Department of Health and Human Services

Compendium of Unimplemented Office of Inspector General Recommendations

OIG Office of Inspector General

May 2009

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Message from the Inspector General

Purpose

The Department of Health and Human Services (HHS), Office of Inspector General (OIG), is pleased to present the "Compendium of Unimplemented Office of Inspector General Recommendations" (Compendium). The Compendium consolidates significant[1] unimplemented monetary and nonmonetary recommendations addressed to the Department into one publication[2] providing information to interested parties about outstanding recommendations, that, if implemented, have the potential to result in cost savings and improvements to program efficiency and effectiveness. These recommendations resulted from our audits and evaluations that were performed pursuant to the Inspector General Act of 1978 (P.L. No. 95-452), as amended. Recommendations require one of, or a combination of, three types of actions: legislative, regulatory, or administrative. Some issues involve more than one type of action.

As part of our effort to track unimplemented recommendations, we perform routine followup with the Department to determine the status of actions being taken in response to our recommendations. This publication includes information about recommendations that had not been fully implemented as of December 31, 2008.

Organization

The Compendium is divided into two sections: monetary and nonmonetary recommendations. Within each section, new recommendations are featured first, followed by those that have been pending from earlier time periods. The sections are further subdivided by program or issue type in the following order:

- **Centers for Medicare & Medicaid Services (CMS) Programs** – CMS's programs, which include Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP), account for most of HHS's budget. They variously provide medical care coverage for adults and children in certain statutorily defined categories.
- **Public Health and Human Service Programs and Departmentwide and Cross-Cutting Issues** –These unimplemented recommendations relate to:
    - public health agencies, such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH); programs of these agencies promote biomedical research; prevent and cure diseases; ensure the safety and efficacy of marketed food, drugs, and medical devices; and conduct other activities designed

1 The Compendium does not include all unimplemented OIG recommendations. For example, it does not include recommendations addressed to specific non-Federal entities or recommendations that involve sensitive security issues.

2 In March 2007, OIG issued the first edition of the Compendium, which compiled significant unimplemented recommendations as of December 31, 2006. In prior years, OIG compiled unimplemented monetary recommendations and unimplemented nonmonetary recommendations in the two separate publications known as the "Red Book" and "Orange Book," respectively.

to ensure the general health and safety of Americans.

- human service agencies, such as the Administration for Children and Families and the Administration on Aging; programs of these agencies provide Federal direction and funding for State-administered efforts designed to promote stability, economic security, responsibility, and self-support for the Nation's families and to establish comprehensive community-based systems to help maintain the dignity and quality of life.
- departmentwide and cross-cutting issues, such as financial accounting, information systems management, and oversight of grants and contracts.

An online version of this document is located at http://oig.hhs.gov/publications.html. If you have questions about this publication, please contact OIG's Office of External Affairs at 202-619-1343.

To report potential instances of waste, fraud, or abuse related to HHS's programs, you may contact the OIG Hotline by phone at 1-800-HHS-TIPS (1-800-447-8477) or by e-mail at HHSTips@oig.hhs.gov. For information about mail, fax, and TTY options and the types of information needed in your report, please visit our Web site at http://oig.hhs.gov/fraud/hotline.

Priority Recommendations

Below is a list of unimplemented recommendations that we refer to as "priority recommendations" because in our view they represent the most significant opportunities to positively impact HHS's programs. The recommendations are not presented in order of priority. The priority recommendations are composed of both monetary and nonmonetary recommendations, representing various timeframes. The list is organized by the various "Top Management and Performance Challenges" that were identified by OIG as part of the Fiscal Year (FY) 2008 Agency Financial Report.

Oversight of Medicare Part D

- Ensure Accurate Medicare Part D Sponsors Bids and Prospective Payments, savings to be determined TBD (p. 3)
- Implement Safeguards To Prevent and Detect Fraud and Abuse in Medicare Prescription Drugs Plan (p.54)

Medicare Integrity

- Ensure Durable Medical Equipment Suppliers' Compliance With Medicare Standards, savings TBD (p. 11)
- Modify Payment Policy for Medicare Hospital Bad Debts, estimated savings $340 million (p. 16)
- Reduce the Rental Period for Medicare Home Oxygen Equipment, estimated savings $3.2 billion (p. 21)
- Modify Payments to Managed Care Organizations, estimated savings $1.97 billion (p. 29)
- Place a Ceiling on Administration Costs Included in Managed Care Organizations' Rate Proposals, savings TBD (p. 30)
- Improve Centers for Medicare & Medicaid Services Performance Evaluation Process for Program Safeguard Contractors (p. 75)

Medicaid and SCHIP Integrity

- Extend Additional Rebate Payment Provision to Generic Drugs, estimated savings $966 million (p. 7)
- Limit Enhanced Payments to Cost and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share, estimated savings $120 million (p. 31)
- Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments, savings TBD (p. 35)

- Ensure That Medicaid Reimbursement for Brand-Name and Generic Drugs Accurately Reflects Pharmacy Acquisition Costs, estimated savings $1.08 billion for brand-name drugs (p. 36) and TBD for generic drugs (p. 37)
- Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement, savings TBD (p. 39)

Quality of Care

- Ensure the Appropriate Processing of Denial of Medicare Payment Remedies for Noncompliant Nursing Homes (p. 56)
- Improve Oversight of Medicare Hospices (p. 63)

Oversight of Food, Drugs, and Medical Devices

- Update and Maintain an Accurate New Drug Code Directory (p. 89)
- Improve Food and Drug Administration Postmarketing Oversight of Drugs (p. 90)

Grants Management

- Increase Oversight of NIH's Grantee Institutions to Ensure Their Compliance With Federal Financial Conflict-of-Interest Regulations (p.59)

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- Strengthen Food and Drug Administration Oversight of Clinical Investigators (p. 88)

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New Monetary Recommendations

Centers for Medicare & Medicaid Services Programs

Medicare Part D Prescription Drugs

Ensure Accurate Medicare Part D Sponsors Bids and Prospective Payments

Background: The Medicare prescription drug program provides an optional drug benefit to Medicare beneficiaries. CMS contracts with private insurance companies, known as Part D sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program. During 2006, the first year of the benefit, Part D expenditures totaled more than $47 billion. CMS makes monthly prospective payments to sponsors for providing prescription drug coverage to Medicare beneficiaries. These payments are based on estimates that sponsors provide in their approved bids prior to the beginning of the plan year. CMS makes prospective payments to sponsors in the form of three separate subsidies to cover the Federal Government's share of the cost of the direct, catastrophic, and low-income prescription drug benefits. The amounts of the three subsidies are based on sponsors' approved bids. After the close of the plan year, CMS must reconcile these prospective payments with sponsors' actual costs to determine whether sponsors owe money to Medicare, Medicare owes money to sponsors, or payment to CMS or to a sponsor is required to share the risk of unexpected losses (or the benefit of unexpected profits).

Finding(s): In August 2007, we estimated that Part D sponsors owed Medicare a net total of $4.4 billion for 2006. Eighty percent of sponsors owed money to Medicare whereas 20 percent of sponsors were to receive money from Medicare. The majority of the funds sponsors owed were a share of profits that they must return to Medicare pursuant to risk-sharing requirements. Additionally, CMS had no mechanisms in place to collect funds owed by sponsors until it had completed reconciliation, which at the time of our review was scheduled to occur more than 9 months after the 2006 plan year had ended. CMS also had no mechanism in place to adjust prospective payments before reconciliation.

Recommendation(s): CMS should ensure that sponsors' bids accurately reflect the cost of providing the benefit to Medicare beneficiaries. Specifically, CMS should use data from 2006 and subsequent future years when reviewing and approving bids and ensure that sponsors incorporate these data into future bids. CMS should also consider implementing an interim reconciliation process to reduce the amounts owed to Medicare. In addition, CMS should better align monthly prospective payments with sponsors' actual costs, and consider seeking legislative changes to delay the adjustments to the risk corridors.

Savings: TBD

Status: CMS agreed with our recommendation that the data collected from 2006 and subsequent years be used in the review of future bid submissions. CMS acknowledged its

authority to change payment methodologies for the low-income cost-sharing and reinsurance and stated that it was carefully examining possible options. The agency did not concur with our recommendations to implement an interim reconciliation process for 2007 or to seek legislation to delay changes to risk corridors.

Since the issuance of our report, CMS has taken actions that partially addressed two of our recommendations. To improve bid accuracy, in April 2007, CMS issued guidance stating "plans with experience providing the Part D benefits in contract year 2006 are expected to use PDE [prescription drug event] transactions including State-to-plan and plan-to-plan PDEs as base period experience for contract year 2008." CMS also required sponsors to use baseline data from 2007 to complete their 2009 bids. However, CMS did not address how it plans to use the data from 2006 and subsequent years in its review and approval of bids. In response to our recommendation to better align low-income cost-sharing payments with costs, CMS published a regulation effective March 2009 that gives CMS the authority to change the methodology for determining interim low-income subsidy payments; however, CMS has not made changes to the payment methodology for this subsidy. As a result, we will monitor the Part D reconciliation for 2007 and the status of collections for 2006. We will also continue to monitor the actions CMS takes to further address all our recommendations.

Report(s): OEI-02-07-00460; issued 10/07

Other Medicare and Medicaid Issues

Identify Duplicate Medicaid and Medicare Home Health Payments

Background: Home health services are intended to restore health and minimize the effects of illness and disability, thereby enabling beneficiaries to reside in community settings and avoid institutionalization. Both Medicaid and Medicare pay home health providers for home health services specified in the plans of care for beneficiaries; however, both programs should not pay for the same supplies or services for the same beneficiaries. When both Medicaid and Medicare cover particular supplies and services, Medicaid is the payer of last resort, and Medicare should pay first for services provided to individuals who meet both Medicaid and Medicare eligibility requirements. We examined Medicaid and Medicare claims during 2005 in five selected States to determine the extent to which improper home-health-related payments for dual-eligible beneficiaries occurred.

Finding(s): In four of the five States, we found that Medicaid inappropriately paid home health providers a combined total of $1 million for claims for nonroutine medical supplies (e.g., catheters, dressings, syringes, and needles) and therapeutic services that were also paid by Medicare. This represented about 1 percent of the $113 million that the four States spent on home health nonroutine medical supplies and therapeutic services. We also found that in two States, Medicaid paid $6.6 million for routine medical supplies (e.g., cotton balls, gloves, and incontinence items) on the same dates that Medicare covered home health services, but the Medicaid claims data did not include enough information to determine whether the supplies qualified for Medicare payment. We also found that each of the five States had established payment system edits to compare claims for home health services to Medicare eligibility information; however, incomplete eligibility information and payment system edit overrides resulted in inappropriate payments. States do not have direct access to Medicare prospective payment system (PPS) data that would provide information about whether and when a beneficiary is receiving Medicare-paid services.

Recommendation(s): CMS should ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and clarify its policy on Medicare PPS coverage of routine medical supplies.

Savings: TBD*

**The estimate of $1 million that Medicaid inappropriately paid for nonroutine medical supplies and therapeutic services in four of the five States in 2005 was not projected to all States.*

Status: In commenting on our draft report, CMS stated that it "did not disagree" with our first recommendation and indicated that it recognized the importance of preventing duplicate Medicaid and Medicare billings. The agency also commented that the absence of medical record reviews limited the findings. CMS indicated that it would develop a process to address duplicate claims for nonroutine medical supplies and disseminate the process to State program integrity directors. CMS concurred with our second recommendation to clarify the policy on coverage of routine medical supplies under Medicare's home health PPS and indicated that it planned

to clarify coverage during the Calendar Year (CY) 2010 rulemaking process. We will monitor CMS's actions in both areas.

Report(s): OEI-07-06-00640; issued 05/08

Medicaid Drug Rebates

Extend Additional Rebate Payment Provision to Generic Drugs

Background: For covered outpatient drugs to be eligible for Federal Medicaid funding, the manufacturers must enter into rebate agreements that are administered by CMS and pay quarterly rebates to the States. Section 1927(b)(3) of the Social Security Act (SSA) requires participating manufacturers to report quarterly to CMS the average manufacturer price (AMP) for covered outpatient drugs. SSA requires the payment of additional rebates for single-source and innovator multiple-source drugs (collectively, "brand-name drugs") under certain situations. For these brand-name drugs, section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a drug increases more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount by which the drug's reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid. There is no similar inflation-based rebate provision for noninnovator (generic) drugs.

Finding(s): From 1991 through 2004, we found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. By applying the method in the SSA for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program would have received a total of $966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

Recommendation(s): CMS should consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

Savings: $966 million*

** We calculated that the Medicaid program would have received a total of $966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.*

Status: In its comments on the draft of our 2007 report, CMS stated that it could not commit to pursuing the legislative change because, at the time of our report, it did not have sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the Deficit Reduction Act of 2005. However, CMS indicated that it would consider our recommendation as it considers future legislative proposals.

Report(s): OAS-06-07-00042; issued 10/07

Previous Monetary Recommendations

Centers for Medicare & Medicaid Services Programs

Medicare Durable Medical Equipment

Ensure Durable Medical Equipment Suppliers' Compliance With Medicare Enrollment Standards

Background: Durable medical equipment prosthetics, orthotics, and supplies (DMEPOS), which include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs, are provided to Medicare beneficiaries by commercial suppliers that are reimbursed by Medicare. The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment and reenrollment of Medicare DMEPOS suppliers. CMS reported that payments for DMEPOS reached $10 billion in FY 2005. OIG conducted two reviews of DMEPOS suppliers to determine compliance with Medicare enrollment standards. We conducted unannounced site visits to 1,581 DMEPOS suppliers in three South Florida counties in 2006 and to 905 DMEPOS suppliers in Los Angeles County in 2007 to evaluate compliance with four selected Medicare requirements related to enrollment standards.

Finding(s): In South Florida, we found that a total of 491 of 1,581 South Florida suppliers (31 percent) failed to maintain physical facilities or were not open and staffed during our unannounced site visits, contrary to regulations containing the DMEPOS supplier standards. Suppliers in Miami-Dade County represented 64 percent of the suppliers we visited but accounted for 80 percent of suppliers that did not maintain physical facilities or were not accessible during business hours.

In Los Angeles County, 115 out of 905 suppliers (13 percent) did not maintain physical facilities or were not open and staffed during our site visits. Another 79 suppliers (9 percent) were open but did not meet at least one of the two additional requirements for the standards we reviewed. In addition, we found that 124 suppliers (14 percent) met the four requirements for the standards we reviewed, but their claims shared an atypical characteristic. More than half of the Medicare beneficiaries for these 124 suppliers did not receive other Medicare services (such as an office visit) from the physicians who ordered the DMEPOS within the 6-month period preceding the DMEPOS claim. Findings in both reports demonstrated continued vulnerabilities in the Medicare DMEPOS benefit.

Recommendation(s): CMS should strengthen the Medicare durable medical equipment (DME) supplier enrollment process and ensure that suppliers meet Medicare supplier standards. We suggested a number of specific options for implementing this recommendation: conduct more unannounced site visits to suppliers to determine whether suppliers exist at the addresses on record, perform more rigorous background checks of applicants, assess the fraud risk of suppliers and focus monitoring and enforcement on high-risk suppliers, increase prepayment review of DMEPOS claims, require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years, and establish a minimum number of hours of operation and minimum inventory requirements for product and service types. We also

recommended that CMS require all suppliers to pay a Medicare enrollment application fee to cover the costs of criminal background checks and site inspections; pay an additional Medicare enrollment fee if, during a site visit (conducted during business hours), the supplier's facility is closed or inaccessible; and seek legislative authority to impose temporary moratoriums, on an as-needed basis, on supplier enrollment in high-fraud areas.

Savings: TBD

Status: In its comments to our March 2007 draft report, CMS either agreed with or stated that it would consider the options we recommended for strengthening the Medicare DME supplier enrollment process. The agency has taken action to implement some of the suggested options, including revising the NSC contractual requirements to increase the number of unscheduled site visits, deactivating suppliers who have billed the Medicare programs for 12 months, adding additional DMEPOS supplier standards, requiring DMEPOS suppliers to post a surety bond, and prioritizing reenrollment applications over processing new applications in highly vulnerable areas of the country. On November 1, 2007, CMS began a 2-year demonstration project involving DMEPOS suppliers in specific counties and informed us in December 2007 that it had started the process of conducting background checks on selected suppliers with high fraud potential. It also began its competitive bidding program; however, the Medicare Improvements for Patients and Providers Act of 2008 (enacted July 15, 2008) has delayed the DMEPOS competitive bidding program, including the accreditation and background check provision. CMS published regulation CMS-6036-P on January 25, 2008, to clarify and enhance supplier standards.

In its comments to our second report, issued in February 2008, CMS stated that suppliers must pay a fee to the accrediting organization for an initial site visit and that "criminal background checks are conducted as required by State standards." In finalizing that report, we noted, however, that our recommendation is that site inspection and application fees would be paid to the Federal Government, not the accrediting organization. CMS also stated it would consider seeking legislative authority to impose temporary moratoriums on supplier enrollment. We will continue to monitor CMS's implementation of program safeguards in the area of DMEPOS, including actions related to temporary moratoriums on supplier enrollments and statutory delay for implementation of competitive bidding.

Report(s): OEI-03-07-00150; issued 03/07
OEI-09-07-00550; issued 02/08

Medicare Hospitals

Continue Mandated Reductions in Hospital Capital Costs

Background: In October 1991, CMS began a 10-year transition period for paying inpatient hospital capital-related costs under the PPS. The rates are based on historical costs less a mandated reduction of 7.4 percent under the Omnibus Budget Reconciliation Act (OBRA) of 1993.

Finding(s): Hospital capital costs soared during the first 5 years of the PPS for inpatient hospital costs, despite low bed occupancy. The Medicare system of reimbursing capital costs on a pass-through basis (i.e., reimbursed outside the diagnosis-related group (DRG)) was a major reason for this increase. Paying capital costs prospectively, as required by regulation, should assist in curbing escalating costs. However, the prospective rates are based on historical costs that are inflated because (1) excess capacity in the hospital industry has caused more capital costs to be incurred than economically necessary and (2) inappropriate elements, such as charges for depreciation on federally funded assets, are included in the historical costs.

Recommendation(s): CMS should (1) seek legislative authority to continue mandated reductions in capital payments beyond FY 1995 and (2) determine the extent to which capital payment reductions are needed to fully account for hospitals' excess bed capacity and report the percentage of reduction to Congress.

Savings: TBD

Status: CMS did not concur with our recommendations. In its comments on the draft of our 1992 report, CMS stated that it believed that section 1886(g)(1)(B)(iv) of the SSA, which states that the Secretary of HHS may provide for an adjustment for occupancy rate, is intended only to provide for an adjustment to capital PPS payments based on a hospital's current occupancy rate. Although the Balanced Budget Act of 1997 (BBA) reduced capital payments, we note that it did not include the effects of excess bed capacity and other elements included in the base-year historical costs. The President's FY 2001 budget proposed reducing capital payments and saving $630 million from FY 2001 through FY 2005. However, this reduction was not made, and we continue to recommend that CMS review the need for capital payment reductions. In the final rule that set FY 2008 hospital inpatient rates (which was published in the August 22, 2007, Federal Register), CMS stated that it was continuing to monitor current capital payment and cost data. The final rule also reduced capital payments by eliminating the large urban add-on adjustment and phasing out the teaching adjustment. We plan to perform a follow-up audit of this issue.

Report(s): OAS-09-91-00070; issued 04/92
OAS-14-93-00380; issued 04/93

More Accurately Reflect Base-Year Costs in Prospective Payment System's Capital Cost Rates

Background: Under section 1886(d) of the SSA, the Medicare program pays for the operating costs attributable to hospital inpatient services under the PPS. The system pays for care using a predetermined specific rate for each discharge. P.L. No. 100-203 required the Secretary of HHS to establish a PPS for capital costs for cost-reporting periods beginning in FY 1992.

