the number of uninsured children and the practice of accepting enrollment data as a proxy, and ensure the integrity, validity, and usefulness of the State Children’s Health Insurance Program (SCHIP) Annual Report and SCHIP enrollment data. (OEI-05-03-00280)</p>	<p>CMS concurred with several of OIG’s specific recommendations and has already implemented steps to improve the integrity of the State Annual Report submissions. In addition, CMS has taken steps to enhance technical assistance (TA) to States to improve their measurement capabilities and held a TA session at the National Academy for State Health Policy’s annual conference in August 2004. CMS is currently reviewing all State reports on progress towards covering the uninsured and providing State-specific TA to the States not measuring progress.</p>

OIG Recommendation	Status
PUBLIC HEALTH AGENCIES	
<p>Oversight of Tissue Banking: The Food and Drug Administration (FDA) should expedite publication of its regulatory agenda requiring registration of tissue banks, enhanced donor suitability screening, and testing the use of good tissue practices. FDA should set a realistic yet aggressive date by which it would complete an initial inspection of all tissue banks. FDA should determine the appropriate minimum cycle for tissue bank inspections and work with States and professional associations to determine in what areas oversight activities could be coordinated. (OEI-01-00-00441)</p>	<p>The Deputy Secretary concurred that FDA should expedite its planned rulemaking activities related to tissues, specifically the final rule to require registration of tissue banks. The Department also found “considerable merit” in OIG’s recommendation for an intensified inspection program directed toward entities that procure, process, and store human tissues. In congressional testimony, FDA said that all three of the proposed rules have been published and one rule (Establishment Registration and Listing) was finalized. FDA has completed contacting the 36 uninspected tissue banks. The results were: 31 inspections were completed, 3 firms were out of business, 1 firm could not be located, and 1 firm was not an FDA obligation because it handled only vascularized organs. In 2004, FDA finalized donor eligibility and good tissue practices regulations, which will become effective on May 25, 2005. This completes the rulemaking activities related to human tissues.</p>
<p>Effectiveness of FDA’s Adverse Event Reporting System for Dietary Supplements: FDA should (1) facilitate greater detection of adverse events by requiring dietary supplement manufacturers to report serious events to FDA for some products, (2) obtain more information on adverse event reports by requiring manufacturers to register themselves and their products with FDA, (3) notify manufacturers when FDA receives a serious adverse event report and develop a new computer database to track and analyze adverse event reports, (4) expedite the development and implementation of good manufacturing practices for dietary supplement manufacturers, and (5) disclose more useful information to the public about dietary supplement adverse events. (OEI-01-00-00180)</p>	<p>In response, the Center for Food Safety and Applied Nutrition (CFSAN) developed a new system for entering adverse events and consumer complaint reports involving foods, the CFSAN Adverse Event Reporting System (CAERS), which became partially operational in June 2003. The new system incorporates all existing adverse event reporting systems into one state-of-the-art reporting and monitoring system. CAERS staff work closely with program experts as well as external stakeholders. FDA intends to improve data links to the Center for Drug Evaluation and Research as funds become available. FDA also published proposed Good Manufacturing Practices regulations for dietary supplements in March 2003 and is now preparing the final regulation. In response to the requirement for food facility registration in the Public Health Security and Bioterrorism Preparedness Act of 2002, FDA now requires facilities that manufacture, process, pack, or hold dietary supplements to be registered with the FDA. FDA informs the public of new developments through its dietary supplements Web site.</p>

OIG Recommendation	Status
<p>Protection for Research Subjects in Foreign Clinical Trials:</p> <p>FDA should examine ways to obtain more information about the performance of non-U.S. Institutional Review Boards (IRBs) and help inexperienced IRBs build their capacities, encourage all non-U.S. investigators participating in research to sign attestations upholding human subject protections, and develop a database to track the growth and location of foreign research. The Office for Human Research Protections (OHRP) should exert leadership in developing strategies to ensure adequate human subject protections for non-U.S. clinical trials funded by the Federal Government and those that contribute data to new drug applications.</p> <p>(OEI-01-00-00190)</p>	<p>OHRP concurred with OIG’s recommendations and emphasized that its new International Activities Program will serve as a focal point and coordinating center for HHS’s efforts to improve human subject protection. In collaboration with the FDA and the Fogarty International Center, OHRP is working with a variety of national, regional, and international organizations with a goal of establishing effective education and review processes around the world. In 2004, OHRP sponsored capacity-building workshops for IRB members, gave presentations at international conferences, and began translating key guidance documents into foreign languages. FDA published a proposed rule in 2004, “Human Subject Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application” (21 CFR 312.120), to promote good clinical practice regardless of the location of the clinical trial. FDA and OHRP have contributed to efforts to strengthen research investigation and harmonize standards through collaboration with the World Health Organization, the Pan American Health Organization, the Council for International Organizations of Medical Sciences, and other organizations. FDA also contributed to the HHS/OHRP/National Institutes of Health Working Group for Equivalent Protections in developing a HHS report and Federal Register Notice announcing proposed criteria for clinical trials conducted outside of the United States. In addition, FDA has assisted other countries with capacity-building activities for international good clinical practices (GCP) inspectorates, including Singapore and Australia. An ongoing FDA initiative to develop better communication with the European Medicines Agency will improve coordination between the respective European and FDA programs involving clinical trials. FDA has also provided staff as faculty to professional associations for outreach training programs, as well as creating a GCP Web site for current information about FDA clinical trial requirements.</p>

OIG Recommendation	Status
ADMINISTRATION FOR CHILDREN AND FAMILIES	
<p>Children’s Use of Health Care Services While in Foster Care: OIG conducted a series of inspections examining the access of foster care children in a number of individual states to Medicaid health care services. The study found that access varied in each state, and the reports generally recommended that CMS and the Administration for Children and Families (ACF) work with the States to increase access to health care services for eligible foster care children and educate foster parents on available services. (OEI-02-00-00360, OEI-02-00-00363, OEI-07-00-00640, OEI-07-00-00642, OEI-07-00-00643)</p>	<p>CMS and ACF generally concurred with the recommendations and in many cases are actively working with the State and local entities to improve access, clarify obligations, and educate all the parties involved regarding Medicaid health care services.</p>
GENERAL OVERSIGHT	
<p>Cost Principles for Federally Sponsored Research Activities: The Department should modernize and strengthen cost principles applicable to hospitals by either revising existing guidelines to conform with Office of Management and Budget (OMB) Circular A-21 or working with OMB to extend Circular A-21 coverage to all hospitals. (A-01-92-01528)</p>	<p>The Department circulated several draft iterations of the hospital cost principles to internal users for comment. Many of the policies in the outdated document have been updated in the draft regulation. The target date for issuing the draft regulation as a notice of proposed rulemaking was December 31, 2004. Once the formal notice and rulemaking process is complete, the updated cost principles will be issued.</p>

Appendix D

Notes to Tables 1 and 2

Notes to Table 1

¹The opening balance was adjusted downward \$443 million.

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

Central Identification Number (CIN): A-06-05-78935 STATE OF LOUISIANA:

The Division of Cost Allocation issued a determination to obtain a refund of Federal funds used to pay claims in lines of insurance.