Finding(s): Although CMS took care to devise and implement an equitable PPS for capital costs, some future cost items had to be estimated. A few years later, when actual data were available, we compared CMS's estimates with the actual data and found, in some cases, that the estimates were too high. A 7.5-percent reduction would correct all forecasting estimates that CMS had to make in arriving at an anticipated rate to implement the capital cost PPS. The total effect of overpayments in relation to costs used as the basis for this system gradually increased from 1996 until the system was fully implemented in 2002.

Recommendation(s): CMS should (1) consider seeking legislation to reduce payment rates by 7.5 percent to reflect more accurately costs of the base year used for the capital cost PPS and (2) continue to monitor the most current data and make any necessary further adjustments to the base rate.

Savings: TBD

Status: In its comments on the draft of our report, CMS concurred that the capital rate reflected an overestimation of base-year costs. Subsequently, the BBA of 1997 provided for a reduction of 2.1 percent in capital payments for FYs 1998 through 2002. No additional adjustments have been made. However, in the final rule that set FY 2008 hospital inpatient payment rates (published in the August 22, 2007, Federal Register), CMS stated that it was continuing to monitor current capital payment and cost data to determine whether additional adjustments were warranted. The final rule also reduced capital payments by eliminating the large urban add-on adjustment and by phasing out the teaching adjustment. The President's FY 2009 budget included a legislative proposal to reduce hospital capital payments by 5 percent to ensure that they are appropriately aligned with capital costs. However, this proposal has not been enacted.

Report(s): OAS-07-95-01127; issued 08/95

Revise Graduate Medical Education Payment Methodology

Background: Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 and section 9314 of OBRA of 1986 changed the way Medicare reimburses hospitals for the direct costs of graduate medical education (GME). Under the revised methodology, costs are reimbursed on a "hospital-specific" prospective payment basis, which is based on a hospital's GME costs per resident in a base year, usually the cost-reporting period that began during FY 1984.

Finding(s): CMS estimated that the revised GME methodology would result in substantial Medicare savings. Our review indicated that because of two factors in the methodology, Medicare will pay a disproportionate share of GME costs. First, the revised system allows hospital cost centers with little or no Medicare patient utilization to receive increased importance in the calculation of GME reimbursement. Second, the Medicare patient load percentage used to compute Medicare's share of these costs is based on inpatient data only and is higher than Medicare's overall share of GME costs as determined under the previous method, which also included ancillary and outpatient data.

Recommendation(s): CMS should (1) revise the regulations to remove from a hospital's allowable GME base-year costs any cost center with little or no Medicare utilization and (2) submit a legislative proposal to compute Medicare's percentage of participation under the former method or a similarly comprehensive system.

Savings:	**Factor 1**	**$39.2 million***
	Factor 2	**$125.6 million***
	Combined	**$157.3 million***

**Estimated savings are based on 4 years of cost reporting beginning October 1, 1985. When the two proposed changes are handled as one combined calculation, the savings are less than those from calculating the effect of the changes separately.*

Status: CMS did not concur with our recommendations, stating in its comments on our draft report that it believed that few Medicare savings would result from implementation of the first recommendation and that a legislative proposal to implement the second recommendation was not appropriate because of pending changes to existing GME programs. Although we note that the BBA of 1997 and the Balanced Budget Refinement Act of 1999 (BBRA) contained provisions to slow the growth in Medicare spending on GME, we continue to recommend that CMS revise GME payment methodology to achieve further savings. In April 2008, CMS informed us that it is continuing to monitor this area.

Report(s): OAS-06-92-00020; issued 04/94

Modify Payment Policy for Medicare Hospital Bad Debts

Background: Under Medicare's inpatient hospital PPS, hospitals are reimbursed for inpatient services rendered to Medicare beneficiaries by a fixed payment amount based on a DRG. However, bad debts related to unpaid Medicare deductible and coinsurance amounts are reimbursed separately as pass through items (i.e., reimbursed outside the DRG) under reasonable cost principles, subject to a 30-percent reduction. Most provider types are also entitled to have their bad debts reimbursed at this rate.

Finding(s): CMS records showed that total Medicare hospital bad debts increased from $159 million in FY 1984 to almost $399 million in FY 1987. During this same period, hospitals continued to earn significant profits. Although regulations provide that hospitals must be able to establish that they made reasonable bad debt collection efforts, such efforts have often been inadequate; hospitals have little incentive to aggressively collect the unpaid deductible and coinsurance amounts when Medicare pays these amounts. As a result, hospitals have received unallowable bad debt payments.

Recommendation(s): CMS should consider various options, including eliminating bad debt payments, and reimbursing PPS hospitals for bad debts only if the hospitals lost money on their Medicare operations. CMS should seek legislative authority to further modify bad debt policies.

Savings: $340 million*

**Savings shown in the President's FY 2001 budget proposal to eliminate bad debt payments to hospitals. Savings of $7.15 billion for FYs 2008–2012 were estimated in the President's FY 2008 budget proposal to eliminate bad debt payments to all providers.*

Status: CMS did not concur with our recommendations. In a February 10, 2003, proposed rule, CMS reiterated that it did not concur with the recommendations because the base period used to derive PPS rates did not include bad debts. Although the BBA of 1997 provided for some reduction of bad debt payments to providers, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) increased bad debt reimbursement. The President's FY 2009 budget included a legislative proposal to eliminate Medicare bad debt payments for all providers over a 4-year period. However, this proposal has not been enacted.

Report(s):

OAS-14-90-00339; issued 06/90
OAS-04-00-06005; issued 12/01
OAS-03-02-00002; issued 06/02
OAS-03-01-00022; issued 07/02
OAS-09-02-00057; issued 07/02
OAS-02-02-01016; issued 09/02
OAS-05-02-00039; issued 10/02
OAS-05-02-00052; issued 10/02
OAS-04-02-02011; issued 10/02
OAS-06-02-00027; issued 10/02
OAS-01-02-00515; issued 01/03
OAS-02-02-01031; issued 01/03
OAS-04-02-02016; issued 01/03

Recover Overpayments and Expand the Diagnosis-Related Group Payment Window

Background: Under the PPS for inpatient hospital services, Medicare fiscal intermediaries reimburse hospitals a predetermined amount for inpatient services furnished to Medicare beneficiaries, depending on the illness and its classification under a DRG. Effective January 1, 1991, separate payments for nonphysician outpatient services (such as diagnostic tests and laboratory tests) provided to a patient during the 3 days before the date of the patient's admission are not permitted under OBRA 1990, section 4003. This 3-day period is known as the DRG payment window. Previously, separate payments for nonphysician outpatient services provided before admission for inpatient stays were not permitted in the 24 hours preceding admission.

Finding(s): For the period November 1990 through December 1991, our review identified approximately $83.5 million in admission-related nonphysician outpatient services rendered 4 to 7 days immediately before inpatient admissions. A subsequent review identified $37 million in preadmission services provided to patients for 10 selected DRGs 4 to 14 days before admissions during CY 2000. Because the intent of the PPS has always been to include related services under one prospective payment, it would seem appropriate that the DRG payment window encompass a longer period.

Recommendation(s): CMS should propose legislation to expand the DRG payment window to at least 7 days immediately before the day of admission.

Savings:	**Diagnostic services provided:**	**4–7 days**	**$83.5 million***
		4–10 days	**$37.0 million****

**The savings estimate is based on nonphysician outpatient services rendered 4 to 7 days immediately before inpatient admissions during the period November 1990 through December 1991.*

***The savings estimate is based on the 10 selected DRGs associated with nonphysician outpatient services rendered 4 to 14 days before inpatient admissions during CY 2000.*

Status: In its comments on the draft of our 2003 report, CMS concurred with our recommendation; it noted, however, that it would need to consider the impact on admission-related outpatient services provided to beneficiaries before a legislative change could be advanced.

Report(s):	**OAS-01-92-00521; issued 07/94**
	OAS-01-02-00503; issued 08/03

Adjust Base-Year Costs in the Prospective Payment System for Hospital Outpatient Department Services

Background: The BBA of 1997 required CMS to develop a PPS for hospital outpatient department services. This legislation required CMS to use 1996 hospital claims data and the most recent available cost report data to develop the rates.

Finding(s): We are concerned about the reliability of the claims and cost data that CMS used in the prospective payment rate calculations. Our previous audit work identified substantial unallowable costs in hospitals' Medicare cost reports and several areas of payment improprieties in Medicare reimbursement for outpatient department services. Because the outpatient PPS is based on prior Medicare outpatient reimbursement, we have concerns that the payment rates may be inflated.

Recommendation(s): CMS should, in conjunction with OIG, further examine the extent to which the base-period costs used in the outpatient prospective payment rate calculations included unallowable costs and improper payments. If this work reveals that excessive unallowable costs and improper payments were included in the calculations, appropriate adjustments should be made.

Savings: TBD

Status: In its comments on our draft report, CMS concurred with our recommendation, but no additional analysis has been performed to examine the adequacy of base-year costs.

Report(s): OAS-14-98-00400; issued 11/98

Medicare Hospital and Nursing Facility Stays

Monitor the Quality and Appropriateness of Consecutive Medicare Stays

Background: Under the authority of the Peer Review Improvement Act of 1982, CMS contracts with quality improvement organizations (QIO) in each State to ensure that quality, effective, efficient, and economical hospital care is provided to Medicare beneficiaries. QIOs are responsible for routinely reviewing items or services provided to Medicare beneficiaries to determine the quality and appropriateness of these services. OIG conducted two reviews to assess the quality of care and medical necessity of services provided to Medicare beneficiaries within sequences of consecutive stays. A "consecutive stay sequence" is a sequence of three or more inpatient or skilled nursing facility (SNF) stays for a beneficiary with multiple admissions when the successive stay occurred within 1 day of discharge of the preceding stay. Our first report, issued in 2005, focused on consecutive inpatient stays in FY 2002 involving acute care facilities that may be found within acute care hospitals: rehabilitation units, psychiatric units, and skilled nursing swing beds. Our second report, issued in 2007, assessed consecutive stay sequences in CY 2004 that included at least one SNF stay.

Finding(s): In our first review, we found that in FY 2002, Medicare paid an estimated $267 million for sequences of Medicare inpatient stays that were associated with quality-of-care problems and/or fragmentation of services. In our second review, we projected that 35 percent of inpatient and SNF consecutive stay sequences in CY 2004 were associated with quality-of-care problems and/or fragmentation of services. Medicare paid an estimated $4.5 billion for these problematic and/or fragmented consecutive stay sequences. Eleven percent of the individual stays within consecutive stay sequences in CY 2004 involved problems with quality of care, admissions, treatments, or discharges. In addition, 20 percent of individual stays within consecutive stay sequences in CY 2004 lacked documentation sufficient for reviewers to determine whether appropriate care was rendered.

Recommendation(s): CMS should direct QIOs to monitor for fragmentation and quality of care across consecutive stay sequences. CMS should encourage fiscal intermediaries and QIOs, as appropriate, to monitor the medical necessity and appropriateness of services provided. It should also collaborate with providers to improve systems of care on the basis of review results and reinforce efforts to educate medical providers on their responsibility for ensuring that medical records contain the information necessary to determine the quality, medical necessity, and medical appropriateness of care provided.

Savings: TBD

Status: In its comments on our 2007 draft report, CMS concurred with our recommendations, noting that it would place greater emphasis on continuity-of-care issues in all settings and on measuring the rate of events, such as hospital readmissions. CMS stated that it would consider incorporating interventions in the ninth Statement of Work (SOW) for the QIO program. CMS indicated that it was working with physician groups to increase the understanding of the "medical home" concept, in which care is coordinated for a patient through a single site, and

would ask QIOs to categorize complaints by type to provide better data on lapses in continuity of care and to emphasize documentation. In August 2008, CMS awarded contracts for the QIO program's ninth SOW, which extends through July 31, 2011. The Care Transitions Project in the ninth SOW emphasizes continuity of care in all settings and is a QIO "subnational" task for 14 States: Alabama, Colorado, Florida, Georgia, Indiana, Louisiana, Michigan, Nebraska, New Jersey, New York, Pennsylvania, Rhode Island, Texas, and Washington. QIOs will work to coordinate care and promote seamless transitions across settings, including from hospital to home, unskilled nursing care, and in-home health care. QIOs will also look to reduce unnecessary admissions to hospitals that may increase risk or harm to patients and cost to Medicare. We will continue to monitor CMS's oversight of the implementation of the ninth Statement of Work.

Report(s): OEI-03-01-00430; issued 06/05
OEI-07-05-00340; issued 06/07

Medicare Durable Medical Equipment

Reduce the Rental Period for Medicare Home Oxygen Equipment

Background: Section 1834(a)(5) of the SSA authorizes Medicare payment for home oxygen equipment under its DME benefit. Medicare covers both stationary and portable oxygen delivery systems, which were payable on a rental-only basis from 1989 (the year in which Medicare implemented the DME fee schedule) until 2006. Since January 1, 2006, the rental period has been 36 months, and Medicare discontinues payments to home oxygen providers after 36 months.

Finding(s): Based on the 2006 median fee schedule amount, Medicare will allow $7,215 for 36 months for concentrators that cost $587, on average, to purchase. Beneficiaries will incur $1,443 in coinsurance. Based on our analysis, minimal servicing and maintenance for concentrators and portable equipment are necessary.

Recommendation(s): CMS should work with Congress to further reduce the rental period for oxygen equipment, determine the necessity and frequency of nonroutine maintenance and servicing for concentrators, and determine whether a new payment methodology is appropriate for portable oxygen.

Savings: $3.2 billion*

**If Medicare rental payments for oxygen concentrators were limited to 13 months, the program and its beneficiaries would save approximately $3.2 billion over 5 years.*

Status: CMS concurred with our recommendations. With regard to the first recommendation, H.R. 3162 was introduced in the 108th Congress; it would have reduced the monthly rental limit for oxygen from 36 to 13 months. On November 2, 2006, CMS issued a final rule that changed how Medicare will pay for oxygen and oxygen equipment. This policy change implements our recommendations on nonroutine maintenance and servicing and established a new payment methodology for portable oxygen. However, reducing the rental period for most oxygen equipment from 36 months to 13 months requires a statutory change. We will continue to monitor CMS's progress related to home oxygen equipment costs and services and congressional action to the reduction of the rental period.

Report(s): OEI-09-04-00420; issued 09/06

End Stage Renal Disease Program

Reduce Medicare End Stage Renal Disease Payment Rates

Background: OBRA 1981 established a PPS for outpatient dialysis treatments under Medicare's end stage renal disease (ESRD) program. To reimburse facilities for these treatments, CMS pays a composite rate per treatment based on audited median costs. In FY 1989, payments averaged $125.05 per treatment for freestanding facilities and $129.11 for hospitals.

Finding(s): Both 1985 and 1988 audited data justify a decrease in the payment rate. The 1985 data showed a median cost, including home dialysis costs, of $108.19 per treatment. Even after considering the effect of home dialysis services, the in-facility costs decreased from 1980 to 1985 without a corresponding reduction in the prospective rates. In addition, our audit of the 1988 home office costs of a major chain of freestanding facilities showed that home office costs decreased from $117 per treatment in 1980 to $89 in 1988. Because of the prominence of this chain, these audited costs have a significant impact on the median cost of dialysis treatments. We estimated that this chain was earning $36 per treatment, a 29-percent profit margin for each treatment in 1988.

Recommendation(s): CMS should reduce the payment rates for outpatient dialysis treatments to reflect current efficiencies and economies in the marketplace.

Savings: $45 million*

**This estimate, which is based on 2004 Medicare payments for dialysis treatments, represents program savings of $45 million for each dollar reduction in the composite rate.*

Status: CMS concurred with our recommendation. However, we note that subsequent legislation enacted in 1999, 2000, 2001, and 2006 increased composite payment rates for outpatient dialysis treatment. The Tax Relief and Health Care Act of 2006, Division B, Title 1, section 103, increased the amount of the composite rate component of the basic case-mix adjusted by 1.6 percent for services furnished on or after April 1, 2007. In April 2008, CMS informed us that it had released a report to Congress regarding its research and analysis of a bundled ESRD payment system and is awaiting congressional action that would allow CMS to implement such a system. Although there has been legislation increasing the composite payment rates for outpatient dialysis treatment, we continue to recommend that these rates reflect the costs of outpatient dialysis treatments in efficiently operated facilities. We plan to reexamine whether the payment rates for outpatient dialysis services reflect current efficiencies and economies in the marketplace.

Report(s): OAS-14-90-00215; issued 07/90

Medicare Reimbursement

Review Payment Levels and Reinstate Beneficiary Cost Sharing for Laboratory Services

Background: Medicare pays for most clinical laboratory tests based on fee schedules. These schedules, effective July 1, 1984, were established by each carrier generally at 60 percent of the Medicare prevailing charge (the charge most frequently used by all suppliers). Over the years, the Medicare fee schedule has gone through several adjustments. OBRA 1993 reduced the cap for the Medicare clinical laboratory fee schedule from 84 percent beginning in 1994 to 76 percent by 1996. The BBA of 1997 reduced fee schedule payments by lowering the cap to 74 percent of the median for all fee schedule payments beginning in 1998, but the BIPA raised the fee schedule amounts to 100 percent of the median for "new tests" performed on or after January 1, 2001. Also, no inflation update was permitted between 1998 and 2002.

Finding(s): Our 1996 follow-up report found that Medicare generally continued to pay clinical laboratories more than physicians pay for the same tests. Our previous work indicated that the clinical laboratories marketed customized panels to physicians at less than what Medicare paid for the same tests. This contributed to a significant increase in the use of laboratory services.

Recommendation(s): CMS should (1) review payment levels for laboratory services and (2) reinstate the beneficiary coinsurance and deductible provisions for laboratory services as a means of controlling utilization.

Savings:	**Copayment**	**$2.4 billion***
	Fee Schedule Adjustment	**TBD**

**The savings estimate is based on the Congressional Budget Office's December 2008 Budget Options Volume I: Health Care. The 10-year savings from making laboratory services subject to standard deductible and coinsurance requirements would be $23.8 billion, resulting in annual savings of $2.4 billion.*

Status: In its comments on the draft of our 1996 report, CMS partially concurred with our recommendations and noted that it had taken some steps to reduce payments for laboratory services. The BBA of 1997 required the Secretary of HHS to request that the Institute of Medicine (IOM) conduct a study of Part B laboratory test payments. As a result of the IOM's recommendations, section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS conduct a demonstration that applies competitive bidding to clinical laboratory services that would otherwise be paid under the Medicare Part B fee schedule. In December 2005, CMS submitted the initial report on the demonstration to Congress. However, before CMS could complete the demonstration, section 145(a) of Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) repealed the project for Medicare clinical laboratory services paid under the Medicare Part B fee schedule. In addition, section 145(b) of MIPPA specifies that the annual clinical laboratory fee schedule update will be reduced each year from 2009 through 2013 by 0.5 percentage points. The update for 2009 equals a 4.5-percent increase for payments made under the Medicare Part B Clinical Laboratory Fee Schedule. Although legislation has reduced the prices for individuals' tests, we continue to recommend that CMS evaluate payments for laboratory services.

CMS did not concur with our 1996 recommendation to reinstate beneficiary coinsurance and deductible provisions for laboratory services, noting that the President's 1996 budget statement did not include such a proposal. Because of the potential for overutilization and the fact that beneficiaries are not always aware of the tests being performed, we continue to recommend that CMS study the reinstatement of beneficiary coinsurance and deductible provisions for laboratory services.

Report(s): OAS-09-89-00031; issued 01/90
OAS-09-93-00056; followup issued 01/96

Require Physician Examination Before Ordering Home Health Services

Background: Section 1861 of the SSA authorized Medicare payments for home health services. Since October 1, 2000, home health agencies have been reimbursed under a PPS system. Federal regulations at 42 CFR § 424.22 require physicians to certify the need for home health services but they do not explicitly require a physician to personally examine a beneficiary before making the certification.

Finding(s): Our audits and investigations have identified medically unnecessary care and inappropriate or fraudulent billing by specific home health agencies. Further, we have conducted studies that describe extreme variations and broad patterns of billing by these agencies, raising questions about the appropriateness of some billings. Accordingly, we find that systemic controls on the home health benefit are warranted to prevent abuse.

Recommendation(s): CMS should revise Medicare regulations to require that physicians examine patients before ordering home health care and see the patient at least every 60 days. As discussed below, other recommendations to correct abusive and wasteful practices are being addressed.

Savings: TBD

Status: In its comments on our July 1997 draft report, CMS partially concurred with our recommendation, stating that it agreed in principle that physicians should certify home health care only on the basis of personal knowledge of the patient's condition and that recertification should be made only when that knowledge is updated. However, CMS stated that it did not support the imposition of specific service requirements or timeframes until it had examined both coverage rules and conditions of participation to develop the discipline necessary for ensuring proper certification. Subsequently, CMS informed us that it began providing additional payments for physician plan care oversight in 1995 and was considering additional education for physicians and beneficiaries as incentives to encourage more physician involvement. However, our four-State review of services provided in 1998 identified unallowable services because of inadequate physician involvement. Although the BBA of 1997 included provisions to restructure home health benefits, we continue to recommend that CMS revise regulations to require that physicians examine Medicare patients before ordering home health services.

Report(s):	**OAS-04-94-02078; issued 02/95**	**OAS-04-95-01107; issued 09/96**
	OEI-12-94-00180; issued 05/95	**OAS-03-95-00011; issued 11/96**
	OEI-02-94-00170; issued 06/95	**OAS-04-96-02121; issued 07/97**
	OAS-04-94-02087; issued 06/95	**OAS-02-97-01026; issued 09/97**
	OEI-04-93-00260; issued 07/95	**OAS-04-97-01166; issued 04/99**
	OEI-04-93-00262; issued 09/95	**OAS-04-97-01170; issued 04/99**
	OAS-04-95-01103; issued 03/96	**OAS-02-97-01034; issued 09/99**
	OAS-04-95-01106; issued 03/96	**OAS-04-98-01184; issued 09/99**
	OAS-04-95-01104; issued 06/96	**OAS-04-99-01194; issued 11/99**
	OAS-04-95-01105; issued 09/96	**OAS-04-99-01195; issued 03/01**

Ensure Appropriateness of Medicare Payments for Mental Health Services

Background: Section 1862(a)(1)(A) of the SSA requires all services, including mental health services, to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Finding(s): Our reviews have found that Medicare allowed inappropriate outpatient mental health services at error rates ranging from 33 percent in 1998 to 47 percent in 2003. Billing abuses involving beneficiaries who are unable to benefit from psychotherapy demonstrate a special need for enhanced program and beneficiary protections. Also, beneficiaries with mental illness sometimes do not receive all the services that they need, so both underutilization and overutilization problems exist.

"Partial hospitalization" services, which may be provided by both hospitals and community mental health centers, have been particularly vulnerable to payment errors. These intensive services are designed to reduce the need for hospitalization of beneficiaries with serious mental illness. We have estimated that Medicare payment error rates for partial hospitalization in community mental health centers were as high as 92 percent. A number of these centers were terminated from the program after CMS determined that they did not meet certification requirements.

Further, we found that in 2003, miscoded and undocumented services accounted for 26 and 19 percent, respectively, of all Medicare mental health services. Medically unnecessary services and services that violated the "incident to" rule each accounted for 4 percent of all Medicare mental health services in 2003. (The "incident to" rule allows a physician to bill for mental health services performed by his or her staff if the services are rendered incident to the physician's professional services.)

Recommendation(s): CMS should ensure that mental health services are medically necessary and reasonable; are accurately billed; and are ordered by an authorized practitioner by using a comprehensive program of targeted medical reviews, provider education, improved documentation requirements, and increased surveillance. Additionally, CMS should revise, expand, and reissue its 2003 Program Memorandum on Part B mental health services with an increased emphasis on proper documentation, coding, and requirements for mental health services billed "incident to."

Savings: $1.44 billion*

**This figure includes $224 million in improper payments for acute hospital outpatient services in 1997, $229 million in improper payments for partial hospitalization in community mental health centers in 1997, $57 million in improper payments for psychiatric hospital outpatient services in 1998, $30 million in improper payments for mental health services in 1999, $185 million in improper payments for other mental health services in 1998, and $718 million in improper payments for mental health services in all settings in 2003.*

Status: In its comments on the draft of our October 1998 report, CMS concurred with the recommendations to strengthen oversight of community mental health centers, noting that it had initiated some efforts to reduce unallowable payments. CMS indicated that it was conducting

site visits at community mental health centers and had terminated noncompliant providers from the Medicare program. Our work during 2006 in the area of community mental health centers indicated that there were still significant unallowable payments. In April 2008, CMS stated that it was considering changes to ensure a more accurate payment policy. CMS concurred with our 2007 report recommendations that it should revise and reissue the 2003 Program Memorandum but noted that significant information on medical documentation requirements, including "incident to" services, is available on its Web site. We determined that guidance on documentation for evaluation and management services can be found in the "Claims Processing Manual" (Pub. 100-04, chapter 12, section 30.6) and that specific guidance on "incident to" services can be found in the "Benefits Policy Manual" (Pub. 100-02, chapter 15, section 60.1). In July 2008, CMS issued a special-edition article (MLN Matters Number SE0816) to explain Medicare's guidelines for payment of Part B mental health services. We believe that CMS still needs to monitor partial hospitalization services provided by community mental health centers, which we consider particularly vulnerable. We will continue to monitor CMS's efforts to ensure that mental health services are medically necessary and reasonable and are accurately billed.

Report(s):	**OAS-04-98-02145; issued 10/98**	**OEI-03-99-00130; issued 05/01**
	OAS-01-99-00507; issued 03/00	**OAS-06-04-00076; issued 03/06**
	OAS-01-99-00530; issued 12/00	**OAS-04-04-02003; issued 04/06**
	OEI-02-99-00140; issued 01/01	**OEI-09-04-00220; issued 04/07**

Reduce Improper Use of Modifier 59 To Bypass Medicare's National Correct Coding Initiative Edits

Background: In January 1996, CMS began the Medicare National Correct Coding Initiative (NCCI) to promote correct coding by providers and to prevent Medicare payment for improperly coded services. The initiative consists of automated edits that are part of the carrier's claims-processing systems. Specifically, NCCI edits contain pairs of Healthcare Common Procedure Coding System codes that generally should not be billed together by a provider for a beneficiary on the same date of services. All code pairs are arranged in a column 1 and column 2 format. Claims given the column 2 code are generally not payable with the column 1 code. Under certain circumstances, a provider may bill for two services in an NCCI code pair and include a modifier on that claim that would bypass the edit and allow both services to be paid. Modifier 59 could be attached in that instance. Modifier 59 is used to indicate that a provider performed a distinct procedure or service for a beneficiary on the same day as another procedure or service.

Finding(s): Medicare allowed payments for 40 percent of code pairs in FY 2003 that did not meet program requirements, resulting in $59 million in improper payments. Modifier 59 was used inappropriately with 15 percent of the code pairs because the services were not distinct from each other. We also found that 11 percent of code pairs billed with modifier 59 were paid when modifier 59 was billed with the incorrect code. In addition, most carriers did not conduct reviews of modifier 59; for those that did, we found that providers had an error rate of 40 percent or more for services billed with modifier 59.

Recommendation(s): CMS should encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59. Also, CMS should ensure that the carriers' claims-processing systems pay claims with modifier 59 only when the modifier is billed with the correct code.

Savings: $59 million*

**Based on a national projection of Medicare claims, $59 million was improperly paid for services in FY 2003 that did not meet the Medicare program requirements.*

Status: CMS concurred with our recommendations to encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59 and to ensure that carriers' claims-processing systems pay claims only when modifier 59 is billed with the secondary code. However, CMS reported in its comments that it was unable to implement system edits to ensure correct coding at the time of the report. In April 2006, CMS published clarifying guidance to chapter 4 of the "Medicare Claims Processing Manual," which includes the use of modifier 59 (CR 4388). In April 2008, CMS issued a Medlearn Matter article (classified as Special Edition 0810) to provide continuing education to physicians on how to bill modifier 59 appropriately. CMS has not yet implemented edits to ensure correct coding. We will continue to monitor CMS's efforts to implement edits to ensure correct coding.

Report(s): OEI-03-02-00771; issued 11/05

Medicare Managed Care

Modify Payments to Managed Care Organizations

Background: The BBA of 1997 established the Medicare+Choice (M+C) program with the primary goal of providing a wider range of health plan choices to Medicare beneficiaries. The BBA of 1997 also modified the existing payment methodology under the program to correct excess payments, reduce geographic variations in payments, and align payments to reflect beneficiaries' health status. The MMA redesignated the M+C program as Medicare Advantage (MA) and increased payments.

Finding(s): Based on numerous reviews (which are summarized in our September 2000 report), studies by other agencies, and MA organization data, we concluded that from CY 1997 through CY 2000, MA organizations received more than adequate funds to deliver the Medicare package of covered services. The data and estimates used as the basis to calculate monthly capitation payments to MA organizations were flawed, resulting in higher than necessary payments. Medicare payments funded excessive administrative costs, and MA organizations did not account for investment income earned on Medicare funds.

Another factor contributing to the flaw in the 1997 managed care base rates was the inclusion of improper payments made in the Medicare fee-for-service (FFS) expenditures identified in our review of Medicare's 1996 and 1997 financial statements. Because the standardized county rates for 1997 were calculated using 1996 base FFS expenditure data, the overpayment errors carried over to the 1997 managed care rates. We estimated the 1996 error rate as 14 percent of the total FFS benefit payments.

Recommendation(s): CMS should modify monthly capitation rates to a level fully supported by empirical data.

Savings: $1.97 billion*

**Estimated savings are based on the 3.077-percent overstatement of 1997 base rates applied to the 2006 managed care payments.*

Status: CMS did not concur with our recommendation to reduce payments to MAs, noting that the BBA of 1997 and the BBRA of 1999 had increased these payments. Because the 1997 base rate was flawed, we continue to have concerns that the Federal payment to MAs is excessive. We plan to update our work to examine MA organization payments as a result of the legislative changes.

Report(s): OAS-14-00-00212; issued 09/00

Place a Ceiling on Administrative Costs Included in Managed Care Organizations' Rate Proposals

Background: Each MA organization is required to submit a bid proposal (formerly adjusted community rate proposals) to CMS before the beginning of the contract period. Administrative costs, which are one component of the proposal, include costs associated with facilities, marketing, taxes, depreciation, reinsurance, interest, and other nonmedical compensation. CMS does not require a reasonable percentage or ceiling on the administrative cost rate proposed, as it does in other areas of the Medicare program.

Finding(s): We found that, as a percentage of the total rate proposed, the administrative rate varied widely among MA organizations reviewed, regardless of the type of MA organization (individual practice association, group, or staff) or the tax status (profit or nonprofit). For the 1999 rate proposals, the amount allocated for administrative purposes ranged from a high of 32 percent to a low of 3 percent. In addition, our reviews of the administrative costs included in the 1997 proposals submitted by nine MA organizations found that $66.3 million of the actual administrative costs incurred would have been recommended for disallowance had the MA organizations been required to follow Medicare's general principle of paying only reasonable costs. In a subsequent review of 10 MA organizations' proposals for 2000, we found that $97.1 million in base-year administrative costs would have been recommended for disallowance.

Recommendation(s): CMS should institute a reasonable ceiling on the administrative costs permitted in an MA organization proposal.

Savings: TBD

Status: In its comments on our January 2000 draft report, CMS did not concur with our recommendation, stating that it expected some MAs to have higher administrative costs than others, depending on how they are structured. CMS also noted that a ceiling on administrative costs may discourage MAs from developing cost-efficient plans. We plan to update our work to examine administrative costs under provisions of the MMA.

Report(s): OAS-14-98-00210; issued 01/00
OAS-03-98-00046; issued 01/00
OAS-03-01-00017; issued 11/01

Medicaid Payment Policies

Limit Enhanced Payments to Cost and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share

Background: Under Medicaid upper payment limit (UPL) rules, States are permitted to establish payment methodologies that allow for enhanced payments to non-State-owned government providers, such as county nursing facilities and hospitals. The enhanced payments, which trigger Federal matching payments, are in addition to the basic payment rates for Medicaid providers.

Finding(s): Enhanced payments to local-government-owned providers were not based on the actual cost of providing services to Medicaid beneficiaries. In addition, a large portion of the enhanced payments were not retained by the health care facilities to provide services to resident Medicaid beneficiaries. Instead, some funds were transferred back to the States for other uses.

Recommendation(s): CMS should provide States with definitive guidance for calculating the UPL, which should include using facility-specific UPLs that are based on actual cost report data, and CMS should require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment.

Savings: $120 million*

**In its January 2007 Notice of Proposed Rulemaking, CMS estimated that if payments to providers operated by units of government were limited to cost and payments returned by providers were considered refunds, Federal Medicaid outlays would be reduced by $120 million in the first year and by $1.2 billion in the fifth year. CMS estimated that the final rule would result in a reduction of Federal Medicaid outlays of a total of $3.87 billion over 5 years.*

Status: In its comments on the draft of our September 2001 report, CMS partially concurred with our recommendations, stating that it would consider further reforms if it finds that States, under UPL rules, are continuing to use public health care facilities as transfer agents to leverage Federal Medicaid funding. Subsequently, CMS published a Final Rule With Comment Period in the Federal Register (72 Fed. Reg. 29748, May 29, 2007) that modified Medicaid reimbursement. Consistent with our recommendations, this regulation requires that health care providers retain the total Medicaid payments received. This change, in addition to the UPL regulatory changes, will help ensure that Medicaid funds are used to provide necessary services to Medicaid beneficiaries. However, implementation of this regulation was delayed by passage of section 7002 of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (P.L. No. 110-28), which prohibited implementation of CMS's regulation for 1 year following the date of the law's enactment on May 25, 2007. In addition, section 7001 of the Supplemental Appropriations Act of 2008 (P.L. No. 110-252) prevents CMS from implementing the regulation until April 1, 2009. In April 2009, CMS informed us that they are awaiting direction from the new administration before proceeding.

Report(s):	**OAS-03-00-00203; issued 02/01**	**OAS-10-00-00011; issued 03/01**
	OAS-07-00-02076; issued 02/01	**OAS-04-00-02169; issued 05/01**
	OAS-05-00-00056; issued 03/01	**OAS-04-00-00140; issued 06/01**
	OAS-04-00-02165; issued 03/01	**OAS-03-00-00216; issued 09/01**

Ensure Compliance With Requirements for Medicaid School-Based Health Services

Background: Section 1903(c) of the SSA was amended in 1988 to make clear that Medicaid payment for school-based health services was allowable for covered Medicaid services that are included in an individualized education plan or individualized family service plan, as required by the Individuals With Disabilities Education Act (IDEA).

Finding(s): Our reviews have identified Medicaid overpayments for school-based health services, with the Federal share of the overpayments totaling an estimated $800 million. Many of the services claimed lacked a referral by an appropriate medical professional or were not provided by or under the direction of a qualified provider. These unallowable claims generally occurred because States did not provide sufficient guidance to and oversight of local education agencies and rates were not developed in accordance with applicable Federal cost allocation requirements or CMS program guidelines.

Recommendation(s): CMS should recover the overpayments identified during our audits of school-based claims in individual States. In addition, States should disseminate CMS guidance and other information to the local education agencies in a timely manner, monitor local education agencies to ensure compliance with Federal and State requirements, and help local education agencies develop written policies and procedures that require service providers to document all health services and to retain those records for review.

Savings: TBD

Status: CMS concurred with our recommendations to address overpayments, indicating that it would recover costs not allowed by individual State plans. CMS reported to us that it began recovering overpayments in 2003. We note through our continuing work in this area that CMS has also undertaken a significant effort to bring State plans into compliance with Federal law, regulations, and policy in the coverage areas that pertain to Medicaid services delivered in school settings. In the December 28, 2007, Federal Register, a final regulation was published to eliminate reimbursement under Medicaid for school administration expenditures and costs related to the transportation of school-aged children between home and school. Section 7001 of the Supplemental Appropriations Act of 2008 (P.L. No. 110-252) prevents CMS from implementing the regulation until April 1, 2009. However, section 5003 (b) of the American Recovery and Reinvestment Act (ARRA) further extended the moratorium on implementing this regulation until July 1, 2009.

Report(s):	**OAS-04-00-02161; issued 11/01**	**OAS-05-02-00049; issued 12/03**
	OAS-10-01-00011; issued 05/02	**OAS-06-02-00037; issued 01/04**
	OAS-01-01-00006; issued 06/02	**OAS-02-02-01030; issued 02/04**
	OAS-10-01-00006; issued 08/02	**OAS-07-02-02099; issued 02/04**
	OAS-06-01-00077; issued 10/02	**OAS-01-02-00014; issued 02/04**
	OAS-02-02-01018; issued 12/02	**OAS-04-01-00005; issued 05/04**
	OAS-03-01-00224; issued 03/03	**OAS-02-03-01008; issued 08/04**
	OAS-05-02-00023; issued 03/03	**OAS-01-02-00016; issued 09/04**
	OAS-02-02-01022; issued 04/03	**OAS-01-03-00004; issued 01/05**
	OAS-06-01-00083; issued 04/03	**OAS-01-04-00004; issued 01/05**
	OAS-01-02-00006; issued 05/03	**OAS-07-03-00154; issued 04/05**
	OAS-10-02-00008; issued 07/03	**OAS-02-02-01029; issued 06/05**
	OAS-01-02-00009; issued 07/03	**OAS-05-02-00050; issued 08/05**

Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments

Background: Section 1923 of the SSA, as amended by OBRA 1993, requires that States make Medicaid disproportionate share hospital (DSH) payments to hospitals that serve disproportionate numbers of low-income patients with special needs. Section 1923(g) of the SSA limits these payments to a hospital's uncompensated care costs, which are the annual costs incurred to provide services to Medicaid and uninsured patients less payments received for those patients. The MMA added a new section to the SSA to require States to report additional information about their DSH programs. Specifically, States must submit an annual report that identifies each hospital that received a DSH payment under the State's Medicaid program in the preceding fiscal year and the amount of DSH payments paid to that hospital in the same year. The MMA also requires States to have their DSH payment programs independently audited and to submit the independent certified audit annual to the Secretary.

Finding(s): Nine of ten States reviewed did not comply with the hospital-specific DSH limits imposed by section 1923(g) of the SSA. As a result, payments exceeded the hospital-specific limits by approximately $1.6 billion ($902 million Federal share); an estimated $679 million of the $902 million was based on historical costs. States did not later adjust the payments using actual costs. States also made approximately $223 million in excess payments because they included unallowable costs in their calculations of hospital-specific limits. In addition, approximately $3.6 billion in DSH payments were not retained by hospitals in three States. Instead, the funds were transferred by the hospitals back to the States for other uses.

Recommendation(s): CMS should ensure resolution of the monetary recommendations to individual States regarding DSH payments that exceeded the hospital-specific limits. It should establish regulations requiring States to (1) implement procedures to ensure that future DSH payments are adjusted to actual incurred costs, (2) incorporate these procedures into their approved State plans, and (3) include only allowable costs as uncompensated care costs in their DSH calculations. CMS should strengthen its review and approval of State plans to ensure consistency with Federal requirements and should use results of audits conducted under the MMA in its review process.