Not detailed are revisions to previously disallowed management decisions totaling \$124,941 million.

³Included are management decisions to disallow \$427.8 that was identified in nonfederal audit reports.

⁴Due to administrative delays, many of which are beyond management control, resolution of the following 230 audits were not completed within 6 months of issuance:

CIN: A-02-02-01030	REVIEW OF SPEECH SCHOOL HEALTH CLAIMS - REST OF STATE, FEB 2004, \$172,553,831
CIN: A-05-01-00099	U OF I HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$140,281,912
CIN: A-09-03-00055	AUDIT OF OREGON'S MEDICAID UPPER PAYMENT LIMITS FOR NON-STATE GOVERNMENT NURSING FACILITIES FOR STATE FISCAL YEARS 2002 AND 2003, FEB 2005, \$137,219,260
CIN: A-09-02-00054	AUDIT OF STATE OF CALIFORNIA DSH PROGRAM FOR FY 1998, MAY 2003, \$128,269,448
CIN: A-04-99-05561	AUDIT ADMIN COST PROPOSALS FY95-98, BCBSFL, JAX, JUL 2002, \$101,671,328
CIN: A-09-02-00071	AUDIT OF CA DSH PROGRAM FOR FY 1998 - LA COUNTY, MAY 2003, \$98,190,042
CIN: A-02-03-01008	REVIEW OF TRANSPORTATION SCHOOL HEALTH CLAIMS - REST OF STATE, AUG 2004, \$53,037,302
CIN: A-05-01-00058	OHIO MEDICAID HOSPITAL-SPECIFIC DSH PAYMENT LIMITS, JUN 2004, \$47,000,000
CIN: A-04-01-02006	MEDICAID DISPROPORTIONATE SHARE PAYMENTS IN ALABAMA, JUN 2004, \$45,763,327
CIN: A-07-01-02093	MISSOURI DSH - UNALLOWABLE COSTS, AUG 2002, \$36,200,000
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL BASED HEALTH SERVICES - CT, MAY 2003, \$32,780,146

CIN: A-03-01-00224	MEDICAID SCHOOL-BASED SERVICES/MARYLAND, MAR 2003, \$19,954,944
CIN: A-09-01-00098	AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$19,446,435
CIN: A-01-02-00509	REVIEW OF MEDICARE ADMINSTRATIVE COSTS - PART A & B - UNITED HEALTHCARE INSURANCE COMPANY, MAR 2005, \$12,991,420
CIN: A-07-02-03032	MEDICARE SEGMENT CLOSING AUDIT OF TRAILBLAZERS, JUN 2004, \$11,152,093
CIN: A-02-02-01028	REVIEW OF RETRO ACUTE CARE HOSPITAL DSH CLAIMS FOR INMATE COSTS, JAN 2004, \$11,114,820
CIN: A-06-02-00034	REV OF COST REPORTS & MEDICARE FEE-FOR-SERVICE PYMTS @ SCOTT & WHITE, MAY 2003, \$8,229,574
CIN: A-09-01-00085	AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFYE 1998, SEP 2002, \$7,999,212
CIN: A-02-02-01024	IMD UNDER 21 AUDIT IN NEW YORK, FEB 2004, \$7,642,194
CIN: A-09-97-44262	STATE OF CALIFORNIA, APR 1997, \$7,300,000
CIN: A-07-02-03033	CAREFIRST SEGMENTATION AUDIT, MAY 2003, \$6,788,644
CIN: A-03-91-00552	INDEPENDENT LIVING PROGRAM -- NATIONAL, MAR 1993, \$6,529,545
CIN: A-03-01-00222	MEDICAL COLLEGE OF VIRGINIA/DSH/MEDICAID, APR 2003, \$6,324,796
CIN: A-07-03-03041	ADULT REHABILITATION SERVICES IN IOWA, MAR 2005, \$6,244,154
CIN: A-05-02-00049	MEDICAL SERVICE COSTS UNDER ILLINOIS SCHOOL-BASED MEDICAID, DEC 2003, \$6,067,669
CIN: A-07-03-03040	PRB COSTS CLAIMED FOR MEDICARE REIMBURSEMENT BY TRAILBLAZERS, OCT 2004, \$6,000,000
CIN: A-04-00-02161	MEDICAID SCHOOL-BASED SERVICES IN NORTH CAROLINA, NOV 2001, \$5,344,160
CIN: A-01-02-00016	MEDICAID SCHOOL-BASED HEALTH SERVICE ADMINISTRATIVE CLAIMING REVIEW-MASSACHUSETTS, SEP 2004, \$5,312,447
CIN: A-09-03-00042	REVIEW OF HHA PRECEEDING HOSPITAL STAY UNDER PPS - UGS, FEB 2004, \$5,306,825
CIN: A-06-02-00060	REVIEW PACIFICARE OK BIPA MODIFICATIONS TO CY 2001 ACRP, JUN 2004, \$5,204,042
CIN: A-05-03-00096	REVIEW OF ADMINISTRATIVE COSTS FOR ADMINASTAR FEDERAL, AUG 2004, \$5,000,598
CIN: A-03-01-00226	UVA MEDICAL CENTER/DSH/MEDICAID/VIRGINIA, MAY 2003, \$4,760,385
CIN: A-09-03-00051	REVIEW OF BLUE SHIELD CALIFORNIA BIPA MODIFICATIONS TO CY 2001 ACRP, OCT 2004, \$4,555,992
CIN: A-05-01-00102	MT. SINAI HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$4,516,112
CIN: A-02-00-01047	DEMO BSWNY - FINANCIAL, MAR 2002, \$4,505,051
CIN: A-07-02-00144	IV-E FOSTER CARE ADMINISTRATIVE COSTS CLAIMED, AUG 2003, \$4,335,542
CIN: A-01-02-00015	REVIEW OF MA MEDICAID USE OF REVISED FEE SCHEDULES FOR CLINICAL DIAGNOSTIC LABORATORY SERVICES, JAN 2004, \$4,100,000

CIN: A-07-04-03053	REVIEW OF CAHABA'S UNFUNDED PENSION COSTS, FEB 2004, \$4,006,541
CIN: A-03-01-00225	VIRGINIA IMD UNDER 21, MAR 2004, \$3,948,532
CIN: A-05-01-00068	PARTNERSHIP PLAN - ILLINOIS PHYSICIAN BILLING-FAMILY DYNAMICS, JUL 2002, \$3,790,846
CIN: A-09-03-00053	AUDIT OF ORGAN ACQUISITION COSTS AT CPMC, JAN 2005, \$3,731,752
CIN: A-04-01-05002	AUDIT MEDICAID PAYMENTS FOR CLINICAL LABORATORIES, JAN 2002, \$3,522,639
CIN: A-09-04-00023	AUDIT OF OREGON'S MEDICAID UPPER PAYMENT LIMITS FOR NON-STATE GOVERNMENT INPATIENT HOSPITALS FOR STATE FISCAL YEAR 2003, FEB 2005, \$3,412,987
CIN: A-01-02-00525	MAINE ANTHEM BCBS - MEDICARE ADMINISTRATIVE COSTS, APR 2004, \$3,389,716
CIN: A-09-02-00061	REVIEW OF MEDICAL CLAIMS FOR PRIVATE IMD PATIENTS, DEC 2002, \$3,083,389
CIN: A-04-01-00005	MEDICAID FFS PAYMENTS TO LEA'S IN NORTH CAROLINA, MAY 2004, \$3,066,806
CIN: A-01-04-00004	REVIEW OF MAINE'S MEDICAID RETROACTIVE CLAIMS FOR SCHOOL-BASED HEALTH SERVICES - JANUARY 2001 THROUGH JUNE 2003, JAN 2005, \$3,044,211
CIN: A-07-03-03046	TRAILBLAZERS - REVIEW OF PENSION COSTS CLAIMED FOR MEDICARE REIMBURSEMENT, JUL 2004, \$3,023,483
CIN: A-09-98-50183	STATE OF CALIFORNIA, MAR 1998, \$3,000,000
CIN: A-01-02-00508	REVIEW OF MEDICARE CONTRACT TERMINATION COSTS - UNITED HEALTHCARE, NOV 2003, \$2,894,010
CIN: A-05-02-00085	MEDICAID FFS PAYMENTS FOR OHIO BENEFICIARIES ENROLLED IN MEDICARE MCOS, JUN 2004, \$2,700,000
CIN: A-01-04-78839	STATE OF NEW HAMPSHIRE, JUN 2004, \$2,631,648
CIN: A-07-03-03039	CAREFIRST OF MARYLAND UNFUNDED PENSION COSTS, MAY 2003, \$2,611,100
CIN: A-09-02-72300	STATE OF CALIFORNIA, JUL 2002, \$2,400,000
CIN: A-07-04-03050	PENSION SEGMENTATION REVIEW AT HIGHMARK, INC. OF PA, JAN 2005, \$2,394,501
CIN: A-04-04-01001	INTERIM CONTRACT AUDIT, AUG 2004, \$2,352,388
CIN: A-10-02-00008	REVIEW OF WASHINGTON STATE'S MEDICAL ASSISTANCE COSTS CLAIMED FOR SCHOOL-BASED HEALTH SERVICES, JUL 2003, \$2,279,752
CIN: A-04-02-07007	MEDICAID FEE FOR SERVICE PAYMENTS FOR DUALY ELIGIBLE MEDICARE MANAGED CARE ENROLLEES, FEB 2003, \$2,231,100
CIN: A-07-04-00173	REVIEW OF UNFUNDED PENSION COSTS FOR PENNSYLVANIA BLUE SHIELD, NOV 2004, \$2,154,481
CIN: A-05-03-00041	HOSPITAL TRANSFERS NORTH CAROLINA, MAY 2004, \$2,151,055
CIN: A-05-03-00063	REVIEW OF INELIGIBLE SNF PAYMENTS UNDER THE ADMINISTRATIVE RESPONSIBILITY OF MEDICARE NORTHWEST (BLUE CROSS BLUE SHIELD OF OREGON), OCT 2003, \$2,100,000

CIN: A-07-01-03001	BCBS OF MN PENSION SEGMENT CLOSING, JAN 2003, \$2,003,341
CIN: A-05-02-00048	REVIEW OF MEDICAID DME CLAIMS - TEXAS, SEP 2002, \$1,969,704
CIN: A-01-02-00516	REVIEW OF POTENTIALLY EXCESSIVE MEDICARE PAYMENTS FOR OUTPATIENT SERVICES UNITED GOVERNMENT SERVICES, MAR 2003, \$1,768,783
CIN: A-09-00-00127	BLUE CROSS OF CALIF - MEDICARE ADMIN COSTS, DEC 2002, \$1,677,822
CIN: A-10-03-00010	REVIEW OF ORGAN ACQUISITION COSTS CLAIMED BY VIRGINIA MASON MEDICAL CENTER FOR THE PERIOD JANUARY 1, 1997 THROUGH DECEMBER 31, 1999, MAR 2005, \$1,579,782
CIN: A-02-04-01010	REVIEW OF PHYSICIAN PLACE OF SERVICE CODING FOR AMBULATORY SURGICAL AND RELATED PROCEDURES, JAN 2005, \$1,467,318
CIN: A-01-03-00004	REVIEW OF VERMONT MEDICAID SCHOOL-BASED SERVICES FOR THE PERIOD OCTOBER 2001-SEPTEMBER 2002, JAN 2005, \$1,463,395
CIN: A-04-01-05011	REVIEW OF FLORIDA MEDICAID PAYMENTS FOR SERVICES PROVIDED TO INMATES, OCT 2002, \$1,450,077
CIN: A-05-03-00094	REVIEW OF ADMINISTRATIVE AND TERMINATION COSTS FOR NATIONWIDE INSURANCE, NOV 2004, \$1,426,267
CIN: A-07-02-03021	ANTHEM BCBS OF CT - PENSION SEGMENT CLOSING, FEB 2004, \$1,351,284
CIN: A-04-03-02024	REVIEW OF BCBSFL RESPONSE TO SET-ASIDE COSTS IN PRIOR FACP AUDIT, APR 2003, \$1,277,247
CIN: A-05-01-00064	REVIEW OF OUTPATIENT REHABILITATION CLAIMS REIMBURSED BY MEDICARE DURING CALENDAR YEAR 1999, FEB 2002, \$1,235,892
CIN: A-03-01-00251	AFDC OVERPAYMENTS - VIRGINIA, MAR 2003, \$1,221,494
CIN: A-07-04-00169	PENSION SEGMENTATION REVIEW AT PBS, NOV 2004, \$1,214,985
CIN: A-04-02-72903	STATE OF TENNESSEE, SEP 2002, \$1,213,353
CIN: A-04-03-01000	REVIEW OF HOME HEALTH SERVICES CLAIMED BY LIFELINE HEALTH GROUP, INC, JUN 2004, \$1,173,330
CIN: A-09-04-00047	WEDGE: REVIEW OF ALASKA'S ACCOUNTS RECEIVABLE SYSTEM FOR MEDICAID PROVIDER OVERPAYMENTS, OCT 2004, \$1,092,663
CIN: A-09-02-01004	USC GRANTS MANAGEMENT REVIEW, JUL 2004, \$1,082,554
CIN: A-02-04-77762	MONTCLAIR CHILD DEVELOPMENT CENTER INC., MAR 2004, \$992,617
CIN: A-09-94-01010	CLOSEOUT AUDIT--CONT NO. N01-ES-75196 (STRATAGENE), MAR 1994, \$983,208
CIN: A-05-01-00059	ILLINOIS MEDICAID HOSPITAL-SPECIFIC DSH PAYMENT LIMITS, AUG 2004, \$972,810
CIN: A-05-04-77356	TRI-VALLEY OPPORTUNITY COUNCIL INC., FEB 2004, \$866,666
CIN: A-02-03-01028	IMD UNDER 21 AUDIT IN NEW JERSEY, OCT 2004, \$848,374
CIN: A-04-01-05004	REVIEW MEDICARE CLAIMS FOR DEPORTED BENEFICIARIES, MAR 2002, \$836,711
CIN: A-06-03-00013	MEDICARE ADMINISTRATIVE COST PROPOSAL-ARKANSAS BCBS, OCT 2003, \$759,748