Savings: TBD

Status: CMS concurred with our recommendations, indicating in its comments that it had published a Notice of Proposed Rulemaking in August 2005 to implement new Medicaid DSH payment reporting and auditing provisions of section 1001(d) of the MMA. The final rule was published in the Federal Register on December 19, 2008, with an effective date of January 19, 2009. The rule includes a transition period related to audit findings for Medicaid State Plan rate year 2005 through 2010. Starting in Medicaid State plan rate year 2011, DSH payments that exceed the hospital-specific eligible uncompensated care cost limits must be returned to the Federal Government or redistributed by States to other qualifying hospitals. CMS also informed us that it has begun resolution of monetary recommendations identified in some individual DSH audits in FY 2005 and that resolution of recommendations in other audits is in progress.

Report(s): OAS-06-03-00031; issued 03/06

Medicaid Prescription Drugs

Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs

Background: Most States use the average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for prescription drugs. We estimated the actual acquisition costs for 200 brand-name drugs with the highest Medicaid reimbursement for CY 1999.

Finding(s): State pharmacy reimbursement formulas discounted below the AWP averaged 10.31 percent nationally in 1999. We found that this discount is not sufficient to ensure that drug reimbursement accurately reflects pharmacy acquisition costs. Our review, based on CY 1999 data, estimated that the actual acquisition cost for brand-name drugs averaged 21.84 percent below the AWP. We estimated that the Medicaid program could have saved as much as $1.08 billion if reimbursement had been based on a 21.84-percent average discount below the AWP. This projection was based on the 200 brand-name drugs with the highest Medicaid reimbursement for CY 1999.

Recommendation(s): CMS should encourage the States to align pharmacy reimbursement more closely with the actual acquisition cost of brand-name drugs paid by their pharmacies in their States. We recommended a four-tier approach to reimbursement as follows: single-source innovator drugs, multiple-source innovator drugs without Federal upper limits (FUL), multiple-source noninnovator drugs without FULs, and multiple-source noninnovator drugs with FULs.

Savings: $1.08 billion*

**Estimated savings are based on a 21.84-percent average discount below AWP for the 200 brand-name drugs with the highest Medicaid reimbursement for CY 1999.*

Status: In its comments on our 2001 draft report, CMS concurred with our recommendation, stating that it was working with States to review their estimates of acquisition costs in light of our 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 a State would have paid, in the aggregate, for covered outpatient drugs based on the manufacturers' average sales prices (ASP). The proposed legislative change was not enacted or included in the President's FY 2007, 2008, or 2009 budgets. We plan to continue to monitor the pricing of Medicaid drug reimbursements for brand-name drugs.

Report(s): OAS-06-00-00023; issued 08/01
OAS-06-02-00041; issued 09/02

Ensure That Medicaid Reimbursement for Generic Drugs Accurately Reflects Pharmacy Acquisition Costs

Background: CMS sets FUL amounts for certain multiple-source drugs (i.e., generic drugs or brand-name drugs with generic equivalents). Federal regulations cap aggregate Medicaid reimbursement for drugs with FULs at the FUL amounts plus a reasonable dispensing fee. FUL amounts are calculated based on 150 percent of the lowest published price (typically AWP or wholesaler acquisition cost) for the least costly, therapeutically equivalent products. For multiple-source or other drugs without FULs, aggregate Medicaid reimbursement is capped at the lower of the estimated pharmacy acquisition cost plus a reasonable dispensing fee or the pharmacy's usual and customary charge. Most States estimate pharmacy acquisition cost using AWP minus a percentage discount, which varies by State. AWP is a published price that is not defined in law or regulation.

In 2002, we issued two reports that estimated pharmacies' actual acquisition costs for 200 generic drugs with the highest Medicaid reimbursement for CY 1999. In 2005, we issued a report that compared Medicaid FUL amounts to average manufacturer prices (AMP) for third quarter 2004. AMPs are statutorily defined prices based drug sales to the retail class of trade.

Finding(s): In 1999, State pharmacy reimbursement formulas, on average, estimated pharmacy acquisition costs to be AWP minus 10.31 percent. We found that this 10.31 percent discount is not sufficient to ensure that drug reimbursement accurately reflects pharmacy acquisition costs. We estimated that pharmacies' actual acquisition costs for generic drugs averaged 65.93 percent below the AWP in 1999. We estimated that changing the reimbursement policy to more accurately reflect pharmacies' actual acquisition costs could have saved the Medicaid program as much as $470 million for the 200 generic drugs with the highest Medicaid reimbursement for CY 1999. Additionally, OIG's subsequent study found that overall FUL 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 FUL amount was, on average, 22 times higher than the lowest reported AMP.

Recommendation(s): CMS should encourage the States to align pharmacy reimbursement more closely with the actual acquisition costs of generic drugs paid by their pharmacies in their States. We recommended a four-tier approach to reimbursement as follows: single-source innovator drugs, multiple-source innovator drugs without FULs, multiple-source noninnovator drugs without FULs, and multiple-source noninnovator drugs with FULs. We also recommended that CMS work with Congress to set FUL amounts that more closely approximate acquisition costs.

Savings: TBD

Status: In its comments on the draft of our March 2002 report, CMS concurred with our recommendation, indicating that it would work with States to strongly encourage them to review their estimates. CMS also concurred with the findings of the 2005 report stating that Congress should take action to ensure that Medicaid reimbursement amounts more closely relate to actual transaction prices.

The Deficit Reduction Act of 2005 (DRA) changed the FUL calculation for generic drugs. For generic drugs with FULs, the Federal Government capped Medicaid drug reimbursement at 250

percent of the lowest AMP for a therapeutically equivalent version of a drug. CMS promulgated a final rule pursuant to this change in July 2007 (72 Fed. Reg. 39142). The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of this rule. Additionally, in July 2008, Congress enacted Public Law 110-275, which prevents CMS from releasing AMP data and from implementing FULs based on AMP until October 2009. While this prohibition is in effect, CMS continues to calculate FUL amounts based on the previous formula (i.e., 150 percent of the lowest published price). In April 2008, CMS informed us that it would follow up to ensure that States take OIG's findings into account. We plan to continue to monitor the pricing of Medicaid drug reimbursements for generic drugs until the injunction is lifted and the rule becomes effective.

Report(s): **OAS-06-01-00053; issued 03/02**
OAS-06-02-00041; issued 09/02
OEI-03-05-00110; issued 06/05

Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement

Background: OBRA 1990 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Rebates are calculated using the AMP, the manufacturer's best price, and other factors. In contrast, most States reimburse pharmacies for Medicaid prescription drugs based on the AWP of a drug.

Finding(s): Requiring manufacturers to pay Medicaid drug rebates using the same basis as reimbursements to pharmacies would establish a much-needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursement for drugs at the pharmacy level.

Recommendation(s): CMS should seek legislation that would require Medicaid drug rebates and reimbursements to be developed using the same basis or study viable alternatives to the current program.

Savings: TBD

Status: CMS did not concur with our recommendation, stating that it did not believe that a legislative proposal was feasible at the time of our report. However, in accordance with the DRA, in July 2006 CMS began providing States with AMP data on a monthly basis. Under the DRA, States may choose (but are not required) to use AMP data to revise their current reimbursement formulas. In July 2007, pursuant to the DRA, CMS promulgated a final rule regarding making AMP data available to States. The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of this rule. Additionally, in July 2008, Congress enacted Public Law 110-275, which prevents CMS from releasing AMP data and from implementing FULs based on the AMP until October 2009. We are concerned that until all States use AMPs in their reimbursement formula, there will be no connection between reimbursement and rebates. We plan to continue monitoring the issue.

Report(s): OAS-06-97-00052; issued 05/98

Implement an Indexed Best-Price Calculation in the Medicaid Drug Rebate Program

Background: OBRA 1990 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Rebates are calculated using the AMP, the manufacturer's best price, and other factors. To discourage drug manufacturers from raising prices, the basic rebate amount for brand-name drugs is increased by the amount that the AMP increases over and above the Consumer Price Index (CPI) for all urban consumers. However, no similar indexing of best price is made, even though best price is part of the basic rebate calculation for brand-name drugs.

Finding(s): Since the inception of the Medicaid drug rebate program, drug manufacturers have consistently increased best prices in excess of the CPI for all urban consumers. To determine the potential effect of increases in best price (beyond the rate of inflation) on rebates, we calculated the difference in rebates that would have resulted from using an indexed best price. We estimated that, in 1993, drug rebates would have increased by about $123 million for the 406 drugs included in our review.

Recommendation(s): CMS should pursue legislation to index the best-price calculation in the Medicaid drug rebate program to the CPI-urban.

Savings: $123 million*

**This savings estimate is based on the best-price indexing in 1993 of the 406 drugs included in our review.*

Status: CMS did not concur with our recommendation. In its comments on our 2002 "Red Book," CMS stated that it believed that savings would be achieved through a President's budget proposal for a legislative change that would have based the Medicaid drug rebate on the difference between AWP and the best price of the drug. However, this proposal was not enacted. In November 2008, CMS noted that the Administration's position, as reflected in the FY 2008 President's budget, was to eliminate the best price; however, this proposal was not enacted. We plan to continue monitoring the drug rebate program through audits focusing on enhancing the collection of rebates and providing potential savings to the rebate program.

Report(s): OAS-06-94-00039; issued 10/95

Medicaid Administration

Establish a National Medicaid Credit Balance Reporting Mechanism

Background: CMS does not require State agencies to routinely monitor providers' efforts to identify and refund Medicaid credit balances in patient accounts.

Finding(s): Two of our reports have indicated that significant outstanding Medicaid credit balances exist nationwide. Between May 1992 and March 1993, we reported that many State agencies' efforts were inadequate to ensure that, nationwide, providers were identifying the majority of Medicaid credit balances and remitting overpayments in a timely manner.

Recommendation(s): CMS should establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. Also, CMS should require its regional offices to actively monitor the reporting mechanism that is established.

Savings: TBD

Status: Initially, when commenting on the 1995 report, CMS concurred with our recommendation to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. CMS decided not to do so, citing the uncertain and minimal savings potential, the Administration's commitment to enhancing States' flexibility, and, specifically, avoiding the imposition of an unfunded mandate. In 2008, CMS described actions it had taken to update its financial management review guides addressing Medicaid provider overpayments and to develop an annual work plan for reviewing high-risk financial management areas. However, CMS has not implemented a credit balance reporting mechanism.

Report(s): OAS-04-92-01023; issued 03/93
OAS-05-93-00107; issued 05/95

Public Health and Human Service Programs and Departmentwide and Cross-Cutting Issues

Eliminate Excessive Costs in the 340B Drug Discount Program

Background: Section 340B of the Public Health Service Act (the PHS Act) created the 340B Drug Pricing Program to lower drug prices for more than 12,300 entities, including community health centers, public hospitals, and various Federal grantees. Pharmaceutical manufacturers calculate the 340B discount using a specified formula and must sell their products at or below this ceiling price to continue to have their products covered by the Medicaid program. The Health Resources and Services Administration (HRSA) Pharmacy Affairs Branch administers the program for the thousands of enrolled entities nationwide, which are estimated to have spent $3.4 billion on drugs in 2003.

Finding(s): Because of systemic problems with the accuracy and reliability of the Government's record of 340B ceiling prices, we found that HRSA could not adequately oversee the 340B Drug Pricing Program. HRSA lacked the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price. We found that in a single month in 2005, 14 percent of total purchases made by 340B entities exceeded 340B ceiling prices, resulting in total projected overpayments of $3.9 million for the year.

Recommendation(s): HRSA should improve its oversight of the 340B Drug Pricing Program to ensure that entities are charged at or below the 340B ceiling price and should work with CMS to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices. HRSA should take four steps to strengthen its administration of the 340B Drug Pricing Program: (1) establish detailed standards for the calculation of 340B ceiling prices; (2) institute oversight mechanisms, including technical assistance to validate its 340B price calculations and the prices charged to participating entities; (3) seek legislative authority to establish penalties for violations of the PHS Act; and (4) provide participating entities with secure access to certain pricing data to help approximate the 340B ceiling prices.

Savings: $46.8 million to federally supported covered entities*

**Estimated savings based on $3.9 million in overpayments by 340B entities in 1 month in 2005, multiplied by 12 to calculate savings for 1 year. Additional indirect savings to the Department are likely but have not been calculated.*

Status: HRSA concurred with our recommendations and stated that it had taken steps to monitor more closely the prices paid by the 340B program. In its comments on our 2005 report, HRSA stated that it anticipated promulgating a penny price policy in conjunction with formalizing the instructions for the calculation of 340B ceiling prices. HRSA indicated that in April 2007, it had implemented a 1-year 340B Drug Pricing Program pilot project requesting manufacturers to voluntarily submit their prices for comparison with the ceiling prices. To the extent that resources permitted, HRSA would review the data that manufacturers and entities voluntarily

submitted. In September 2008, HRSA informed us that it continues to seek the authority and resources needed to impose fines and civil penalties for violations of section 340B of the PHS Act, that it was working with CMS to maximize the acquisition of manufacturers' data and to resolve problems related to missing data, and that it planned to publish detailed standards for the calculation of 340B ceiling prices on its Web site. We continue to encourage HRSA to seek legislative authority to establish penalties for violations of the PHS Act and, during FY 2009, have work underway to evaluate the 340B Program.

Report(s): OEI-05-02-00072; issued 10/05
OEI-05-02-00073; issued 07/06

Use Voluntary Contributions To Expand Services for the Elderly

Background: Current Administration on Aging (AoA) regulations permit States to use voluntary contributions to meet cost-sharing or matching grant requirements. However, during the audit period, this use of contributions was contrary to the Older Americans Act (OAA), which requires that voluntary contributions be used to increase services for the elderly.

Finding(s): According to their financial status reports, 28 States and the District of Columbia erroneously used $90.8 million in voluntary contributions in FY 1996 to meet cost-sharing or matching grant requirements.

Recommendation(s): AoA should revise its regulations in accordance with OAA.

Savings: $90.8 million*

**Estimated savings are based on information in FY 1996 financial status reports for all States, the District of Columbia, and Puerto Rico.*

Status: AoA concurred with the recommendation in its comments on our draft report. Subsequently, AoA informed us that because the OAA Amendments of 2006 (P.L. No. 109-365, October 17, 2006; 120 Stat. 2522) changed provisions relating to voluntary contributions, AoA was determining the kinds of regulatory changes needed as a result. To date, no regulatory changes have been made.

Report(s): OAS-12-00-00002; issued 02/01

Advise States of Their Authorities To Collect From Noncustodial Parents With the Ability To Contribute Towards Their Children's Medicaid or State Children's Health Insurance Program Costs

Background: Current regulations require the State Title IV-D agency to petition the court or administrative authority, unless the custodial parent and children have satisfactory health insurance other than Medicaid, to include health insurance that is available to the noncustodial parent at reasonable cost in new or modified orders for support. Title XXI of the SSA, which authorizes SCHIP, is silent with regard to collecting SCHIP costs from noncustodial parents who have medical support orders.

Finding(s): States can reduce State and Federal Medicaid costs by increasing the number of noncustodial parents who provide medical support for their children. Although Federal regulations authorize States to recover Medicaid costs from third-party payers, Title IV-D regulations do not provide specific guidance for collecting Medicaid costs from noncustodial parents who have the financial ability to pay and who do not have affordable employer-sponsored health coverage available. Moreover, Medicaid regulations do not address how State Medicaid agencies should coordinate with State Title IV-D agencies or how the States should establish and administer Medicaid fee-for-service recoveries.

States also have an opportunity to enroll uninsured Title IV-D children in SCHIP and provide a means for noncustodial parents to fulfill their medical support obligations. Unlike Federal Medicaid laws, SCHIP laws are silent with regard to an "assignment of rights" that would allow States to recover children's medical expenses from their noncustodial parents. Although some States have taken steps to collect SCHIP costs from noncustodial parents, others have questioned their authority to do so or expressed concern about the costs that would be incurred.

Recommendation(s): CMS should (1) clarify third-party liability regulations to help State Medicaid agencies coordinate with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders and (2) seek legislation that would allow States to accumulate medical support payments to offset Medicaid fee-for-service costs for a reasonable period. CMS should also determine whether additional Federal funds are needed to help States interface their Title IV-D and SCHIP databases and implement a process to collect SCHIP costs from noncustodial parents and, as appropriate, provide such funds.

Savings:	$99 million – Medicaid* $14 million – SCHIP**

**Based on an eight-State review, we estimated that Title IV-D children who were enrolled in Medicaid had noncustodial parents who were financially able to contribute $99 million based on the most recent data available from each State in 2001 or 2002.*

***Based on an eight-State review, we estimated that Title IV-D children who received SCHIP benefits had noncustodial parents who could potentially contribute $14 million toward the SCHIP premiums based on the most recent data available from each State in 2001 or 2002.*

Status: CMS did not concur with our recommendation to clarify third-party liability regulations; it agreed, however, to work with us to draft legislation to allow States to accumulate medical

support payments because existing Federal laws and regulations prohibit States from accumulating additional medical support payments. CMS did not concur with our recommendations that issuing formal guidance on SCHIP costs was necessary but agreed to alert States to their option to pursue the Federal and State shares of these costs. Subsequent to our reports, CMS informed us during a series of Medical Support Collaboration meetings in 2005 sponsored by the Administration for Children and Families (ACF) that it had provided guidance to States on the collection of Medicaid costs from available employer-sponsored health care coverage of noncustodial parents and on their authority under Federal law to collect SCHIP costs from noncustodial parents. CMS also noted that States had the authority to fund the administrative costs of building an infrastructure with the State Title IV-D agency under their 10-percent administrative SCHIP cap and recognized that there is no mechanism in SCHIP to provide States with additional funding if they spend funds up to the 10-percent cap. We continue to recommend that CMS consider alternative methods to ensure that States receive adequate funds, especially if States are at or near their 10-percent administrative cap. We plan to perform follow-up work to determine whether appropriate action has been taken on our recommendations.

Report(s): OAS-01-03-02502; issued 05/05
OAS-01-03-02501; issued 06/05

New Nonmonetary Recommendations

Centers for Medicare & Medicaid Services Programs

Medicare Part D Prescription Drugs

Ensure That Medicare Part D Drugs Are Available to Dual-Eligible Nursing Home Residents

Background: Before the implementation of Medicare Part D, Medicaid paid for most prescription drugs for dual-eligible nursing home residents. Under Part D, dual-eligible residents receive drug coverage through Medicare and are eligible to have their premiums, deductibles, and copayments fully subsidized. In this review, we assessed the availability of Medicare Part D drugs to dual-eligible nursing home residents.

Finding(s): In our review, 93 percent of nursing home administrators, medical directors, and long term care pharmacy directors reported that between September 2006 and March 2007, dual-eligible residents were receiving all necessary Part D drugs. However, they raised concerns that nursing homes and long-term care pharmacies sometimes paid for Part D drugs that were not covered by Part D plans; that formularies, the prior authorization process, and misapplication of copayments may pose problems for dual-eligible nursing home residents; and that long term care pharmacies generally did not disclose to physicians that they had received rebates from drug manufacturers.

Recommendation(s): CMS should (1) work with Part D plans to ensure that formularies meet the needs of dual-eligible nursing home residents and put additional emphasis on ensuring that plans include the drugs and alternative dosages and forms that meet the needs of dual-eligible nursing home residents; (2) continue to work with Part D plans to improve the prior authorization process, clarify guidance to ensure that plans pay for a supply of drugs for current enrollees during routine prior authorization requests, specify the circumstances under which a supply of drugs would qualify as an emergency supply, and work with plans to ensure that plan staff are responsive and knowledgeable about Part D formulary and coverage issues specific to dual-eligible nursing home residents; (3) ensure that copayments for dual-eligible nursing home residents are subsidized, as appropriate; and (4) consider methods to encourage long term care pharmacies to disclose to physicians information about rebates and other financial incentives received from drug manufacturers.