CIN: A-09-04-00040	WEDGE: REVIEW OF ALASKA'S MEDICAID PAYMENTS FOR SKILLED PROFESSIONAL MEDICAL PERSONNEL REIMBURSED AT THE ENHANCED RATE, NOV 2004, \$758,215
CIN: A-05-02-00041	INDIANA MEDICAID HOSPITAL PATIENT TRANSFERS, JAN 2003, \$730,061
CIN: A-09-03-00046	AUDIT OF ORGAN ACQUISITION COSTS AT ST VINCENT, JUL 2004, \$683,315
CIN: A-06-03-00032	AUDIT OF ADMIN COSTS PART A & PART B OF MEDICARE PROGRAM-TRAILBLAZERS, APR 2004, \$622,078
CIN: A-04-00-00138	MEDICAID ESCHEATED WARRANTS - FLORIDA, JAN 2002, \$613,891
CIN: A-07-04-00170	REVIEW OF PENSION COSTS CLAIMED FOR MEDICARE REIMBURSEMENT FOR VERITUS, AUG 2004, \$594,806
CIN: A-02-03-01024	MEDICAID DRUG REBATE COLLECTIONS - NEW JERSEY, OCT 2004, \$567,186
CIN: A-09-01-00055	REVIEW OF IMD CLAIMS - STATE OF CALIFORNIA, MAR 2002, \$551,394
CIN: A-07-02-03015	BCBS OF MN PENSION COSTS CLAIMED FOR MEDICARE REIMBURSEMENT, FEB 2003, \$550,083
CIN: A-05-02-72811	COMMUNITY ACTION OF GREATER INDIANAPOLIS INC., AUG 2002, \$547,899
CIN: A-01-04-00008	AUDIT OF MEDICAID PAYMENTS FOR SKILLED PROFESSIONAL MEDICAL PERSONNEL REIMBURSED AT ENHANCED RATES OCTOBER 1, 2002 THROUGH SEPTEMBER 30, 2003 OFFICE OF VERMONT HEALTH ACCESS, MAR 2005, \$534,438
CIN: A-05-04-00034	REVIEW OF INELIGIBLE SNF PAYMENTS UNDER THE ADMINISTRATIVE RESPONSIBILITY OF RHODE ISLAND MEDICARE SERVICES, NOV 2004, \$510,163
CIN: A-03-92-16229	STATE OF PENNSYLVANIA, MAR 1992, \$496,876
CIN: A-02-02-01004	MEDICAID PPS TRANSFERS, MAY 2003, \$493,158
CIN: A-03-04-00205	MEDICAID PROVIDER OVERPAYMENTS--DELAWARE, OCT 2004, \$437,592
CIN: A-01-04-00506	REVIEW OF DISPROPORTIONATE SHARE HOSPITAL PAYMENTS CLAIMED BY SAINT MARY'S HOSPITAL FOR FISCAL YEAR ENDING DECEMBER 31, 2002, MAY 2004, \$433,502
CIN: A-05-03-00053	ESRD PRICING ERRORS AT INDEPENDENT FACILITIES, NOV 2003, \$407,300
CIN: A-02-01-67912	STATE OF NEW YORK, MAR 2001, \$389,536
CIN: A-01-02-73084	STATE OF MAINE, SEP 2002, \$362,326
CIN: A-09-04-00058	REVIEW OF ALASKA'S CLAIM FOR FEDERAL MATCHING FUNDS FOR REIMBURSABLE SERVICE EXPENDITURES CLAIMED AS OTHER FINANCIAL PARTICIPATION, OCT 2004, \$346,217
CIN: A-02-04-01003	ORGAN ACQUISITION COST SURVEY - REGION II, DEC 2004, \$343,272
CIN: A-05-01-00096	PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355
CIN: A-09-03-00032	BLUE CROSS OF CALIFORNIA, MEDICARE, TERMINATION COSTS, OCT 2003, \$319,187

CIN: A-05-02-00023	SCHOOL-BASED MEDICAID ADMIN & SERVICE COSTS - WISCONSIN, MAR 2003, \$315,474
CIN: A-03-04-00204	SKILLED PROFESSIONAL MEDICAL PERSONNEL (SPMP) - WEST VIRGINIA, DEC 2004, \$299,360
CIN: A-09-03-01017	REVIEW OF RYAN WHITE TITLE I SF CONTRACTOR - BAKER PLACES, AUG 2004, \$297,237
CIN: A-09-03-00050	OREGON MEDICAID REIMBURSEMENT RATE FOR NURSING FACILITY ADMINISTRATIVE COSTS, OCT 2003, \$290,769
CIN: A-01-04-00522	THE MID COAST HOSPITAL IN MANIE DSH PAYMENT, SEP 2004, \$289,936
CIN: A-01-04-00003	APPLICATION CONTROLS AT NEW HAMPSHIRE MEDICAID STATE AGENCY, FEB 2005, \$274,370
CIN: A-09-94-30178	STATE OF ARIZONA, JUN 1994, \$267,021
CIN: A-07-04-00175	REVIEW OF UNFUNDED PENSION COSTS AT VERITUS, INC., OCT 2004, \$266,052
CIN: A-05-02-00047	UNITED GOVERNMENT SERVICES, MEDICARE PART A ADMIN. COSTS FY 1999-2001, JUN 2003, \$260,831
CIN: A-07-03-02662	REVIEW OF MULTIPLE ASC PROCEDURES IN THE SAME SESSION NORDIAN, DEC 2002, \$258,112
CIN: A-02-03-04001	AUDIT OF RUTGERS CONTRACT NO. SPO 103-96-D-0016/0001, AUG 2003, \$249,381
CIN: A-05-01-00094	PAYMENTS TO KAISER OF OAKLAND FOR INSTITUTIONAL BENEFICIARIES, OCT 2002, \$229,656
CIN: A-02-03-04006	GRANT REVIEW DAAG55-97-1-0281, MAR 2004, \$221,365
CIN: A-05-01-00103	PAYMENTS FOR SERVICES TO DECEASED BENEFICIARIES - MICHIGAN, OCT 2003, \$211,894
CIN: A-02-01-01019	DEMO BSWNY - CASH MANAGEMENT, OCT 2002, \$208,271
CIN: A-05-04-00058	REVIEW OF INELIGIBLE SNF PAYMENTS UNDER THE ADMINISTRATIVE RESPONSIBILITY OF ANTHEM HEALTH PLANS OF NEW HAMPSHIRE, INC., JUL 2004, \$206,495
CIN: A-01-04-01501	NORTHEASTERN UNIVERSITY DHHS GRANT COSTS GRANT #S 9274, 4000 AND 4111, JAN 2005, \$194,890
CIN: A-09-02-00084	REVIEW OF MEDICAID PAYMENT FOR RESIDENTS UNDER 21/22 IN STATE IMDS, NOV 2004, \$190,460
CIN: A-07-03-02656	REVIEW OF MULTIPLE ASC PROCEDURES IN SAME SESSION KANSAS, DEC 2002, \$190,106
CIN: A-04-04-78917	STATE OF FLORIDA, AUG 2004, \$186,096
CIN: A-03-01-00555	PDPI INC. — HEAD START, JUN 2001, \$185,577
CIN: A-07-01-02094	SURVEY OF OUTPATIENT OBSERVATION SERVICES, OCT 2002, \$165,125
CIN: A-09-02-00083	REVIEW MEDICAID PAYMENTS FOR RESIDENT UNDER 21/22 IN PRIVATE IMDS, NOV 2004, \$155,133
CIN: A-07-04-03051	MEDICAID PROVIDER OVERPAYMENTS IN UTAH, AUG 2004, \$132,749
CIN: A-05-03-00067	ADMINISTRATIVE COSTS - WI MEDICAID WAIVERS, JUN 2004, \$129,663