Status: In commenting on our draft report, CMS concurred with our first two recommendations and the intent of the third recommendation; it did not concur with our fourth recommendation to consider methods to encourage long term care pharmacies to disclose to physicians information about rebates they receive from drug manufacturers, citing a lack of authority under Part D to impose this requirement. In April 2009, CMS informed OIG that it had implemented three of the four report recommendations. The agency stated that it had incorporated new treatment guidelines into the formulary checks that are specific to nursing home residents, improved the transparency of the prior approval process under Part D, announced the standardization of plan prior authorization criteria, and implemented system changes that permit States to submit

updated information on beneficiary dual-eligibility and institutional status to CMS as often as weekly and enable CMS to process the State-reported information as often as daily. CMS published a best available evidence policy in regulation CMS-4131-FC on January 12, 2009, which requires Part D sponsors to use best available evidence to substantiate beneficiaries' eligibility for a reduced premium and/or cost sharing. We continue to recommend that CMS consider additional ways to encourage pharmacies to disclose information about financial incentives to physicians, so that physicians are aware of any potential financial incentives pharmacists might have to recommend one drug over another.

Report(s): OEI-02-06-00190; issued 06/08

Review Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit

Background: The Medicare Prescription Drug program, known as Medicare Part D, provides an optional prescription drug benefit for all Medicare beneficiaries. Beneficiary, Medicare, and plan sponsor cost sharing obligations vary across four phases of the standard Part D benefit-deductible, initial coverage, coverage gap, and catastrophic coverage. Part D plans are responsible for tracking beneficiaries' true out-of-pocket (TrOOP) costs. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold beneficiaries must reach before catastrophic drug coverage begins. Medicare beneficiaries enrolled in Part D plans may also have additional prescription drug coverage. Tracking TrOOP costs involves coordination and communication between CMS, contractors such as the coordination of benefits contractors, Part D plans, and other payers of prescription drug benefits. The amount of beneficiaries' TrOOP costs impacts their cost sharing as well as CMS payments to Part D plans.

Finding(s): We found that information on Part D plan enrollees' additional prescription drug coverage was not consistently submitted in 2006. Nearly two-thirds of Part D plans cited problems with transferring TrOOP balances when enrollees changed plans. More than one-third of Part D plans failed in 2006 to submit prescription drug event data to CMS in accordance with CMS requirements. We also found that CMS has conducted limited oversight of Part D plans tracking of TrOOP costs.

Recommendation(s): CMS should ensure that Part D plans collect, process, and submit all data required to track enrollees' TrOOP costs in a timely manner. CMS and its contractors should also consider options for increasing the number of data-sharing agreements and for seeking to expand its authority to collect data under those agreements. CMS should begin or complete implementation of oversight activities regarding tracking TrOOP costs.

Status: CMS agreed that the report identified potential issues regarding the accurate tracking of TrOOP costs and that additional work is needed to ensure that Part D plans are calculating TrOOP costs correctly. The agency did not concur with our three recommendations in its comments on the draft of our report but noted that it had taken or will take steps in responding to each of our recommendations. In its March 2009 status update to OIG, CMS implemented an automated TrOOP balance transfer process among Part D plans and between Point-of-Sale Facilitated Enrollment (POS FE) Contractor and Part D plans that went into effect January 1, 2009. CMS stated that it would monitor their performance via standard and exception reporting. With the passage of section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007, all group health plans are mandated to report coverage information related to hospital and medical benefits that are primary to Medicare. CMS expects a significant number of the reporting entities to report prescription drug data to CMS via the Section 111 process. CMS also told us in its March 2009 status update that it was conducting audits of one-third of the Medicare Advantage and Medicare Prescription Drug plans. The audit protocol includes a review to verify that PDPs are accurately calculating TrOOP. However, until one-third of financial audits are completed and show that TrOOP is calculated correctly, our recommendations are not

fully implemented. We continue to monitor CMS's implementation of oversight activities related to the tracking of TrOOP costs.

Report(s): OEI-03-06-00360; issued 12/07

Ensure That Prescription Drug Plan Sponsors' Compliance Plans Address All Requirements

Background: In January 2006, Medicare beneficiaries became eligible to enroll in the new Part D prescription drug benefit established through the MMA of 2003. Part D coverage is provided through private drug plans offered by plan sponsors. Regulations require that Part D sponsors have in place a compliance plan that consists of eight specified elements, including one that requires a comprehensive fraud, waste, and abuse plan. CMS also issued a summary document in June 2005, entitled "Review of Sponsor Fraud, Waste and Abuse Responsibilities," that included 17 additional requirements, each associated with one of the eight elements. One of the additional requirements reiterated the eighth element that PDP sponsors develop fraud and abuse plans. In the subsequent "Prescription Drug Benefit Manual" chapter (the manual chapter) issued in April 2006, CMS outlined requirements that sponsor compliance plans must address to ensure that the eight elements established by regulation are met. The manual chapter incorporates the 17 requirements and also offers additional recommendations. Specifically, the manual chapter had 11 recommendations relating to the fraud, waste, and abuse plan requirement.

Finding(s): We found that although all prescription drug plan sponsors had compliance plans, 72 of 79 compliance plans did not address one or more of CMS's 17 requirements in the summary document. One of the elements in the regulation is the development of a fraud and abuse plan. OIG found that all compliance plans addressed this element in some way, yet only 15 of 79 addressed all 11 recommendations in the manual chapter regarding fraud detection, correction, and prevention.

Recommendation(s): CMS should ensure that PDP sponsors' compliance plans address all requirements presented in its manual chapter regarding the eight elements set forth in regulation. CMS should also encourage sponsors to provide sufficient detail in their compliance plans to clearly demonstrate how sponsors are actually implementing the compliance plan requirements.

Status: CMS agreed with our recommendation. In its comments on our draft report, CMS indicated that it planned to conduct routine audits of PDP sponsors' compliance plans beginning in 2007 and that sponsors will be accountable for meeting all requirements. However, in follow-up work, OIG found that CMS conducted only one focused audit of a drug plan sponsor's compliance plan in 2007. CMS published "Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions" (72 Fed. Reg. 68700) on December 5, 2007. That regulation provided clarification to Part D sponsors about compliance plans. In April 2009, CMS informed us that it had initiated audits on Part D sponsors' compliance plans in September 2008. The agency indicated that these audits consisted of a limited number of desk audits; and, as more resources became available, would include more audits, additional onsite reviews, and other more comprehensive fraud prevention activities. We will continue to monitor CMS's implementation of compliance plan audits and actions taken based on the results of the audits.

Report(s): OEI-03-06-00100; issued 12/06

Implement Safeguards To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans

Background: CMS is responsible for safeguarding the Medicare Part D program against fraud and abuse. CMS is statutorily required to perform financial audits of PDPs contracted to provide drug benefits to Medicare beneficiaries. Beyond this requirement, CMS holds considerable discretion in structuring safeguards for the program. We identified six major safeguard activities conducted by CMS during FY 2006: implementation of a complaint process, data-monitoring activities, financial audits, monitoring PDP sponsors' compliance with contract requirements, oversight of PDP sponsors' efforts to reduce fraud and abuse, and providing education and guidance to a number of stakeholders on fraud and abuse identification. During FY 2006, CMS had contracted with one Medicare Prescription Drug Integrity Contractor (MEDIC) to perform some of these functions. We reviewed a variety of documents and conducted a series of interviews with CMS and MEDIC staff to determine the implementation status of safeguard activities at the time of our review.

Finding(s): We found that CMS implemented safeguard activities throughout fiscal year 2006; however, further development or application of these activities is needed. CMS relied largely on complaints to identify potential fraud and abuse; however, not all complaints were investigated in a timely manner. Limits to legal authority, jurisdiction, and CMS's ability to monitor enrollees switching plans complicated CMS's efforts to safeguard Medicare Part D PDPs.

Recommendation(s): CMS should develop a comprehensive safeguard strategy for Medicare Part D prescription drug plans, ensure that all fraud complaints receive proper attention, and address legal concerns that may impede program integrity efforts.

Status: CMS did not express concurrence or nonconcurrence with our recommendations in its comments on our final report but responded that many of its ongoing activities already satisfy our recommendations. The agency emphasized the immense workload required to develop and administer the benefit in its first year and indicated that processes and procedures had improved over time. CMS reported several advances in this safeguard strategy that occurred after the end of our data collection period. These advances include continued progress towards commencement of the financial audits; successful negotiations to allow MEDICs sufficient access to PDP data; improvement in processing complaints in a timely fashion; issuance of a self-assessment tool to assist PDPs in improving their fraud, waste, and abuse compliance plans; and issuance of new chapters of the PDP manual. In its March 2009 status to OIG, CMS reported it had developed a corrective action plan to address OIG's recommendations and had completed the following activities to close the recommendations: (1) implemented a regional TriMEDIC structure in which the three MEDICs work collaboratively to analyze data and identify national fraud schemes, (2) assigned a Government Task Leader to each regional MEDIC to oversee and monitor all MEDIC activities, and (3) rewrote the MEDIC Umbrella Statement of Work to further refine CMS's coordination and oversight of the MEDICs. Instead, in September 2008, CMS began its transition to consolidate the work of Medicare's program safeguard contractors (PSC), and the MEDICs with new Zone program integrity contractors (ZPIC). The new contractors will eventually be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, and durable medical equipment claims); Part C (Medicare Advantage health plans); Part D

(prescription drug plans); and coordinating Medicare-Medicaid data matches (Medi-Medi). The first two ZPIC contracts were awarded to Health Integrity (Zone 4) and SafeGuard (Zone 7). In light of these changes, we continue to monitor CMS's implementation of its safeguard strategy.

Report(s): OEI-06-06-00280; issued 10/07

Nursing Homes

Ensure the Appropriate Processing of Denial of Medicare Payment Remedies for Noncompliant Nursing Homes

Background: Denial of payment for new admissions (DPNA) is an enforcement remedy that CMS may use to address noncompliance with Federal quality of care standards in skilled nursing facilities. CMS is responsible for imposing denial of payment remedies but relies on its fiscal intermediaries (FIs) to identify and reject the relevant Medicare claims. Once CMS instructs an FI to put a remedy into effect, the FI creates an edit (known as a Medicare Medical Policy Parameter) to identify and suspend claims meeting certain parameters. Those claims are reviewed and then paid, rejected, or returned to the facility as appropriate. (The work of FIs is being transitioned to Medicare administrative contractors (MACs).) We reviewed information and supporting documentation from CMS and FIs for a random sample of cases in which CMS imposed DPNA remedies during FY 2004.

Finding(s): We found that CMS and its FIs had incorrectly processed 74 percent of DPNA actions, with 40 percent of the cases resulting in overpayments to SNFs. These overpayments exceeded $5 million. We identified various DPNA processing errors, including CMS not providing FIs with the instructions on a timely basis or at all, CMS providing information to the wrong FIs, and FIs misinterpreting CMS's instructions. We also found that approximately half of claims involving readmissions lacked codes indicating readmission status, which made their claims incorrectly appear to be new admissions subject to the DPNA remedy.

Recommendation(s): CMS should manage DPNA cases to ensure that all DPNA instructions are sent promptly and that FIs and MACs retrospectively review cases that are processed late to correct any payment errors, address communication breakdowns by implementing a standard format to notify FIs or MACs that a DPNA remedy will be in effect, require confirmation that instructions are received and understood, and update guidance on coding readmissions and verifying readmission status for DPNA claims.

Status: In its comments on our draft report, CMS agreed with our recommendations and outlined specific actions to address each recommendation. The agency indicated that it would develop internal procedures to effectively communicate DPNA instructions to FIs and MACs, create a protocol so contractors notify CMS that a DPNA had been implemented as requested, and update manual instructions to clarify coding and verification requirements for DPNA readmissions. In July 2008, CMS issued CMS Manual System Transmittal 1555 Change Request 6116, which implemented new coding requirements for SNF provider billing services during a DPNA period. This action implemented our recommendation to update guidance on coding and billing for admissions. In April 2009, CMS informed OIG that it had established a work group to improve practices to reduce improper payments to nursing homes subject to DPNAs. According to CMS, the work group is developing a formal administrative policy guidance memorandum for internal use by CMS and MACs regarding consistency in effectuating DPNAs. The guidance is scheduled to be issued in summer 2009. We continue to monitor CMS's progress in implementing its guidance concerning DPNA instructions and protocols with contractors.

Report(s): OEI-06-03-00390; issued 05/08

Medicaid Managed Care

Oversee and Support States' Use of External Quality Review Organizations

Background: Federal regulations require States to provide for an external, independent review of their Medicaid managed care organizations (MCO), which, as of 2006, enrolled 65 percent of the 45.6 million Medicaid beneficiaries. States may contract with an independent entity called an external quality review organization (EQRO) to conduct the review.

Finding(s): In our review of the 37 States that had arranged for external quality reviews of their MCOs in 2005, we determined that most of the States found the results of such reviews useful, although more than half cited concerns about the external review process. We found that 33 States required their MCOs to make changes on the basis of EQRO reports; that the three primary concerns about external quality reviews cited by 24 States related to staffing (turnover and training), EQRO report quality (timeliness and feasibility of recommendations), and redundancy with other monitoring efforts; and that some EQRO reports did not include all the information required by the EQRO contracts.

Recommendation(s): CMS should work with States to ensure that EQROs are providing complete information and should provide States with additional technical assistance and written guidance.

Status: In commenting on our draft report, CMS agreed with our recommendations and stated that it had provided feedback to Medicaid directors in 40 States regarding deficiencies in EQRO reports; focused one of its triennial audio conferences (which are available to States and EQROs) on external quality reviews; helped the National Committee on Quality Assurance create a document for States on using accreditation data in their reviews; and initiated work with a second managed care accreditation agency, the Utilization Review and Accreditation Committee, on a similar document. We continue to recommend that CMS work with States regarding the external quality review process and ensure that EQROs are providing complete information.

Report(s): OEI-01-06-00510; issued 06/08

Public Health and Human Service Programs and Departmentwide and Cross-Cutting Issues

Increase the Percentage of Original Abbreviated New Drug Applications Reviewed Within 180 Days

Background: To market a generic drug—which is comparable to the innovator drug in dosage form, strength, route of administration, quality, performance characteristics and intended use—a pharmaceutical company must obtain Food and Drug Administration (FDA) approval of an original Abbreviated New Drug Application (ANDA). FDA is required by Federal law to approve or disapprove an ANDA within 180 days of receipt. FDA was appropriated a 74-percent increase in funding for the generic drug program between FY 2001 and FY 2006 and experienced a 158-percent increase in original applications during this period. Three divisions in FDA's Office of Generic Drugs (OGD) review ANDAs: Chemistry, Bioequivalence, and Labeling. A fourth division, Microbiology, reviews a subset of ANDAs. Almost all original ANDAs contain deficiencies that are identified by the Chemistry Division and disapproved. We reviewed original ANDAs that were approved, tentatively approved, pending, or disapproved during 2006 and original ANDAs that were pending at the end of 2006.

Finding(s): We found that of the original ANDAs FDA reviewed in 2006, 96 percent did not meet review standards and were disapproved. We found that FDA exceeded the 180-day statutory review requirement for nearly half of the ANDAs under review in 2006 because the reviews by the Chemistry Division exceeded this timeframe. The reviews by the division of Microbiology, Bioequivalence, and Labeling exceeded the 180-day review period for more than half of the original ANDAs reviewed in 2006. Of sampled reviews exceeding 180 days, 70 percent did not begin before the 180-day review period ended. We also found that OGD's divisions did not consistently classify or prioritize amendments, nor did they consistently assign high priority to approvable ANDAs.

Recommendation(s): FDA should identify common original ANDA deficiencies and offer more guidance to industry to decrease the percentage disapproved, increase the percentage of original ANDAs reviewed by all OGD divisions within 180 days, and identify new prioritization practices to reduce review times for ANDAs that are close to approval.

Status: In commenting on our draft report, FDA stated that it agreed with our first recommendation but did not indicate whether it concurred with the other two recommendations. FDA noted that it was implementing improvements similar to those in our recommendations by providing guidance to help industry submit more easily reviewed ANDAs, developing a focused hiring program to increase staff and decrease review times, and prioritizing ANDAs on the basis of potential market entry date.

Report(s): OEI-04-07-00280; issued 06/08

Increase Oversight of NIH's Grantee Institutions To Ensure Their Compliance With Federal Financial Conflict-of-Interest Regulations

Background: Federal regulations establish standards to ensure that the design, conduct, or reporting of research funded under Public Health Service grants is not biased by any conflicting financial interest of an investigator. The regulations require each institution that receives NIH funds to have a written policy for identifying financial conflicts of interest and ensuring that such conflicts are managed, reduced, or eliminated. Of NIH's 27 Institutes and Centers, 24 have grant-making authority and are responsible for managing and overseeing grants. NIH's Office of Extramural Research (OER) develops and implements policies and regulations governing NIH grants and develops and maintains information systems related to extramural research grants administration. Grantees must inform their respective funding institutes of any financial conflicts of interest before spending any NIH grant funds. Conflicts identified during the grant period must be reported, via conflict-of-interest reports, to the institutes within 60 days. Institutes are asked but not required to forward reports of grantee conflicts of interest to OER. We examined the extent to which NIH oversees grantee institutions' financial conflicts of interest for FY 2004 through FY 2006.

Finding(s): Our examination of financial conflict-of-interest reports and related documentation revealed that NIH institutes and OER could not provide an accurate count of the financial conflict-of-interest reports they received from grantees because the regulations did not explicitly require reporting of the nature of the conflicts or other details; grants officials did not know what types of conflicts existed and had little information on which to follow up; and the institutes' primary method of oversight was to rely on grantees' assurances that financial conflict-of-interest regulations were being followed.

Recommendation(s): NIH should (1) increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations; (2) require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated and work with the Secretary of HHS to amend the current regulation to require the submission of such details; and (3) require institutes to forward to OER all financial conflict-of-interest reports they receive from grantee institutions and ensure that OER's conflict-of-interest database contains information on all conflict-of-interest reports provided by grantee institutions.

Status: In its comments on our draft report, NIH concurred with two of our three recommendations. It did not concur with our recommendation to require grantee institutions to provide details regarding the nature of financial conflicts of interest, stating that grantee institutions are responsible for identifying and managing financial conflicts of interest. We continue to recommend that NIH collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions; work with the Secretary to amend the current regulation; and, in the interim, use its authority pursuant to 42 CFR § 50.604(g)(3) to request details regarding the nature and management of financial conflicts of interest at grantee institutions.

Report(s): OEI-03-06-00460; issued 01/08

Enforce the Division of Unaccompanied Children's Services' Documentation Requirement

Background: An unaccompanied alien child is defined in 6 U.S.C. § 279(g)(2) as a child under the age of 18 who has no lawful immigration status in the United States and who has no parent or legal guardian in the United States available to provide care and physical custody. When an unaccompanied alien child is found, the Department of Homeland Security (DHS) apprehends and detains the child and contacts ACF's Office of Refugee Resettlement (ORR), which contacts a facility funded by the Division of Unaccompanied Children's Services (DUCS). Pursuant to the Homeland Security Act of 2002, the Director of ORR is responsible for the care and custody of unaccompanied alien children and DHS is responsible for immigration benefits and enforcement. The Flores Agreement (so named for a class action lawsuit challenging detention policies and procedures for children in Federal custody) includes minimum standards for placement, care, and release to sponsors of alien children in Federal custody.

Finding(s): In our case file reviews of unaccompanied children apprehended by DHS who were in DUCS-funded facilities between April 1 and September 30, 2006, we found that most children were placed in and released from such facilities in accordance with Federal standards. However, we determined from our file reviews and facility visits that improvements were needed with respect to case file documentation, DUCS's program oversight, and the delineation of responsibilities between DHS and HHS.

Recommendation(s): ACF should enforce documentation requirements to ensure that children's needs are assessed and care is provided, define and enhance field staff roles in ongoing oversight to ensure that each child is safe and is receiving needed care, and establish a memorandum of understanding (MOU) between HHS and DHS to clearly delineate the roles and responsibilities of each Department.

Status: In commenting on our draft report, ACF did not indicate whether it concurred with our recommendations. It agreed that more monitoring of facility documentation and practices is needed. ACF stated that ORR would include random interviews with children and case file reviews as part of the routine responsibilities for Federal field specialists and that ORR was drafting a "Joint Operations Manual" (JOM) with DHS, with the ultimate goal of drafting an MOU. In April 2009, ACF informed OIG that ORR and DHS were updating the draft version of the JOM to conform to the new statutory requirements in the Trafficking Victims Protection Reauthorization Act of 2008. We continue to recommend establishing an MOU between HHS and DHS.

Report(s): OEI-07-06-00290; issued 03/08

Previous Nonmonetary Recommendations

Centers for Medicare & Medicaid Services Programs

Hospice

Improve Oversight of Medicare Hospices

Background: Section 1812(a) of the SSA provides coverage of hospice care for beneficiaries who qualify for Medicare Part A and are terminally ill. In recent years, this Medicare benefit has grown in terms of patients served, expenditures, and number of hospices. Organizations that provide hospice care must be certified by a State agency or a recognized accreditation organization as meeting minimum participation standards prescribed by CMS. CMS uses Federal comparative surveys and annual performance reviews to evaluate State agencies' survey and certification operations. Although the frequency of certification is not addressed in statute or regulations, for the period of our review (July 2005), CMS policy required hospice recertification every 6 years. Subsequently, CMS changed its policy to require recertification every 8 years, on average, beginning in FY 2006.

Finding(s): We found that, as of July 2005, 86 percent of hospices had been certified within 6 years, as required, while 14 percent averaged 3 years past due. For the period of our review, neither law nor regulation specified certification frequency, but CMS policy required hospice certification every 6 years. Health deficiencies were cited for 46 percent of hospices surveyed and for 26 percent of hospices investigated for complaints. The most frequently cited health deficiencies for both surveys and investigations centered on patient care planning and quality. We also found that CMS and State agencies rarely used methods other than certification surveys and complaint investigations to monitor hospice performance and enforce standards. Both CMS and State agencies infrequently analyzed existing hospice performance data, although CMS had directed State agencies for FY 2006 to target 5 percent of the hospices most at risk for having quality problems. At the time of our review, CMS had not given State agencies any direct guidance or specific criteria to identify the at-risk hospices.

Recommendation(s): CMS should provide guidance to State agencies and CMS regional offices regarding analysis of existing data and identification of at-risk hospices; include hospices in Federal comparative surveys and annual State performance reviews; seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification; and seek legislation to establish additional enforcement remedies for poor hospice performance.

Status: CMS partially concurred with our recommendations. In its comments on our draft report, CMS indicated that it had developed reports to support the oversight efforts of the regional offices and was exploring and implementing methods to become more efficient in targeting its resources toward providers most in need of closer oversight. CMS stated that its management challenge was to make the most effective use of appropriated resources. On June 5, 2008, CMS published the hospice final rule to revise the existing conditions of participation, which was last amended in 1990. This final rule became effective on December 2, 2008. It focuses on the care delivered to patients and their families by hospices and the outcome of care. CMS did not concur with the

recommendation to include hospice in Federal comparative surveys, citing budget limitations, and it did not agree to make regulatory changes to require shorter timeframes for hospice certification, stating that it considered the issue to be a statutory matter for Congress. We continue to recommend that CMS seek regulatory or statutory changes to establish specific requirements for (1) the frequency of hospice performance certification and (2) enforcement remedies for poor hospice performance.

Report(s): OEI-06-05-00260; issued 04/07

Medicare End Stage Renal Disease Program

Improve the Availability of Quality-of-Care Data in the Medicare End Stage Renal Disease Program

Background: Patients with ESRD rely on dialysis treatment to compensate for kidney failure. In 2000, both OIG and the Government Accountability Office (GAO) issued reports documenting problems with CMS's oversight of ESRD facilities. National aggregate data suggest that dialysis care has improved overall. However, questions remain about the quality of care provided at some ESRD facilities. To help monitor and improve quality of care, CMS oversees ESRD facilities through contracts with State survey and certification agencies and ESRD networks. This study assessed the extent to which data were available to help networks identify facilities with quality improvement needs.

Finding(s): We found that between 2004 and 2005, although networks had access to multiple sources of data about quality of care, each source had limitations in its ability to help networks identify facilities with quality improvement needs. Limitations included lack of facility-specific, comprehensive, or current clinical performance measures (CPM). We also found that CMS had taken action toward providing a streamlined source of data that could help networks identify facilities with quality improvement needs; however, the source had not yet been implemented.

Recommendation(s): CMS should develop facility-specific quality improvement information and increase its efforts to regularly collect data on all CPMs identified by CMS to address quality-of-care issues in the ESRD program.

Status: CMS did not indicate in its response to our final report whether it concurred or did not concur with our recommendations. The agency stated that it had made progress in collecting data to improve the quality of care in the ESRD program and indicated that opportunities for improvement remain. CMS stated that steps had been taken to improve quality of care for the ESRD program, including the development of CPMs, definition of the core data set, and proposed regulations that would require facilities to electronically submit all CPMs on all ESRD patients. CMS also stated that it would develop a new Web-based data collection system called Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which would consolidate existing data sources into one system. On April 15, 2008, CMS published final rule CMS-3818-F entitled "Conditions for Coverage for End-Stage Renal Disease Facilities," which established new conditions that facilities must meet to be certified under the Medicare program. The rule states that beginning on February 2, 2009, ESRD facilities must electronically collect and report to CMS on an ongoing basis the administrative and CPM data annually for all eligible ESRD patients via CROWNWeb. According to a January 16, 2009 CMS email announcement published on the internet, CMS stated it was moving CROWNWeb from its testing environment to a production/implementation environment, in phases, beginning on February 1, 2009 starting with a small, select group of providers and that it will expand implementation as it learns about how the system functions within facilities. We will continue to monitor CMS's implementation of CROWNWeb.

Report(s): OEI-05-05-00300; issued 11/06

Medicare Ambulatory Surgical Centers

Improve Quality Oversight of Ambulatory Surgical Centers in the Medicare Program

Background: Ambulatory surgical centers (ASC) are one of the fastest growing settings for ambulatory surgery in the Medicare program. CMS is responsible for the oversight of care provided in this health care setting. Quality oversight of ASCs revolves around the Conditions for Coverage (CfC), Medicare's set of minimum health and safety requirements. CMS requires that ASCs become Medicare-certified by a State survey and certification agency or be privately accredited to show that they meet the Conditions. Although ASCs are free to choose which route they take, over 90 percent elect to become certified by State agencies rather than through accreditation.

Finding(s): We found that the number of Medicare ASCs more than doubled from 1990 to 2000 and that major procedures performed in ASCs increased by 730 percent. Medicare's system of quality oversight was not sufficient, in that one-third of ASCs certified by State agencies had not been recertified in 5 or more years when our review was performed in 2000. CMS had done little to hold State certification agencies and accreditors accountable to the Medicare program and the public.

Recommendation(s): CMS should determine an appropriate minimum cycle for surveying ASCs certified by State agencies and should hold State agencies and accreditors fully accountable to the Medicare program for their performance in overseeing ASCs. CMS should ensure that State agency certification and accreditation strike an appropriate balance between compliance and continuous quality improvement.

Status: CMS generally concurred with our recommendations. CMS updated its "State Operations Manual" (section 2008F) on May 21, 2004, to state that "resurveys are generally conducted annually, but depending on national initiatives and budget constraints, the cycle may vary." On August 21, 2006, CMS posted a public notice that it was making available Medicare payment information for 61 procedures performed in ASCs. CMS indicated that this information "will help patients undergoing surgical procedures select the most appropriate setting for the delivery of high quality, efficient care." In August 2007, CMS issued CMS-3887-P, entitled "Ambulatory Surgical Centers, Conditions for Coverage," with proposed revisions to the existing CfCs for ASCs and indicated that some of the changes being proposed are the result of the February 2002 OIG report. The preamble mentions that CMS proposes to "replace the current Evaluation of Quality requirement with a new Quality Assessment and Performance Improvement (QAPI) requirement" and "to add a new Patient Rights requirement." It also states that "from both a policy perspective and an operational perspective, we are unable to propose different sets of ASC CfCs that are based on the scope of severity of the procedures offered by an ASC." Instead, CMS stated that it "would expect each ASC's QAPI program to reflect the scope and severity of the surgical services they perform." We continue to recommend the implementation of a minimum cycle for the survey of ASCs and will monitor the status of the proposed regulations. In April 2009, CMS informed OIG that, due to budgetary constraints, it had deferred reporting of ASC quality data for CY 2010 in the CY 2009 Outpatient Prospective Payment System (OPPS) final rule. We will continue to monitor for implementation of our recommendations.

Report(s): OEI-01-00-00450; issued 02/02

Medicare Rural Health Clinics

Improve Oversight of Rural Health Clinics

Background: The Rural Health Clinic (RHC) program, created in 1977 by P.L. No. 95-210, is intended to increase access to health care for rural medically underserved areas and to expand the use of midlevel practitioners in rural communities. In 1996, OIG and GAO issued reports that raised concerns about the inappropriate growth and locations of RHCs. Both organizations recommended changes to ensure that RHCs are located in areas that would otherwise be underserved. OIG reexamined this program and issued a follow-up report in 2005.

Finding(s): We found that between 1990 and 1995, the number of RHCs and associated Medicare and Medicaid expenditures grew substantially. Four interrelated factors appeared to drive the growth of RHCs: (1) providing access to care, (2) reimbursement, (3) managed care, and (4) the certification process. RHCs may have increased access to care in some areas but not in others. They are paid based on their costs, which are difficult and sometimes impossible to verify or audit without significant resource expenditure by the Government. As of May 2003, 61 percent of RHCs were located in areas that were not designated as shortage areas and 39 percent were located in urban areas.

Recommendation(s): CMS, in conjunction with HRSA, should modify the certification process to increase State involvement and ensure more strategic placement of RHCs. CMS should expedite the issuance of the regulations under development and take immediate steps to improve the oversight and functioning of the current cost reimbursement system, with a long-term goal of implementing an improved method of reimbursement.

Status: CMS and HRSA generally concurred with our recommendations. The BBA of 1997 refines the requirements for RHC designations and provider-based reimbursement. CMS developed a program memorandum consolidating and clarifying the policy regarding provider-based and freestanding designation conditions. CMS published a final rule in 2003 amending, among other things, the criteria for designating a clinic as an RHC. However, because the date on which CMS published this rule was 3 years beyond that of the proposed rule, contrary to statutory requirement, CMS determined that the rule needed to be republished as a notice of proposed rulemaking. On February 29, 2008, HHS published a notice of proposed rulemaking, "Designation of Medically Underserved Populations and Health Professional Shortage Areas" (73 FR 11232), to revise and consolidate the criteria and processes for designating these shortage areas. On July 23, 2008, HRSA published a notice in the Federal Register indicating that it had received many substantive comments on the proposed rule and, based on a preliminary review of the comments, it may need to make a number of changes. In HRSA's March 2009 status update, it indicated that, instead of issuing a final regulation as the next step, HHS planned to issue a new notice of proposed rulemaking for further review and public comment before issuing a final rule.

Report(s): OEI-05-94-00040; issued 07/96
OEI-05-03-00170; issued 08/05

Nursing Homes

Ensure That States Properly Maintain Nurse Aide Registries

Background: Amending sections 1819 and 1919 of the SSA, sections 4201 and 4211 of OBRA 1987 include numerous provisions intended to improve the quality of care in long term care (LTC) facilities. Among these provisions is the requirement that each State establish and maintain a registry of individuals who have completed training and whom the State finds competent to function as nurse aides. In addition, Federal regulations (42 CFR § 483.13(c)(1)) prohibit LTC facilities from employing individuals who have had substantiated adverse findings entered into the State nurse aide registry or who have been found guilty in a court of law of abusing, neglecting, or mistreating LTC facility residents.

Finding(s): Based on data from September 2003, we found that some States had failed to update registries with substantiated adverse findings and that some LTC staff reported checking only their own State's registries before hiring employees. Many States reported failure to remove records of inactive nurse aides from registries, and some individuals with substantiated adverse findings in one State were actively certified in other States. Some States reported using State-specific practices that could make it more difficult to prevent certain individuals from working as nurse aides. We also found that some facilities employed nurse aides without the required registration for longer than the allowed 4 months.

Recommendation(s): CMS should (1) ensure that States update information regarding nurse aides with substantiated adverse findings in a timely manner and remove registry records of nurse aides who have not performed nursing or nursing-related services for 24 consecutive months, (2) reduce the potential for nurse aides with substantiated findings to offend again in another State and work with States to ensure that registry records contain current information on nurse aides, (3) use existing communication channels (e.g., survey and certification processes) to ensure that LTC facilities comply with Federal regulations that require them to check the nurse aide registries of other States that they believe may contain information about individuals and to not employ individuals as nurse aides for more than 4 months without registration, and (4) ensure that LTC facilities use available resources to prevent nurse aides with substantiated adverse findings or criminal backgrounds in other States from being employed.

Status: CMS concurred with our recommendations. In commenting on our draft report, CMS indicated that it had developed and disseminated the "Abuse and Neglect Detection and Prevention Training Manual" to provide surveyors and other reviewers with additional resources to support the detection and prevention of abuse and neglect. In April 2008, CMS informed us that it had issued a survey and certification letter (S&C 05-46) to State survey agency directors requesting that they review the Federal requirements related to the operation and maintenance of the nurse aide registry. In 2005, pursuant to the MMA, CMS implemented a 2-year Criminal Background Check Demonstration for nurse aides in seven States. CMS released the final evaluation report on the results of the Criminal Background Check Demonstration in September 2008. In April 2009, CMS informed OIG that it planned to issue a survey and certification letter detailing the Background Check Pilot States' lessons learned. We are continuing to monitor CMS's actions through current work to ensure that States are in compliance with Federal

nurse aide registry regulations and will conduct additional work in the area of nursing home background checks. We will reevaluate this item when the ongoing work is published.

Report(s):	**OAS-12-97-00003; issued 09/98** **OEI-07-03-00380; issued 02/05** **OEI-07-04-00140; issued 07/05**

Update Nursing Home Nurse Aide Training Curriculum

Background: OBRA 1987 mandated that the Nurse Aide Training and Competency Evaluation Program establish minimum requirements for nurse aide competency.

Finding(s): As of July 2001, 90 percent of surveyed nursing home experts reported that the medical and personal care needs of today's nursing home residents have changed since the implementation of OBRA. We found that nurse aide training had not kept pace with the demands of the changing care environment. We also found that teaching methods were often ineffective, clinical exposure was too short, and in-service training may not be meeting Federal requirements.

Recommendation(s): CMS should improve nurse aide training and competency program requirements to ensure that the content of the training curriculum and testing remain relevant to the current complex resident care needs. We also recommended that CMS continue to work with States to ensure that training is effective and efficient and that nursing homes comply with in-service training requirements.

Status: CMS concurred with our recommendations. Following the issuance of our report, CMS informed us that it intended to use a contractor to document the problem more extensively and develop specific policy and program options for improvement. In April 2009, CMS informed us that its final report on improving nurse aide training completed in September 2008 contained a conclusion that statutory change is necessary to address improvement to nurse aide training requirements. We encourage CMS to work with Congress to ensure the necessary statutory changes to nurse aide training requirements.

Report(s): OEI-05-01-00030; issued 11/02

Medicare and Medicaid Administration

Improve Medicare Information Systems Control

Background: The Federal Financial Management Improvement Act of 1996 requires Federal agencies to maintain acceptable accounting systems. Also, the Federal Managers' Financial Integrity Act of 1982 requires agencies to develop, maintain, and test their internal controls and financial management systems and to report any material weaknesses and planned corrective actions.

A substantial portion of CMS transactions and administration of programs is performed by geographically diverse contractors. The contracts between CMS and its contractors that have IT responsibilities include provisions requiring the contractors to follow security standards detailed in CMS's "Business Partners Systems Security Manual" (BPSSM), version 9. Specific security standards followed by a contractor are to be documented in the contractor's System Security Plan.

Finding(s): Information systems controls was considered a material weakness in the FY 2008 financial statement audit for the following reasons: (1) CMS central office did not have a security software or operating systems software baseline for the IBM mainframe computer that processes a significant portion of CMS's financial applications, including the general ledger system; (2) four of the eight data centers and software maintainers tested did not have baseline security standards for the computer systems used to process Medicare data, as required by CMS's BPSSM and the CMS System Security Plans Methodology; (3) because contractors' system security plans did not have consistent content as to the baseline security settings, it was not possible to determine whether the information security requirements accepted by CMS were the information security controls implemented or that such settings were contemplated to appropriately consider risks pursuant to National Institute of Standards and Technology (NIST); (4) CMS's Office of Financial Management did not segregate duties between its business function and its information security administration function relating to the Financial Accounting Control System (FACS) general ledger-related application (although the review did not disclose any exploitation of critical systems tested, the security weakness noted could allow internal users to access and update sensitive systems, program parameters, and data without proper authorization); and (5) the software maintainers contracted to support the shared systems used to process Medicare claims did not demonstrate the successful execution of 8 of the 100 application edits tested.

Recommendation(s): CMS should continually monitor to ensure that contractors have implemented BPSSM requirements and embedded NIST standards, documented actual security settings, and maintained documentation to support certifications reports provided to CMS. Furthermore, CMS should analyze contractors' self-assessments and reviews conducted by independent public accounting firms to determine whether these activities provide assurance that contractors are complying with CMS information security requirements. To address the FACS deficiency, CMS should move the application security administration process and configuration management process to its Office of Information Security. CMS management should focus on the requirements set forth in the software maintainer contracts to ensure that all changes follow control processes and that the contractors provide the services and activities required by their contracts in support of the overall protection of CMS computer integrity and security.

Status: According to CMS's Financial Report for Fiscal Year 2008, CMS systems have undergone significant changes that have led to improvements by remediating specific security weaknesses. The agency believes that the findings related to information control systems do not rise to the level of a material weakness. During FY 2008, the OIG attended CMS's monthly Risk Management meetings that discussed and tracked the progress of CMS's corrective action plans. CMS has developed and is implementing corrective actions to address the FY 2007 Medicare claims processing material weakness, and believes that these actions would reduce last year's issues to a significant deficiency. In response to the FY 2008 Report on Internal Controls, CMS did not describe its planned corrective actions; however, we understand that the agency is developing corrective actions. As part of our FY 2009 financial statement audit, we will be reviewing CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations.

Report(s): **OAS-17-98-00098; issued 02/99**
OAS-17-00-00500; issued 02/00
OAS-17-00-02001; issued 02/01
OAS-17-01-02001; issued 02/02
OAS-17-02-02002; issued 01/03
OAS-17-04-02002; issued 12/04
OAS-17-05-02005; issued 11/05
OAS-17-06-02006; issued 11/06
OAS-17-07-02007; issued 11/07
OAS-17-08-02008; issued 11/08

Improve CMS's Financial Reporting Systems and Processes

Background: Financial management in the Federal Government requires accountability by financial and program managers, control over the Federal Government's financial resources, and protection of Federal assets. To meet these needs, financial management systems must be in place to process and record financial events effectively and efficiently and to provide complete, timely, and reliable financial information. Office of Management and Budget (OMB) Circular No. A-127, "Financial Management Systems," prescribes the policies and standards that each agency should follow in developing, operating, evaluating, and reporting on financial management systems. CMS relies on a decentralized organizational structure and complex financial management systems—not only within its central office and regional offices' processes, but also within many of the Medicare contractor organizations—to accumulate data for its financial reporting.