CIN: A-02-01-04000	INTERIM AUDIT OF RUTGER'S CONTRACT NO.SP0103-96-D-, JAN 2002, \$125,415
CIN: A-01-03-00010	MEDICAID SCHOOL-BASED HEALTH SERVICES ADMINISTRATIVE CLAIMING REVIEW - RHODE ISLAND, JUN 2004, \$123,010
CIN: A-05-01-00069	MERITER - MC/MA CREDIT BALANCES, JUL 2002, \$122,713
CIN: A-05-01-00091	PAYMENTS TO UNITED HC OF FLA FOR INSTITUTIONAL BENEFICIARIES, SEP 2002, \$121,023
CIN: A-02-96-02001	INTERNATIONAL RESCUE COMMITTEE - REFUGEE PROGRAM, JAN 1998, \$114,631
CIN: A-09-02-71247	WATTSHEALTH FOUNDATION INC., APR 2002, \$113,000
CIN: A-01-02-00527	REVIEW OF ANTHEM BLUE CROSS/BLUE SHIELD MEDICARE CONTRACT TERMINATION AND SEVERANCE COSTS, SEP 2003, \$104,468
CIN: A-05-01-00079	PAYMENTS TO BLUE CARE MID-MI FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$100,692
CIN: A-04-03-06007	NURSING HOME QUALITY OF CARE SANCTIONS - FLORIDA, FEB 2004, \$99,957
CIN: A-05-02-00067	REVIEW OF MEDICARE FEE-FOR-SERVICE PAYMENTS & COST REPORTS @ WELBORN, JUN 2003, \$97,623
CIN: A-10-05-80407	FIRST A.M.E. CHILD & FAMILY CENTER, MAR 2005, \$96,803
CIN: A-09-97-00066	WALTER MCDONALD - INDIRECT COST RATE AUDIT, MAR 1998, \$95,733
CIN: A-05-02-00074	IL PARTNERSHIP PLAN - TRANSPORTATION DURING AN INPATIENT STAY, APR 2003, \$89,147
CIN: A-05-01-00090	PAYMENTS TO AETNA OF FOR INSTITUTIONAL BENEFICIARIES, JUL 2002, \$87,516
CIN: A-01-04-77722	STATE OF RHODE ISLAND & PROVIDENCE PLANTATIONS, JAN 2004, \$86,792
CIN: A-05-04-00061	REVIEW OF INELIGIBLE SNF PAYMENTS UNDER THE ADMINISTRATIVE RESPONSIBILITY OF BLUE CROSS BLUE SHIELD OF NEBRASKA, DEC 2004, \$78,352
CIN: A-05-01-00089	ADDITIONAL BENEFITS REVIEW ON MANAGED CARE ORGANIZATION, OCT 2002, \$77,000
CIN: A-05-03-00085	NURSING HOME QUALITY OF CARE SANCTIONS - ILLINOIS, MAY 2004, \$69,892
CIN: A-03-05-79945	BOARD OF EDUCATION OF PRINCE GEORGE'S COUNTY MARYL, DEC 2004, \$67,937
CIN: A-01-03-75448	STATE OF NEW HAMPSHIRE, APR 2003, \$65,917
CIN: A-08-03-74429	PORCUPINE CLINIC, JUL 2003, \$65,027
CIN: A-05-01-00086	PAYMENTS TO HMO OF NE PA FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$62,432
CIN: A-01-04-02501	REVIEW OF COMMUNITY RENEWAL TEAM, INC. COMPENSATION PRACTICES FOR EXECUTIVES AND TEACHERS, MAR 2005, \$57,483
CIN: A-04-02-68936	STATE OF TENNESSEE, JUN 2002, \$50,717

CIN: A-05-02-00054	UNITED GOVERNMENT SERVICES, Y2K COSTS FY 1998 & 1999, APR 2003, \$49,923
CIN: A-02-99-58263	PUERTO RICO OFFICE OF THE GOVERNOR OFFICE OF CHILD, JUL 1999, \$49,684
CIN: A-03-93-03306	SURVEY RESEARCH ASSOC. CACS NO1-ES-45067, DEC 1993, \$48,779
CIN: A-08-05-79580	PORCUPINE CLINIC, OCT 2004, \$45,688
CIN: A-03-02-00373	REVIEW OF US HELPING US, DEC 2003, \$45,558
CIN: A-09-03-01018	REVIEW OF RYAN WHITE TITLE I SF CONTRACTOR - CONTINUUM, FEB 2005, \$42,625
CIN: A-01-03-01500	REVIEW OF CDC HIV PROGRAMS AT GREATER BRIDGEPORT ADOLESCENT PREGNANCY PROGRAM, JUL 2003, \$41,088
CIN: A-10-03-00003	REVIEW OF DUPLICATE MEDICARE FEE-FOR-SERVICE PAYMENTS AT REGENCE BLUESHIELD OF IDAHO, OCT 2003, \$39,660
CIN: A-05-03-00105	AUDIT OF MEDICAID NURSING FACILITY ADMINISTRATIVE COSTS, OCT 2004, \$39,104
CIN: A-03-03-00211	MEDICAID DENIAL OF PAYMENT REMEDY FOR SANCTIONED NURSING HOMES - PA, JUN 2004, \$39,074
CIN: A-02-00-65502	ABYSSINIAN DEVELOPMENT CORP., AUG 2000, \$34,737
CIN: A-06-03-74833	AMIGOS VOLUNTEERS IN EDUCATION & SERVICES INC. (AV, APR 2003, \$31,180
CIN: A-05-02-69155	STATE OF WISCONSIN, DEC 2001, \$30,900
CIN: A-01-02-71527	STATE OF MASSACHUSETTS, APR 2002, \$29,260
CIN: A-08-03-73541	SOUTH DAKOTA FOUNDATION FOR MEDICAL CARE, JAN 2003, \$28,573
CIN: A-03-98-03301	AAUAP — INCURRED COST REVIEW — HHS 105-95-7011, APR 1998, \$28,289
CIN: A-05-03-00097	MEDICARE OUTPATIENT CARDIAC REHAB - NORTHFIELD HOSPITAL, NOV 2003, \$27,013
CIN: A-09-03-01013	REVIEW OF UNIVERSITY MEDICAL CENTER RYAN WHITE TITLE I FUNDING, FEB 2005, \$26,760
CIN: A-04-03-01004	OUTPATIENT CARDIAC REHAB SERVICES - HEALTHSOUTH SEA PINES REHAB HOSPITAL, DEC 2003, \$26,279
CIN: A-07-02-00150	PAYMENTS TO COVENTRY--PITTSBURG FOR INSTITUTIONAL BENEFICIARIES, JUN 2003, \$26,000
CIN: A-09-05-80636	SOUTH COUNTY ECONOMIC DEVELOPMENT COUNCIL, FEB 2005, \$25,000
CIN: A-01-04-78952	STATE OF CONNECTICUT, AUG 2004, \$24,457
CIN: A-09-03-01019	REVIEW OF AID FOR AIDS OF NEVADA RYAN WHITE TITLE I FUNDING, MAR 2005, \$24,355
CIN: A-06-02-70732	UNITED STATES-MEXICO BORDER HEALTH ASSOCIATION, JAN 2002, \$23,483
CIN: A-05-01-00078	PAYMENTS TO HEALTH NET-TUCSON, AZ.- FOR INSTITUTIONAL BENEFICIARIES, APR 2002, \$21,233
CIN: A-02-03-04004	CONTRACT CLOSING - NAS 9-19441, JUL 2003, \$20,595
CIN: A-05-02-72480	HANSEL NEIGHBORHOOD SERVICE CENTER INC., SEP 2002, \$20,266

CIN: A-05-02-00079	MEDICAID FFS PAYMENTS FOR MEDICAID MANAGED CARE ENROLLEES, SEP 2003, \$20,165
CIN: A-05-02-70624	STATE OF OHIO, JAN 2002, \$19,970
CIN: A-04-01-67441	CATAWBA INDIAN NATION, APR 2001, \$19,204
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-10-04-76879	STATE OF ALASKA, DEC 2003, \$18,226
CIN: A-01-02-01504	REVIEW OF CDC'S HIV PROGRAMS AT FENWAY COMMUNITY HEALTH CENTER, JUN 2003, \$18,028
CIN: A-05-03-00037	NURSING HOME QUALITY OF CARE SANCTIONS - OHIO, MAY 2004, \$17,796
CIN: A-05-03-00052	NURSING HOME QUALITY OF CARE SANCTIONS - MICHIGAN, APR 2004, \$17,564
CIN: A-06-04-77400	UNIV. OF ARKANSAS FOR MEDICAL SCIENCES, JAN 2004, \$14,989
CIN: A-05-01-00044	MINNESOTA MEDICAID PERSONAL CARE SERVICES REVIEW, APR 2002, \$14,844
CIN: A-09-04-00056	REVIEW OF CARE PLAN OVERSIGHT SERVICES PAID MORE THAN \$150, JAN 2005, \$14,800
CIN: A-09-04-00041	WEDGE: AUDIT OF MEDICAID VACCINES FOR CHILDREN - ARIZONA, NOV 2004, \$14,162
CIN: A-05-05-80308	INDIANHEAD COMMUNITY ACTION AGENCY INC., MAR 2005, \$13,655
CIN: A-07-04-01011	PAYMENTS FOR UNITED HEALTHCARE FOR INSTITUTIONAL BENEFICIARIES, MAR 2005, \$13,128
CIN: A-03-03-72847	DISTRICT OF COLUMBIA DEPT. OF HEALTH, OCT 2002, \$12,850
CIN: A-08-03-74361	PORCUPINE CLINIC, JUL 2003, \$12,611
CIN: A-04-04-79536	STATE OF SOUTH CAROLINA, AUG 2004, \$12,154
CIN: A-05-03-00012	FROEDTERT MEDICAID CREDIT BALANCES, FEB 2003, \$12,066
CIN: A-05-01-00070	PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$11,089
CIN: A-03-03-00004	MEDICARE AUDIT CARDIAC REHABILITATION CENTERS-SHADY GROVE, OCT 2003, \$9,127
CIN: A-03-02-72715	DISTRICT OF COLUMBIA DEPT. OF HEALTH, JUL 2002, \$7,851
CIN: A-06-03-00040	LONG-TERM CARE TEXAS MEDICAID PAYMENTS FOR DUAL ELIGIBLES, MAR 2004, \$7,801
CIN: A-05-01-68270	LAKE COUNTY COMMUNITY ACTION PROJECT, MAY 2001, \$7,614
CIN: A-06-97-48062	SER-JOBS FOR PROGRESS NATIONAL INC., MAY 1997, \$5,924

CIN: A-15-02-20006	REVIEW OF CDC COOPERATIVE AGREEMENT AND HRSA RYAN WHITE ACTIVITIES AT HEALTH EDUCATION RESOURCE ORGANIZATION (HERO), INC. (BALTIMORE EMA/BALTIMORE CITY HEALTH DEPT), MAR 2003, \$5,010
CIN: A-05-04-00030	PAYMENTS FOR SERVICES TO DECEASED MEDICAID BENEFICIARIES - MASSACHUSETTS, FEB 2005, \$4,696
CIN: A-04-03-01006	OUTPATIENT CARDIAC REHAB SERVICES AT MORTON PLANT HOSPITAL, JAN 2004, \$4,426
CIN: A-05-04-78989	STATE OF WISCONSIN, JUL 2004, \$4,009
CIN: A-02-02-01035	EVALUATION OF BID PROPOSAL - MEDICARE HELP LINE, AUG 2002, \$3,760
CIN: A-05-03-00084	MEDICARE OUTPATIENT CARDIAC REHAB - NORTHERN MICHIGAN HOSPITAL, OCT 2003, \$3,738
CIN: A-02-04-04001	GRANT REVIEW N00014-93-1-1380, MAY 2004, \$3,376
CIN: A-03-01-03303	JOHNS HOPKINS UNIVERSITY/KPMG/NIDA/N01DA-3-7301, FEB 2001, \$3,347
CIN: A-03-95-03318	TRANS-MANAGEMENT SYSTEMS 105-92-1527 (CCO), MAY 1996, \$3,016
CIN: A-02-03-04002	GRANT REVIEW DAAH04-93-G-0234, SEP 2003, \$2,576
CIN: A-04-03-01002	OUTPATIENT HOSPITAL CARDIAC REHAB - MEMORIAL HOSPITAL JACKSONVILLE, NOV 2003, \$2,123
CIN: A-04-03-01005	OUTPATIENT CARDIAC REHAB SERVICES CENTRAL FL REGIONAL HOSPITAL, NOV 2003, \$2,003
CIN: A-02-03-01026	MEADOWLANDS HOSPITAL MEDICAL CENTER CARDIAC REHAB SERVICES, JAN 2004, \$1,703
CIN: A-04-04-02002	MEDICAID PAYMENTS TO SNFS FOR MEDICARE COVERED SERVICES, AUG 2004, \$1,554
CIN: A-06-02-00032	CMS FY 01 MEDICARE ERROR RATE - ARK BC/BS REPORT, NOV 2002, \$1,311
CIN: A-05-03-00070	MEDICARE OUTPATIENT CARDIAC REHAB - ST.CHARLES MERCY HOSP, OCT 2003, \$1,158
CIN: A-03-03-00393	AUDIT OF CDC HIV/AIDS GRANT TO SEXUAL MINORITY YOUTH ASSISTANCE LEAGUE, OCT 2003, \$1,155
CIN: A-07-00-02082	REVIEW OF A COST HMO - IOWA, FEB 2002, \$1,006

Notes to Table 2

¹The opening balance was adjusted downward by \$69 million.