Finding(s): The FY 2008 financial statement audit noted that: (1) CMS needed to improve its process for managing cross-functional teams of financial management, information technology, actuarial, general counsel, operations, and other personnel that develop or provide critical accounting and financial reporting information; (2) CMS's central office performed limited analytical procedures on financial information provided by its regional offices and Medicare contractors, increasing the likelihood that any necessary adjustments to its financial statements would not be made in a timely manner; (3) CMS did not perform a claims-level detailed look-back analysis of the $20.4 billion accrual for Medicaid Entitlement Benefits Due and Payable (EBDP) to determine the reasonableness of the various State calculations of unpaid claims; (4) CMS needed to do more to ensure that its monitoring activities regarding the Comprehensive Error Rate Testing (CERT) and Payment Error Rate Measurement (PERM) programs were well understood, susceptible to replication, and highly credible; and (5) some internal controls related to the Medicare Secondary Payor (MSP) recovery contractor, including CMS's oversight of the contractor, segregation of incompatible duties, and the untimely application of cash receipts, were not designed well or operating effectively. Although reductions have been made in the amount of funds advanced to Part D plans as compared with prior years, the substantial amount of cash being advanced to plans in anticipation of future beneficiary prescription drug claims increases the risk of loss of Federal funds if plans have financial difficulties. Although CMS continued its efforts to implement the Healthcare Integrated General Ledger Accounting System (HIGLAS), the lack of a single integrated accounting system impairs CMS's ability to efficiently and effectively support and analyze financial reports. Medicare contractors that have not implemented HIGLAS continue to rely on manual processes that are subject to increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS.

Recommendation(s): CMS should (1) establish a protocol with specific policies and procedures to address situations or transactions that require cross-functional involvement in developing or revising financial information, estimates, or reports and continue to enhance its process related to the development, documentation, and validation of critical accounting matters; (2) perform more analytical analysis of accounting information and circulate it for review as part of the monthly, quarterly, and annual financial report closing process; (3) establish a process to perform a claims-level detailed look-back analysis on the Medicaid EBDP to determine the reasonableness of the methodology used to estimate the accrual; (4) continue the process of improving the integrity

and efficiency of CERT and PERM tools; (5) continue to implement an integrated financial management system to promote consistency and reliability in accounting and financial reporting; (6) evaluate the timing of certain payments advanced to Part D plans and consider a payment process that matches the timing of these payments with the incurrence of the related claims; and (7) implement and monitor controls at the MSP recovery contractor.

Status: CMS concurred with these recommendations made in the FY 2008 financial statement audit report. In FY 2008, the agency continued to improve its financial management performance in many areas. We acknowledge that CMS is in the process of developing corrective actions for the FY 2008 audit; and as part of our FY 2009 financial statement audit, we will be reviewing CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations**.**

Report(s): **OAS-17-97-00097; issued 04/98**
OAS-17-98-00098; issued 02/99
OAS-17-00-00500; issued 02/00
OAS-17-00-02001; issued 02/01
OAS-17-01-02001; issued 02/02
OAS-17-02-02002; issued 01/03
OAS-17-03-03003; issued 11/03
OAS-17-04-02004; issued 12/04
OAS-17-05-02005; issued 11/05
OAS-17-06-02006; issued 11/06
OAS-17-07-02007; issued 11/07
OAS-17-08-02008; issued 11/08

Improve Centers for Medicare & Medicaid Services Performance Evaluation Process for Program Safeguard Contractors

Background: The Health Insurance Portability and Accountability Act of 1996 (P.L. No. 104-191), section 202, authorized CMS to contract with entities to fulfill program integrity functions for the Medicare program and required a competitive process for awarding contracts. CMS entered into the first contract under this authority in 1999. Entities awarded such contracts are called program safeguard contractors (PSC). Once under contract, PSCs are awarded task orders to carry out specific duties.

Finding(s): We found that performance evaluation reports issued by CMS from 1999 to 2004 contained minimal information about PSC achievements related to detecting and deterring fraud and abuse under benefit integrity task orders. Because these reports were limited in their description of the results that PSCs may have been achieving, they provided limited information on which to base task order renewal decisions. We also found that 72 percent of final performance evaluation reports were issued on time. However, only 5 of 32 final reports were issued 3 months before the task order ended, which is the time by which CMS was required to notify the PSC whether the contract would be renewed. The unavailability of milestone dates prevented us from identifying where delays occurred in the evaluation process.

Recommendation(s): CMS should (1) address PSC results in performance evaluation reports and include quantitative as well as qualitative information, (2) include information about required fraud and abuse detection and deterrence activities in the reports, (3) ensure that all draft and final reports are issued on time, and (4) establish a means to track and save evaluation milestone dates.

Status: In its comments on our draft report, CMS partially concurred with our recommendations. The agency disagreed with our first two recommendations regarding the areas that should be addressed in PSC performance evaluation reports. In April 2009, CMS stated that it has been collecting and tracking quantitative data about PSCs in its CMS-ARTS database. It did not indicate that these data have been included in performance evaluation reports; nor did it provide documentation showing that these data are now used in performance evaluation reports. CMS also stated that it continues to review and reevaluate the PSC statement of work in order to emphasize the most crucial activities but did not state whether these activities have been addressed in the performance evaluation reports; nor did it provide documentation showing that these activities are being addressed in the performance reports. Although the umbrella statement of work was revised, it no longer contains a timetable for issuing both a draft and final report. CMS also indicated that it complies with the time constraints associated with contract renewal dates so that only PSC contracts with acceptable performance are renewed. However, it has not explained how it ensures that performance evaluation reports are issued by the time the task order renewal notices are due and has not provided documentation showing how or whether this has been accomplished. It also reported in its March 2009 status update that it developed a milestone date chart reflecting the significant evaluation dates. However, because of resource constraints, the chart is updated manually and CMS has not been able to enhance CMS-ARTS to capture this information. The purpose of central tracking is to identify where delays occur so that improvements can be made to the agency's performance evaluation process. Thus, we continue to recommend that the milestones be tracked in a central system that can be accessed

by management. Additionally, CMS began its transition to consolidate the work of Medicare's program safeguard contractors and the MEDICs with new ZPIC. The new contractors will eventually be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, and durable medical equipment claims); Part C (Medicare Advantage health plans); Part D (prescription drug plans); and coordinating of Medicare-Medicaid data matches (Medi-Medi). The first two ZPIC contracts were awarded to Health Integrity (Zone 4) and SafeGuard (Zone 7). In light of these changes, we continue to monitor CMS's implementation of its safeguard strategy.

Report(s): OEI-03-04-00050; issued 03/06

Improve Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program

Background: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established quality standards for all laboratory testing to ensure the accuracy and timeliness of test results. CLIA waives the standards for laboratories that use only tests that the Secretary of HHS has determined have insignificant risk of erroneous results. In addition to performing waived tests, provider-performed microscopy procedures laboratories may perform certain microscopic examinations during the course of a patient visit using specimens that are not easily transportable. Laboratories conducting only such simple tests must apply for a certification of waiver from the Secretary of HHS. Regulations require that laboratories eligible for a certification of waiver follow the manufacturers' instructions when conducting waived tests.

Finding(s): We found that as of July 2000, there were significant vulnerabilities in the CLIA certification process for laboratories performing waived procedures and provider-performed microscopy. Many certifications of waiver and provider-performed microscopy laboratories did not follow manufacturers' instructions or conducted testing that was beyond the scope of their certifications. Moderate- and high-complexity laboratories also failed to meet requirements for waived testing.

Recommendation(s): CMS should provide educational outreach and self-assessment tools to laboratories, require laboratories applying for certifications of waiver or provider-performed microscopy to identify which test systems they use, and conduct inspections each year of a random sample of waived and provider-performed microscopy laboratories to assess compliance with program requirements.

Status: CMS concurred with our recommendations to decrease vulnerabilities in the CLIA enrollment and certification processes; however, it noted that resource limitations could affect implementation. CMS worked collaboratively with CDC to develop a document outlining laboratory practices for waived tests; it was published in November 2005 in CDC's "Morbidity and Mortality Report." We recommend that CMS implement all our recommendations, including inspections each year of a random sample of waived and provider-performed microscopy laboratories to assess compliance with the program requirements.

Report(s): OEI-05-00-00251; issued 08/01

Medicaid Prescription Drugs

Review Impact of New Federal Upper Limit Calculations

Background: Pursuant to section 1927(e) of the SSA, CMS is required to establish FUL amounts to reduce the amount that Medicaid reimburses for multiple-source drugs. Before 2007, Federal regulations set the FUL amount at 150 percent of the national compendia published price for the least costly therapeutically equivalent drug. Section 6001(a) of the DRA makes significant changes to the FUL program. As of January 1, 2007, a drug needs only two therapeutically equivalent versions to be included on the FUL list, and FUL amounts are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the national compendia published price for the least costly, therapeutically equivalent drug. In response to these changes, industry groups have expressed concerns that pharmacies will not be able to acquire drugs for prices at or below the new FUL amounts. The Congressional Budget Office estimates that changes to the FUL threshold will reduce Medicaid expenditures for FUL drugs by $3.6 billion over 5 years.

Finding(s): We found that the FUL amounts set under the previous calculation method were more than double the pharmacy acquisition costs for 23 of 25 selected high-expenditure Medicaid drugs in the second quarter of 2006. Under the new calculation method established by the DRA, the FUL amounts are likely to decrease substantially. We determined that on average, pharmacies would have been able to purchase 6 of 25 selected high-expenditure drugs for less than the new FUL amount in the second quarter of 2006. Furthermore, we found that the AMP used to set a new FUL amount may be substantially lower than other AMPs associated with a drug (i.e., the second-lowest AMP and volume-weighted AMP).

Recommendation(s): CMS should take steps to identify cases in which a new FUL amount may not be representative of a drug's acquisition cost to pharmacies and, in those situations, determine the proper course of action (working with Congress if necessary). One option that we recommended was that CMS issue a final regulation to remove the lowest AMP from the FUL calculation when it is significantly lower than the volume-weighted AMP for a drug.

Status: CMS did not concur with our findings concerning the effect of the DRA-related changes on the FUL calculation. It believed that we should have waited until the final AMP regulation had been promulgated before completing this study and requested that we revise our analysis. According to CMS, as of the first quarter of FY 2008, it changed the way it identifies which drugs are subject to FUL and the way it calculates prices. The DRA required CMS to change its FUL calculation to base these limits on AMP, a sales-based price, by January 2008. However, in December 2007, a Federal district court issued a preliminary injunction that prevented CMS from implementing these new FULs. Additionally, in July 2008, Congress enacted P.L. No. 110-275 delaying the implementation of the new FULs and prohibiting disclosure of AMP until October 2009. Therefore, FULs are calculated using the prior formula based on the lowest published prices (i.e., AWP or wholesale acquisition costs), which OIG has found to result in inflated payments. We continue to monitor FUL amounts through our work on FUL calculations using the pre-DRA methodology compared to prices available through discount programs at large chain pharmacies.

Report(s): OEI-03-06-00400; issued 06/07

Provide Additional Guidance to Drug Manufacturers To Better Implement the Medicaid Drug Rebate Program

Background: Section 1927 of the SSA requires drug manufacturers to enter into and comply with rebate agreements with the Secretary of HHS for States to receive Federal funds for a manufacturer's covered outpatient prescription drugs. The Secretary may also authorize States to enter into direct agreements with drug manufacturers. Pursuant to section 1927, manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period. The manufacturer is required to report on a quarterly basis the AMP and the best price for each covered outpatient drug. In our 1992 report, we evaluated the methods used by selected manufacturers to determine the AMP and the best price and verified the accuracy of pricing information supplied to CMS by the drug manufacturers. Section 6001 of the DRA required OIG to review the requirements for and the manner in which AMPs are determined under section 1927 of the SSA and to recommend appropriate changes by June 1, 2006.

Finding(s): Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work, which has focused primarily on how manufacturers calculate the AMP, has found that manufacturers interpret AMP requirements differently. Specifically, our findings demonstrate the need to clarify the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales in AMP calculations. In addition, work related to the use of the AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, industry groups raised additional issues related to the implementation of DRA provisions. Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts, as well as rebate errors.

Recommendation(s): CMS should clarify requirements with regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and should consider addressing issues raised by industry groups, such as administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMPs. Also, CMS should issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and should encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Status: CMS concurred with our recommendations. In July 2007, CMS issued a final rule that modified the definition of the AMP and appears to increase the transparency of the AMP calculation. The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of this rule. Additionally, in July 2008, Congress enacted Public Law 110-275, which prevents CMS from releasing AMP data and from implementing FULs based on AMP until October 2009. OIG audits continue to identify variation among calculation methods, so

we continue to recommend that CMS provide oversight to ensure that methods used to calculate AMPs are consistent among manufacturers.

Report(s): OAS-06-91-00092; issued 11/92
OAS-06-06-00063; issued 05/06

State Children's Health Insurance Program

Strengthen Federal and State Oversight of Separate State Children's Health Insurance Program Fraud and Abuse Safeguards

Background: Federal and State governments jointly fund SCHIP to provide health assistance to low-income children who do not qualify for Medicaid. A State may structure its respective SCHIP as an expansion of Medicaid, as a program separate from Medicaid, or as some combination of these. As of January 2005, 39 States had all or some of their SCHIP programs separate from Medicaid. Medicaid expansion programs are subject to the Medicaid integrity requirements under Title XIX of the SSA. Separate SCHIP programs are subject to more flexible SCHIP integrity regulations, which require that States establish procedures for ensuring program integrity and detecting fraud and abuse. We examined the extent to which States had met requirements to establish fraud and abuse safeguards.

Finding(s): The six States we reviewed met requirements for prevention and detection of fraud and abuse by assigning responsibility to SCHIP contractors that had established such procedures. However, one of the six States did not meet Federal requirements for investigating suspected SCHIP fraud and abuse cases and referring cases to law enforcement. Although oversight mechanisms in the six States addressed Federal requirements, they did not always enable States to know how well SCHIP contractors were performing safeguard activities. Also, CMS relied primarily on States for oversight of SCHIP fraud and abuse safeguards, although it had completed some onsite reviews.

Recommendation(s): CMS should ensure that the noncompliant States institute procedures to meet Federal requirements for investigating cases of suspected SCHIP fraud and abuse and referring cases to law enforcement. CMS should also take steps to strengthen Federal and State oversight of separate SCHIPs' fraud and abuse safeguards.

Status: CMS did not indicate whether it concurred or did not concur with our recommendations. In its comments, CMS suggested clarifying the language in our report to emphasize that the SCHIP statute is not prescriptive in describing Federal oversight of fraud and abuse. In its March 2009 status update to OIG, CMS indicated that it is working with the noncompliant State to bring it into compliance with Federal requirements and noted that it had assisted States in strengthening fraud and abuse efforts, which included assessing CMS's mechanisms and revising the SCHIP annual report template to collect information from States about their fraud and abuse safeguards. We continue to recommend that CMS determine whether all States with separate SCHIPs have appropriate investigation and referral procedures.

Report(s): OEI-06-04-00380; issued 03/07

Public Health and Human Service Programs and Departmentwide and Cross-Cutting Issues

Improve Health Resources and Services Administration Alert List Practices

Background: The purpose of the Alert List is to safeguard HHS funds by alerting agencies to potential risks in awarding grants. The Alert List is posted on the HHS Intranet site, and all agencies that award grants have access to it. If an awarding agency has concerns about a grantee because of his or her inexperience in handling Federal funds, financial instability, inadequate management systems, a history of poor programmatic performance, or other reasons, the agency may place the grantee on the Alert List.

Finding(s): We found that as of 2003, HRSA had not consistently followed Alert List policies. Specifically, we determined that HRSA did not (1) consistently place high-risk grantees on the Alert List, (2) consistently check the Alert List or accurately document checking it, (3) regularly consult with other agencies to obtain information about grantees, (4) consistently document certain monitoring activities for Alert List grantees, (5) provide justification for retaining grantees whose names appear on the Alert List for more than 2 years, or (6) use the information on the Alert List to make grant decisions.

Recommendation(s): HRSA should develop methods to ensure that grants officers follow Alert List policies.

Status: In its July 2006 comments on our final report, HRSA indicated that it concurred with our recommendation. HRSA indicated that the consolidation of its grants management operations into a single operating unit, with standardized operating procedures and uniform guidance, would prevent a recurrence of the types of adverse findings identified in our report. The agency also indicated that it was working closely with grants officers to ensure that Alert List procedures are followed. However, an Office of Grants Action Transmittal issued on February 6, 2008, noted that the Office of Grants confirmed our findings during HHS training and therefore suspended the departmental Alert List and all associated policies, pending reconsideration of the process, procedures, and appropriate management of this type of information. In March 2009, HRSA informed OIG that the Alert List had not been reinstated and did not specify any plans for its reinstatement. The agency also reported that it continues to perform assessments of grantees to determine whether special award conditions are warranted. We continue to recommend that HRSA reinstate the Alert List or an appropriate alternative solution.

Report(s): OEI-02-03-00011; issued 05/06

Improve Financial Analysis and Reporting Processes

Background: The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. Government Auditing Standards and OMB Bulletin 07-04, "Audit Requirements for Federal Financial Statements," provide auditors with guidance regarding how to audit and report on the Federal financial statements. OMB Bulletin A-127 requires that financial statements be the culmination of a systemic accounting process. The statements are to result from an accounting system that is an integral part of a total financial management system containing sufficient structure, effective internal control, and reliable data.

Finding(s): The FY 2008 financial statement audit noted that internal control weaknesses continued in HHS's financial management systems and financial analyses and oversight. HHS's lack of an integrated financial management system impaired its ability to support and analyze account balances. Manual intervention was required to correct transactions that did not post in accordance with standards and to transfer information between systems that did not interface electronically.

In addition, certain reconciliations and account analyses were not adequately or promptly performed to ensure that differences were identified and resolved and that invalid or old transactions were identified and closed. HHS's financial management systems did not substantially comply at the transaction level with Federal financial management systems requirements or the U.S. Government Standard General Ledger.

Furthermore, general control, design, and operation issues related to security management and access controls were noted in systems relevant to the financial reporting process. In addition, weaknesses were noted in general controls, business process controls, interface controls, and data management system controls for specific financial applications.

Recommendation(s): HHS should continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity. Additionally, HHS should provide a secure computing environment for critical applications throughout all the operating divisions.

Status: In the FY 2008 Agency Financial Report (AFR), issued in November 2008, HHS acknowledged that it continued to have material weaknesses in internal control relating to financial reporting system analytics and oversight and in financial management information systems. HHS indicated that it plans to resolve these weaknesses by continuing its efforts to improve financial management processes and oversight and to strengthen information technology systems.

Report(s):	**OAS-17-98-00001; issued 04/98**	**OAS-17-03-00001; issued 11/03**
	OAS-17-98-00015; issued 01/99	**OAS-17-04-00001; issued 12/04**
	OAS-17-99-00002; issued 02/00	**OAS-17-05-00001; issued 11/05**
	OAS-17-00-00014; issued 02/01	**OAS-17-06-00001; issued 11/06**
	OAS-17-01-00001; issued 02/02	**OAS-17-07-00001; issued 11/07**
	OAS-17-02-00001; issued 01/03	**OAS-17-08-00001; issued 11/08**

Strengthen State Protections for Persons With Disabilities in Residential Settings

Background: Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid funds—including nursing homes, psychiatric facilities, and intermediate care facilities for persons with mental retardation—CMS has established conditions of participation requiring that residents and patients be protected from abuse or neglect. ACF and the Substance Abuse and Mental Health Services Administration (SAMHSA) provide States with grants to establish protection and advocacy systems for investigating allegations of abuse or neglect. Also, FDA oversees the regulation of medical devices, including physical restraints, and receives information on deaths that occur during the use of restraints.

Finding(s): We found that between 1999 and 2000, approximately 90 percent of persons with disabilities in residential facilities were in facilities that are not subject to CMS oversight and relied solely on protections offered by State systems to identify, investigate, and resolve reports of abuse or neglect, including the misuse of restraints and seclusion. The level of protection provided by State systems varies widely. Limited Federal standards, partly because of HHS's limited statutory authority to set requirements for many facilities and homes, have left persons with disabilities more vulnerable in residential facilities in which State systems are not well developed. Also, HHS was at a disadvantage in identifying systemic problems because it received limited information on occurrences of abuse or neglect.

Recommendation(s): CMS, ACF, SAMHSA, and FDA should work cooperatively to provide information and technical assistance to States to (1) improve the reporting of potential abuse or neglect of persons with disabilities, (2) strengthen investigation and resolution processes, (3) assist in analyzing incident data to identify trends that indicate systemic problems, and (4) identify the nature and causes of incidents to prevent future abuse.

Status: CMS, ACF, SAMHSA, and FDA concurred with our recommendation to work cooperatively and provide information and technical assistance to States. Each agency detailed actions that it was taking or planned to take to improve safeguards. For example, SAMHSA noted that it had established a grant program, initiated in FY 2001, to identify effective alternative practices (e.g., training efforts) to reduce restraint and seclusion practices and that it would promote the application of the findings from these grants. We plan to perform follow-up work to determine whether appropriate action has been taken on our recommendations.

Report(s): OAS-01-00-02502; issued 05/01

Report Medical Malpractice Cases to the National Practitioner Data Bank

Background: Pursuant to an HHS policy directive issued on October 15, 1990, all settled or adjudicated HHS medical malpractice cases must be reported to the National Practitioner Data Bank (NPDB).

Finding(s): We found that as of October 2004, HHS agencies had failed to report as many as 474 medical malpractice cases to the NPDB. Individual agency underreporting was as follows: Indian Health Service (IHS), 290 cases; HRSA, 179 cases; and NIH, 5 cases.

This underreporting was caused by a number of factors, including: (1) lost medical malpractice files; (2) incomplete information in medical malpractice files; (3) a decision by the HHS peer review entity, the Medical Claims Review Panel, not to identify practitioners who met the standard of care (a decision that was inconsistent with existing policy); and (4) the failure to replace a key Program Support Center claims official or to reassign the person's reporting duties.

Recommendation(s): IHS, HRSA, and NIH should each take steps to (1) implement corrective action to address unreported cases, (2) improve internal controls involving file management, and (3) assign staff to assume responsibility for addressing practitioner questions/complaints and data entry of reports to the NPDB.

Status: There was partial concurrence with our recommendations. Before OIG issued its October 2005 report, IHS initiated reporting of cases in which the standard of care was not met. HRSA started reporting such cases soon thereafter. At the time of our report, HRSA's Administrator indicated that HHS was working to develop a policy on the reporting of cases in which the standard of care was not met.

As of April 2008, IHS had submitted 205 additional reports of practitioners to the NPDB; HRSA had submitted 297 reports. As of April 2008, NIH had not submitted any reports. In March 2009, HRSA informed OIG that it had submitted 17 medical malpractice payment reports between January 1 through December 31, 2008. For the same period, IHS reported to OIG that it had submitted 33 malpractice payment reports, and assigned a specific risk-management team to address complaints and questions to perform data entry of NPDB reports. IHS also informed us that it has a risk management and medical liability manual and had established file management controls. We will continue to monitor (1) implementation of new processes to address unreported cases and (2) improvements in internal controls.

Report(s): OEI-12-04-00310; issued 11/05

Improve Hospital Reporting to the National Practitioner Data Bank

Background: Section 423 of the Health Care Quality Improvement Act of 1986 (HCQIA) (42 U.S.C. § 11133) requires that each hospital or health care entity taking a professional review action that adversely affects the clinical privileges of a physician or dentist for a period of longer than 30 days report to the NPDB.

Finding(s): We found that between 1990 and 1993, hospitals may not have been complying with the reporting requirements of the HCQIA and that approximately half of hospitals had never reported an adverse action to the NPDB.

Recommendation(s): HRSA should more fully encourage hospitals to follow the intent of section 423 of the Health Care Quality Improvement Act by proposing legislation that would establish a civil monetary penalty of up to $10,000 for each instance of a hospital's failure to report to the NPDB.

Status: HRSA concurred with our recommendations and indicated that its legislative proposal would cover reporting by all health care entities (including managed care organizations). In March 2009, HRSA informed us that it is pursing the development of a legislative proposal to provide for a civil monetary penalty of up to $11,000 for each instance of a hospital's failure to report to the NPDB. We will continue to monitor HRSA's implementation of such a proposal.

Report(s): OEI-12-99-00250; issued 07/99

Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

Background: The Ryan White Comprehensive AIDS Resources Emergency Act (P.L. No. 101-381) was passed in 1990 and reauthorized in 1996 and 2000. In FY 2001, Congress provided $597.3 million under Title I and $977.4 million under Title II. Congress enacted the Ryan White HIV/AIDS Treatment Modernization Act in 2006. Title I provides emergency relief grants to cities disproportionately affected by HIV/AIDS. Title II provides grants to States to improve the organization of HIV/AIDS-related health and support services. States distribute Title II (P.L. No. 109-415) funds to subgrantees.

Finding(s): We found that in 2000, Title I and Title II project officers had not adequately monitored sampled grantees (e.g., progress reports were missing, monitoring visits were not conducted, grantee applications were not used as management tools). HRSA provided limited support to project officers to systematically monitor grantees (e.g., little guidance/training, lack of corrective action plans, high staff turnover, minimal coordination). Grantees' monitoring of subgrantees was limited (75 percent of the sampled grantees did not have comprehensive documentation to demonstrate that they were monitoring subgrantees).

Recommendation(s): HRSA should (1) specify and enforce standards and policies regarding how project officers should monitor grantees, (2) address ongoing training of project officers, (3) standardize a corrective action process, (4) increase the number of site visits, (5) improve project officer continuity and coordination, (6) set standards for grantees' monitoring of subgrantees, (7) require grantees to report how they monitor subgrantees, and (8) increase efforts to monitor grantees' oversight of subgrantees.

Status: HRSA concurred with our recommendations and indicated that significant administrative changes had occurred since the studies had been conducted. In May 2008, HRSA informed OIG that it had taken a variety of steps to implement our recommendations. These steps include enhancing training for project officers, developing a site visit protocol for onsite monitoring, and increasing the number of grantee site visits. Additionally, HRSA reported that in March 2009 it had consolidated its grants operations and project officers, monitoring of Part A and Part B (formerly Title I and II) grantees and through its Office of Performance Review was receiving additional information with regard to grantee performance. OIG is in the process of conducting a review of HRSA's oversight of grantee compliance with the core medical service requirement in the Ryan White HIV/AIDS Treatment Modernization Act of 2006. We continue to monitor HRSA's progress toward implementing our recommendations.

Report(s): **OEI-02-01-00640; issued 03/04**
OEI-02-01-00641; issued 03/04

Strengthen Food and Drug Administration Oversight of Clinical Investigators

Background: To ensure the quality and integrity of data submitted to FDA and to protect the rights and welfare of human subjects, FDA's bioresearch-monitoring program inspects clinical investigators involved in the development and testing of new drugs, medical devices, and biologicals. In most cases, these inspections occur after clinical work is complete. FDA staff from the Office of Regulatory Affairs conduct onsite inspections as part of the FDA's review of applications for experimental products.

Finding(s): We found that between 1995 and 1998, in general, oversight of clinical investigators by sponsors, institutional review boards (IRB), and FDA was limited and problematic. We found that data integrity concerns, rather than human subject protections, drove FDA's oversight of clinical investigators and that the bioresearch-monitoring program lacked clear and specific guidelines.

Recommendation(s): FDA should define cross-center goals for the bioresearch-monitoring program and develop criteria to determine whether the program is achieving these goals. In addition, FDA should develop internal guidance on the thresholds that violations must meet to justify disqualifying a clinical investigator from receiving investigational products.

Status: In its comments on our draft report, FDA did not indicate whether it concurred or did not concur with our recommendations. After we issued our report, FDA indicated that it had completed a number of activities to strengthen IRB oversight and acknowledged that efforts were ongoing. In July 2004, FDA issued a proposed rule to require IRBs to register at sites maintained by HHS (69 FR 40556.) In 2003 and 2004, the Office for Human Research Protections, partnering with FDA and other Federal agencies and departments, sponsored national and regional training conferences for IRBs, clinical investigators, clinical staff, and institutional officials on good clinical practice and human subject protection issues. In June 2006, FDA established the Human Subject Protection/Bioresearch Monitoring Modernization Initiative to strengthen its oversight and protection of human subjects in clinical trials and the integrity of the resulting data. In April 2008, FDA informed us that it had established several working groups to examine the process for disqualification and identify best practices for enhanced communications between the centers that conduct the studies and field investigations in FDA's Office of Regulatory Affairs. FDA also indicated that it had developed draft guidance for sponsors, clinical investigators, and IRBs to provide advice on a range of topics such as information sharing, data retention, and informed consent. While recognizing these efforts, we continue to recommend that FDA publish guidance for justifying disqualifying clinical investigators.

Report(s): OEI-05-99-00350; issued 06/00

Update and Maintain an Accurate New Drug Code Directory

Background: Section 3 of the Drug Listing Act of 1972 (P.L. No. 92-387) amended the Food, Drug, and Cosmetic Act to require drug firms engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to FDA. Drug products are uniquely identified and reported using a three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA assigns the first segment, and drug firms assign the other two segments. FDA enters the full NDC number and information submitted as part of the listing process into a database known as the Drug Registration and Listing System. FDA extracts information from this database several times a year and publishes that information in the "NDC directory" (the directory). When drug firms introduce a new drug product or discontinue a product, they must report the complete NDC and associated information to FDA as part of the drug-product listing process.

Finding(s): We found that the directory was neither complete nor accurate. An estimated 9,187 prescription drug products were missing from the list, while another 5,150 had not cleared the listing process. Further, an estimated 34,257 drug products listed were no longer on the market or were listed in error. Problems with the directory resulted primarily from drug firms' failure to report when drugs are placed on or taken off the market and their failure to provide sufficient and accurate information to complete the listing process.

Recommendation(s): FDA should finalize the draft listing instructions referenced on its Web site, provide greater control over the assignment of NDCs, continue efforts to implement electronic submission of listing forms by firms, implement a mechanism to routinely identify drug product omissions and inaccuracies, resolve the status of currently pending drug product listings, enhance communication with drug firms to facilitate accurate and complete reporting of drug products, and identify and take appropriate action against drug firms that consistently fail to list drug products and update information.

Status: FDA concurred with our recommendations and requested access to our data files to follow up on identified problems. In comments on our draft report, FDA delineated a number of initiatives to improve the directory's completeness and accuracy, such as conversion to an electronic listing system for use by drug firms. Subsequent to our report, FDA indicated that it had updated the draft listing instructions on its Web site. It published a proposed rule, 71 FR 51276, on August 29, 2006, with the intent to clarify listing requirements, enhance control of the drug establishment registration and drug-listing process, and improve data accuracy and completeness. FDA also stated that in December 2006 it held a public hearing on the proposed rule that would change the NDC system. On July 11, 2008, FDA issued "Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing: Availability." In addition to comments on the draft guidance, FDA requested comments on adequacy and usefulness of the technical documents that are available on FDA's web site. With publication of the guidance, FDA is launching a voluntary pilot program that will enable industry to begin submitting drug establishment registration and drug listing information in electronic format. Based on comments received on the draft guidance and information obtained during the voluntary pilot program, FDA intends to issue final guidance before June 1, 2009.

Report(s): OEI-06-05-00060; issued 08/06

Improve Food and Drug Administration's Postmarketing Oversight of Drugs

Background: FDA requires all new drugs to undergo clinical testing to demonstrate their safety and efficacy before approval for sale in the United States. FDA has the authority to require postmarketing study commitments in certain situations (e.g., accelerated approval), but most postmarketing study commitments are requested by FDA and agreed to by drug applicants. The Food and Drug Administration Modernization Act of 1997 provided FDA with new authorities for monitoring certain types of postmarketing studies. Regulations at 21 CFR § 313.81(b)(2)(vii) require that drug applicants submit annual status reports (ASR) with information on the status of certain postmarketing studies. Reviewers within FDA's Center for Drug Evaluation and Research are charged with validating the accuracy of these reports.

Finding(s): We found that, between FY 1990 and FY 2004, 48 percent of new drug applications had at least one postmarketing study commitment. We identified vulnerabilities that raised concerns that FDA was not able to readily determine whether or how promptly postmarketing study commitments were progressing toward completion. We found that about one-third of ASRs were missing or incomplete and that they contained information that was of limited utility. We also found limitations associated with the management information system for monitoring postmarketing study commitments. Further, we found that monitoring postmarketing study commitments was not a top FDA priority.

Recommendation(s): FDA should instruct drug applicants to provide additional, meaningful information in their ASRs; improve the management information system for monitoring postmarketing study commitments; ensure that postmarketing study commitments are being monitored; and ensure that ASRs are being reviewed.

Status: In its comments on our draft report, FDA partially concurred with our recommendations. It disagreed with our finding that it could not readily identify whether and how timely postmarketing study commitments are progressing toward completion. It concurred with our recommendations to improve the management information system for monitoring postmarketing study commitments and to ensure that postmarketing study commitments were being monitored and that the ASRs were validated. Subsequent to our report, FDA informed us that it had begun to enhance its postmarketing study commitment database and reporting capabilities; to train its review division staff on ASR validation procedures; to standardize the process by which postmarketing study commitments are requested and reviewed; and to hire contractors to conduct a thorough analysis of the postmarking commitment process to gain greater internal consistency regarding how FDA requires, requests, facilitates, and reviews postmarketing study commitments. FDA also informed us that in February 2006, it issued industry guidance to describe in greater detail the content, form, and timing of postmarketing reports; in July 2006, it enhanced its database to include new functionalities and improvements. The FDA Amendment Act of 2007, section 921, added a requirement for FDA to review the entire backlog of postmarketing safety commitments on an annual basis to determine which commitments require revision or should be eliminated and to report to Congress on these determinations. In April 2008, FDA informed us that it had prepared a report to Congress on postmarketing safety commitments, which was in the clearance process. Although we acknowledge FDA's efforts, we continue to recommend that FDA improve

its management information system for monitoring postmarking study commitments and ensure that ASRs are being validated.

Report(s): OEI-01-04-00390; issued 06/06

Children, Families, and Aging

Administration on Aging

Ensure That States' Cost-Sharing Practices Comply With Older Americans Act Requirements and Improve Quality of Data

Background: In 2000, amendments to the OAA allowed States to implement cost sharing for certain OAA services. The AoA defines "cost sharing" as a method of requiring a recipient to share in the cost of the service received. The amendments include a number of requirements that are intended to protect low-income older individuals' access to services.

Finding(s): We found that as of March 2005, States' implementation of cost sharing had been limited. Twelve States had implemented cost sharing for at least one OAA service in at least one part of the State. None of these States had implemented cost sharing for all allowed OAA services. AoA had provided limited guidance to States about implementing cost sharing. States had not implemented cost sharing in accordance with the OAA requirements designed to protect low-income older individuals' access to services. Also, AoA's participation data could not be used to determine the impact of cost sharing on participation, primarily because States reported participation data in the National Aging Program Information System/State Program Reports (NAPIS/SPR) differently.

Recommendation(s): AoA should ensure that States' cost-sharing practices comply with OAA requirements, provide additional guidance to States about cost sharing, and improve the quality of its data so that any effects of cost sharing can be determined.

Status: In its comments on our draft report, AoA partially concurred with our recommendations. AoA indicated that it had taken several actions, including holding senior agency staff meetings with regional administrators to review OAA cost-sharing requirements and establishing technical assistance and guidance for State Units on Aging. AoA did not concur with the recommendation to improve the quality of the NAPIS/SPR data, noting that it had made several improvements to these data, such as developing a software reporting structure and training manual. Despite these improvements, our work indicated that States varied in their reporting of data. Given that these data are essential for cost-sharing and AoA performance measurements, we continue to recommend that AoA improve the quality of participation data.

Report(s): OEI-02-04-00290; issued 09/06

Children, Youth, and Family Services

Improve Methods of Recruiting Foster Parents

Background: ACF has regulatory oversight of the Title IV-E foster care program, an entitlement program designed to help States cover the costs for children in foster care by providing States with unlimited matching funds for children who meet income eligibility and other program requirements.

Finding(s): We found that as of 1999, recruitment methods were general and did not focus on finding foster parents for children with special needs. Moreover, more could be done to effectively use participating foster parents for this purpose, as they themselves may be the most effective recruitment tool. Both recruitment and retention efforts were hampered by a negative public image of foster care. We also found that foster parents wanted more caseworker support and help in obtaining necessary services (e.g., medical and dental services for children in their care). States were unable to measure the success of their recruitment and retention methods.

Recommendation(s): ACF and State foster care program managers should collaborate with national organizations to promote more positive media coverage of foster care. ACF should enhance information sharing and assessment of recruitment efforts. ACF should provide States with guidance focused on enhancing the effectiveness of States' recruitment efforts. In addition, to the extent that resources are available, ACF should provide technical support to help States improve retention through the (1) development of outcome-based retention strategies to determine why families choose not to continue fostering, (2) development of data-tracking tools to collect retention information, (3) establishment of benchmarks and performance indicators, and (4) collection of retention data.

Status: Although ACF concurred with our findings and recommendations, it did not initially indicate how it planned to address them. ACF noted that States may use some Federal funds for child care and respite care services. In March 2008, ACF reiterated to us its commitment to provide technical assistance to States and Tribes to facilitate foster parent recruitment and provide information regarding collaboration at the national level. ACF also informed us that it had addressed OIG's recommendation to collaborate with national organizations to promote more positive media coverage of foster care and had partnered with organizations to bring attention to National Foster Care Month. We continue to recommend that ACF implement the remaining recommendations, including providing States with guidance focused on effective recruitment efforts and providing technical assistance to States to improve the retention of foster parents.

Report(s): OEI-07-00-00600; issued 05/02

Acronyms

ACF	Administration for Children and Families
AMP	Average Manufacturer Price
AoA	Administration on Aging
ASC	Ambulatory Surgical Center
ASP	Average Sales Price
AWP	Average Wholesale Price
BBA	Balanced Budget Act
BBRA	Balanced Budget Refinement Act
CC	Commissioned Corps
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CY	Calendar Year
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DRA	Deficit Reduction Act of 2005
DRG	Diagnosis-Related Group
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
FUL	Federal Upper Limits
FY	Fiscal Year
GAO	Government Accountability Office
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
LTC	Long Term Care
MA	Medicare Advantage
MCO	Managed Care Organization
MIPPA	Medicare Improvement for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NIH	National Institutes of Health
NPDB	National Practitioner Data Bank
OAA	Older Americans Act
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of Inspector General
P.L.	Public Law
PPS	Prospective Payment System
SCHIP	State Children's Health Insurance Program
SNF	Skilled Nursing Facility
SSA	Social Security Act
TBD	To Be Determined
UPL	Upper Payment Limit

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