²A management decision has not been made within 6 months on the following reports. Discussions with management are on going.

CIN: A-10-00-00011	MEDICAID INTERGOVERNMENTAL TRANSFERS - WA STATE, MAR 2001, \$427,500,000
CIN: A-06-01-00041	AUDIT OF THE TX DISPROPORTIONATE SHARE HOSP PROG PAYMENT METHODOLOGY, FEB 2003, \$319,200,000
CIN: A-09-03-00055	AUDIT OF OREGON'S MEDICAID UPPER PAYMENT LIMITS FOR NON-STATE

	GOVERNMENT NURSING FACILITIES FOR STATE FISCAL YEARS 2002 AND 2003, FEB 2005, \$45,917,548
CIN: A-01-02-00503	FURTHER EXPANSION OF THE DRG PAYMENT WINDOW, AUG 2003, \$37,000,000
CIN: A-05-02-00078	ROLLUP OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, FEB 2004, \$12,764,202
CIN: A-03-91-00552	INDEPENDENT LIVING PROGRAM — NATIONAL, MAR 1993, \$10,161,742
CIN: A-05-03-00019	PAYMENTS FOR SERVICES TO DECEASED RECIPIENTS - NEW YORK, OCT 2004, \$6,707,623
CIN: A-05-02-00077	MICHIGAN MEDICAID/SCHIP REVIEW, NOV 2003, \$5,908,350
CIN: A-01-97-02506	REVIEW OF THE AVAIL OF MEDICAL COVERAGE/CSE SUPORT, JUN 1998, \$5,704,585
CIN: A-03-02-00203	VIRGINIA - SCHIP/TITLE IV - D SURVEY, JUL 2004, \$5,402,491
CIN: A-06-00-00073	REV OF MGR CARE ADDTL BENEFITS FOR CY 00 OF NYLCAR, MAR 2002, \$4,000,000
CIN: A-05-02-00066	REVIEW OF RFP CMS-02-001/ELH1, MAY 2002, \$1,885,793
CIN: A-05-02-00075	INDIANA MEDICAID/SCHIP REVIEW, NOV 2003, \$1,885,708
CIN: A-05-04-00025	REVIEW OF MEDICARE PHYSICIAN PLACE OF SERVICE CODING FOR AMBULATORY SURGICAL AND RELATED PROCEDURES, OCT 2004, \$742,510
CIN: A-05-02-00082	BID PROPOSAL FOR 1-800 MEDICARE HOTLINE ADMINISTRATION, AUG 2002, \$609,950
CIN: A-05-02-00080	SINAI - MC/MA CREDIT BALANCES, JAN 2003, \$515,942
CIN: A-05-03-00021	CIMRO PRO PRE-AWARD AUDIT FOR NEBRASKA, NOV 2002, \$504,650
CIN: A-05-04-00030	PAYMENTS FOR SERVICES TO DECEASED MEDICAID BENEFICIARIES - MASSACHUSETTS, FEB 2005, \$503,715
CIN: A-05-03-00052	NURSING HOME QUALITY OF CARE SANCTIONS - MICHIGAN, APR 2004, \$280,879
CIN: A-07-04-01008	FAMILY PLANNING - FEE-FOR-SERVICE - COLORADO, JAN 2005, \$269,024
CIN: A-05-04-00023	HEAD START COMPENSATION REVIEW - CEOGC, JAN 2005, \$178,000
CIN: A-01-02-73084	STATE OF MAINE, SEP 2002, \$149,082
CIN: A-05-02-00023	SCHOOL-BASED MEDICAID ADMIN & SERVICE COSTS - WISCONSIN, MAR 2003, \$144,909
CIN: A-05-03-00059	ESRD #9 PRE-AWARD AUDIT (RFP-CMS-03-001/JAC), MAY 2003, \$139,816
CIN: A-04-03-08013	ESRD NETWORK COST PROPOSAL, MAY 2003, \$116,085
CIN: A-05-03-00060	ESRD #10 PREAWARD AUDIT (RFP-CMS-03-001/JAC), MAY 2003, \$114,289
CIN: A-05-01-00070	PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$98,698
CIN: A-02-96-02001	INTERNATIONAL RESCUE COMMITTEE - REFUGEE PROGRAM, JAN 1998, \$90,528
CIN: A-05-02-00089	REVIEW OF RFP CMS-500-97-0408/0008, NOV 2002, \$84,457

CIN: A-05-02-00084	MEDICARE OUTPATIENT CARDIAC REHAB - ST.LUKE'S MEDICAL CENTER, JUL 2003, \$47,247
CIN: A-09-04-00047	WEDGE: REVIEW OF ALASKA'S ACCOUNTS RECEIVABLE SYSTEM FOR MEDICAID PROVIDER OVERPAYMENTS, OCT 2004, \$10,085
CIN: A-05-04-00051	ALLOWABILITY OF CDC BIOTERRORISM COSTS - OHIO DEPARTMENT OF HEALTH, FEB 2005, \$4,154

Appendix E

Reporting Requirements of the Inspector General Act of 1978, as Amended

The reporting requirements of the Inspector General Act of 1978, as amended, are listed below with reference to the page in the semiannual report on which each is addressed. Where there are no data to report under a particular requirement, the word “none” appears in the column. A complete listing of audit and inspection reports is being furnished to Congress under separate cover. Copies are available upon request.

Section of the Act	Requirement	Page
Section 4(a)(2)	Review of legislation and regulations	41
Section 5		
(a)(1)	Significant problems, abuses, and deficiencies	Throughout
(a)(2)	Recommendations with respect to significant problems, abuses, and deficiencies	Throughout
(a)(3)	Prior significant recommendations on which corrective action has not been completed	Appendixes B & C
(a)(4)	Matters referred to prosecutive authorities	42
(a)(5)	Summary of instances where information was refused	None
(a)(6)	List of audit reports	Under separate cover
(a)(7)	Summary of significant reports	Throughout
(a)(8)	Statistical Table 1—Reports With Questioned Costs	39
(a)(9)	Statistical Table 2—Funds Recommended To Be Put to Better Use	40
(a)(10)	Summary of previous audit reports without management decisions	Appendix D
(a)(11)	Description and explanation of revised management decisions	Appendix D
(a)(12)	Management decisions with which the Inspector General is in disagreement	None

Appendix F

Status of Public Proposals for New and Modified Safe Harbors to the Anti-Kickback Statute Pursuant to Section 205 of the Health Insurance Portability and Accountability Act of 1996

Pursuant to section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, the Inspector General is required annually to solicit proposals via *Federal Register* notice for developing new and modifying existing safe harbors to the anti-kickback statute and for developing special fraud alerts. The Inspector General is also required annually to report to Congress on the status of the proposals received.

In crafting safe harbors for a criminal statute, it is incumbent upon the Office of Inspector General (OIG) to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area, so as to uncover all potential opportunities for fraud and abuse by unscrupulous providers. Having done so, OIG must then determine, in consultation with the Department of Justice, whether it can develop effective regulatory limitations and controls that will permit beneficial or innocuous arrangements, but also protect the Federal health care programs and their beneficiaries from abusive practices.

In response to the 2004 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
New safe harbor for physician-owners of ambulatory surgical centers permitting such owners to divide profits from facility fees based on physician productivity as long as physician-owners do not cross-refer patients.	OIG is not adopting this suggestion. The arrangements described are subject to abuse and should be evaluated on a case-by-case basis, such as under the advisory opinion process.
New safe harbor for implementing electronic health record systems among hospitals, health systems, and multispecialty group practices and to provide standardized software and hardware to physicians without charge.	Rulemaking on this topic is forthcoming.
New safe harbor for implementation of a “community wide” health information network.	A solicitation of comments on this topic is forthcoming.
Modification of existing safe harbor for obstetrical malpractice insurance subsidies to include additional types of physicians and subsidies where there is documented need and the subsidy amount is limited in scope and duration.	This suggestion requires further study.

Proposal	OIG Response
New safe harbor for retention payments by hospitals to practitioners.	OIG is not adopting this suggestion. Retention arrangements are subject to abuse and should be evaluated on a case-by-case basis, such as under the advisory opinion process.
Modification of existing safe harbor for hospital recruitment payments to practitioners to protect arrangements outside of Health Professional Shortage Areas and to permit payments to an existing practice for recruiting a practitioner to join the practice.	OIG is not adopting this suggestion. The recruitment arrangements described are subject to abuse and should be evaluated on a case-by-case basis, such as under the advisory opinion process.
Modification of existing safe harbor for group purchasing organizations (GPO) to limit product bundling, to limit sole-source contracts, and to limit administrative fees.	OIG is not adopting this suggestion. The GPO safe harbor is statutory, and OIG has no authority to modify the substantive elements of the statutory exception.
Rescission of the safe harbor for GPOs.	OIG is not adopting this suggestion. The GPO safe harbor is statutory.

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

Proposal	OIG Response
New safe harbor for manufacturer donations to charitable organizations that provide items or services to financially needy patients, including copayment assistance.	OIG is considering this suggestion.
Modification of the discount safe harbor to clarify its application to the additional entities with which pharmaceutical manufacturers may contract under Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (e.g., discount drug card sponsors, pharmacy benefits managers, retail pharmacies, and Part D drug plan sponsors).	This suggestion requires further study.
New safe harbor for certain practices related to “economic credentialing” of physicians by hospitals.	This issue was addressed in OIG Supplemental Compliance Program Guidance for Hospitals, issued on January 31, 2005. Public comments previously received variously suggest issuance of different types of guidance; some comments suggest that OIG take no action. OIG is reviewing the comments and studying the issue.

Proposal	OIG Response
Modification of the Medicare SELECT safe harbor to cover coinsurance waivers for inpatient services negotiated between a hospital and an Employee Retirement Income Security Act employee welfare benefit plan that covers retirees and Part B waivers for employer group plans.	These suggestions require further study. In September 2002, OIG issued a notice of proposed rulemaking to make certain modifications to the safe harbor. The public comments to that rulemaking are under review.
New safe harbor for inducements offered to beneficiaries that fit in an exception to the beneficiary inducements statute at section 42 U.S.C. § 1320a-7a(a)(5).	OIG is considering this suggestion.
Modification of the existing shared risk exception to cover second tier contractors of federally qualified health centers (FQHC) and the TRICARE program.	OIG is considering these suggestions.
New safe harbor for certain fee-for-service arrangements between FQHCs and other providers, practitioners, and suppliers.	OIG published a proposed rule regarding FQHC arrangements. <u>See</u> 70 FR 38081 (July 1, 2005).
Modification of the discount safe harbor to include a discount obtained by a commercial health plan that does not file claims with the Federal health care programs, where the discount otherwise meets the safe harbor conditions.	OIG is considering this suggestion.
Modification of the discount safe harbor to clarify its application to discounts applied to a manufacturer's full product line.	This suggestion requires further study.
Modification of the discount safe harbor's reporting requirements.	This suggestion requires further study.
Modification of the existing safe harbors to make them conform to the final regulations under the physician self-referral statute published by the Centers for Medicare and Medicaid Services (CMS), and creation of new safe harbors analogous to the new self-referral exceptions created by the CMS regulations.	OIG is considering making some conforming changes with respect to the group practice safe harbor. With respect to other safe harbors, the statutes generally serve somewhat different purposes and conforming the safe harbors to the self-referral exceptions may not be appropriate.
Modification of the ambulatory surgery center (ASC) safe harbor to address protection of startup multispecialty ASCs that otherwise comply with the current safe harbor conditions.	OIG is considering this suggestion.
Modification of the safe harbor for ASCs jointly owned by hospitals and physicians to add conditions under which a hospital would not be in a position to make or influence referrals.	OIG is considering this suggestion.

Proposal	OIG Response
Modification of the ASC safe harbor to indicate whether an ASC can require investors to comply with safe harbor conditions.	OIG is considering this suggestion.
Modification of the ASC safe harbor to clarify the use of “pass-through” entities to hold ownership interests and the treatment of physician investors who invest at different times.	OIG is considering this suggestion.
New safe harbor for rural health networks operating pursuant to the Medicare Rural Hospital Flexibility Program.	OIG is considering this suggestion.
New safe harbor for arrangements that comply with section 513 of the IRS Code pertaining to the provision of certain supporting goods and services by tax-exempt hospitals to other tax-exempt hospitals.	OIG is considering this suggestion.

Appendix G

Summary of Sanction Authorities

The Inspector General Act of 1978 (Public Law 95-452), as amended, sets forth specific requirements for semiannual reports to be made to the Secretary for transmittal to Congress. A selection of other authorities appears below:

Program Exclusions

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

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

Patient Dumping

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

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

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

Civil Monetary Penalties Law

Under the Civil Monetary Penalties Law (CMPL), section 1128A of the Social Security Act, 42 U.S.C. § 1320a-7a, a person is subject to penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits to a Federal health care program a claim for items and services

that the person knows or should know is false or fraudulent is subject to a penalty of up to \$10,000 for each item or service falsely or fraudulently claimed, an assessment of up to three times the amount falsely or fraudulently claimed, and exclusion.

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

Summary of Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

Anti-Kickback Statute

The anti-kickback statute authorizes penalties against anyone who knowingly and willfully solicits, receives, offers, or pays remuneration, in cash or in kind, to induce or in return for (1) referring an individual to a person or entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs; or (2) purchasing, leasing or ordering, or arranging for or recommending the purchasing, leasing or ordering of any good, facility, service, or item payable under the Federal health care programs (Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b).

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

False Claims Act

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

The FCA defines “knowing” to include not only the traditional definition, but also instances in which the person acted in deliberate ignorance of the truth or falsity of the information or in 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 private individuals to file suit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries.