Department of Health and Human Services

Compendium of Unimplemented Office of Inspector General Recommendations

OIG Office of Inspector General

May 2008

Office of Inspector General Components

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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A Message From the Office of 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 purpose of the Compendium is to combine significant[1] unimplemented monetary and nonmonetary recommendations addressed to the Department into one publication[2] for interested parties to obtain information about outstanding recommendations, which, if implemented, have the potential to result in cost savings and improvements to program efficiency and effectiveness. OIG recommendations stem from audits and evaluations that have been performed pursuant to the Inspector General Act of 1978 (P.L. No. 95-452), as amended. Recommendations may require one of three types of actions: legislative, regulatory, or administrative. Some complex issues may involve two or three types of actions.

As part of its effort to track unimplemented recommendations, OIG performs routine followup with the Department to determine the status of actions that have been taken to implement the recommendations. This publication includes information about recommendations that had not been implemented as of December 31, 2007.

Organization

The Compendium is divided into a monetary recommendations section and a nonmonetary recommendations section. 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 type, as follows:

- **Centers for Medicare & Medicaid Services (CMS)** – This section describes unimplemented recommendations focusing on programs administered by CMS, including Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). These programs, which account for most of the majority of HHS's budget, provide medical care coverage for senior citizens, people who have disabilities or who are economically disadvantaged, and children whose families have limited income.
- **Public Health and Human Service Programs and Departmental Issues** –This section describes unimplemented recommendations addressing programs administered by:

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 "Red Book" and "Orange Book," respectively.

- 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), Indian Health Service (IHS), and the National Institutes of Health (NIH). These divisions promote biomedical research and disease cure and prevention; ensure the safety and efficacy of marketed food, drugs, and medical devices; and conduct other activities designed 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.

- Also included in this section are departmentwide 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 file a report with the OIG Hotline at 1-800-HHS-TIPS (1-800-447-8477) or HHSTips@oig.hhs.gov.

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 comprises three categories—savings, integrity and efficiency, and quality of care—that reflect OIG's mission to ensure the appropriate expenditure of Federal dollars; protect the integrity of HHS's programs against waste, fraud, and abuse; improve program efficiency; and protect the health and safety of program beneficiaries.

Savings

- Ensure Durable Medical Equipment Suppliers' Compliance With Medicare Standards, savings to be determined (TBD) (p. 2)
- Modify Payment Policy for Medicare Hospital Bad Debts, estimated savings $340 million (p. 8)
- Reduce the Rental Period for Medicare Home Oxygen Equipment, savings $5 billion (p. 12)
- Modify Payments to Managed Care Organizations, estimated savings $1.97 billion (p. 21)
- Place a Ceiling on Administration Costs Included in Managed Care Organizations' Rate Proposals, savings TBD (p. 22)
- 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. 23)
- Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments, savings TBD (p. 25)
- 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. 26) and $470 million for generic drugs (p. 27)
- Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement, savings TBD (p. 28)

Integrity and Efficiency

- Improve Centers for Medicare & Medicaid Services Performance Evaluation Process for Program Safeguard Contractors (p. 56)
- Update and Maintain an Accurate New Drug Code Directory (p. 64)
- Improve Food and Drug Administration Postmarketing Oversight of Drugs (p. 65)

Quality of Care

- Improve Oversight of Medicare Hospices (p. 37)
- Strengthen Food and Drug Administration Oversight of Clinical Investigators (p. 63)

Table of Contents

New Monetary Recommendations

Medicare and Medicaid

Medicare Hospitals

Adjust Medicare Outpatient Outlier Payments

Background: Under the Medicare prospective payment system (PPS), the Centers for Medicare & Medicaid Services (CMS) reimburses outpatient providers, including hospital outpatient departments and community mental health centers, based on predetermined, fixed payment amounts. Section 1833(t)(5) of the Social Security Act (SSA) requires that CMS make additional payments, called outlier payments, if the cost of care is extraordinarily high in relation to the average cost of treating comparable conditions or illnesses, established by CMS. In a series of reviews, we identified significant outpatient outlier overpayments to community mental health centers that resulted from clerical or mathematical errors. In response to our recommendations to recoup these overpayments, the fiscal intermediaries stated that CMS had not authorized them to do so because CMS considered outpatient outlier payments to be final payments not subject to retroactive adjustments. However, neither the SSA nor Medicare regulations specifically state that outlier payments are final payments. Further, a provision of the "Medicare Financial Management Manual" states that providers are liable for overpayments that result from clerical or mathematical errors. Prior to 2003, CMS's longstanding practice, under both inpatient PPS and the outpatient PPS, was to consider all outlier payments as final payments not subject to retroactive adjustment. In 2003, CMS modified its policy under the inpatient PPS to require retroactive adjustments of outlier payments in certain circumstances. However, CMS has not similarly modified its practice to allow retroactive adjustment of outlier payments under the outpatient PPS.

Finding(s): CMS's practice of not retroactively adjusting outpatient outlier payments creates significant vulnerabilities and is inconsistent with CMS's policy of retroactively adjusting inpatient PPS outlier payments. This practice results in losses to the Medicare Trust Fund, creates payment inequities, and may penalize providers that comply with Medicare requirements. Although our work was specific to community mental health centers, similar vulnerabilities may exist in the outpatient outlier programs for other types of providers.

Recommendation(s): CMS should issue regulations to require retroactive adjustments of outpatient outlier payments within appropriate thresholds.

Savings: TBD*

**To be determined*

Status: CMS did not express concurrence or nonconcurrence with our recommendation in its comments on the draft of our report but did agree to explore the feasibility and cost-effectiveness of implementing our recommendation. In April 2008, CMS informed us that it is continuing to study the possibility of not considering outpatient PPS outlier payments as final payments and the possibility of reopening the cost reports to determine whether there are provider or contractor errors.

Report(s): OAS-07-06-04059; issued 06/07

Medicare Durable Medical Equipment

Ensure Durable Medical Equipment Suppliers' Compliance With Medicare Standards

Background: CMS reported that payments for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) reached $10 billion in fiscal year (FY) 2005. DMEPOS are covered under Medicare Part B and include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs. DMEPOS suppliers must enroll in the Medicare program to sell or rent medical equipment and supplies to Medicare beneficiaries and to submit claims for Medicare reimbursement. At the time of our review, DMEPOS suppliers had to comply with 21 Medicare DMEPOS supplier standards to enroll in the Medicare program. We conducted unannounced site visits to DMEPOS suppliers in three South Florida counties in 2006.

Finding(s): A total of 491 of 1,581 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 located 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.

Six percent of the suppliers we visited (98 of 1,581) did not maintain physical facilities. An additional 25 percent of suppliers (393 of 1,581) were not accessible during reasonable business hours. Of these suppliers, 385 were closed during unannounced site visits on a minimum of 2 weekdays during reasonable or posted business hours. Fourteen percent of suppliers (216 of 1,581) were open and staffed but failed to meet at least one of the three remaining requirements we reviewed. Of the 216 suppliers, 204 did not post hours of operation and 10 did not have listed telephone numbers. Eight suppliers were open but not staffed during a minimum of two unannounced site visits.

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.

Savings: TBD

Status: In its comments on our draft, CMS agreed with, or stated that it would consider, the options we recommended for strengthening the Medicare DMEPOS supplier enrollment process. CMS has taken action to implement these suggested options, including revising the National Supplier Clearinghouse contractual requirements to enhance the number of unscheduled site visits, adding DMEPOS supplier standards, 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 all DMEPOS suppliers located in Miami-Dade, Broward, and Palm Beach Counties in Florida and Los Angeles, Orange, Riverside, and San Bernardino Counties in California. CMS informed us in December 2007 that it had initiated the process of conducting background checks on selected suppliers with high fraud potential. CMS has also begun its competitive bidding program within 10 of the largest metropolitan statistical areas with plans to expand to an additional 70 communities in 2009 and more thereafter. CMS published regulation CMS-6036-P on January 25, 2008, to clarify and expand upon additional standards for

suppliers including changes to minimum inventory and business hours and the deactivation of DMEPOS suppliers that have been inactive for significant periods of time. We will continue to monitor the implementation and results of CMS background demonstrations and its competitive bidding program.

Report(s): OEI-03-07-00150; issued 03/07

Previous Monetary Recommendations

Medicare and Medicaid

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 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 during FY 2008.

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 more accurately reflect 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, which was 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 phrasing out the teaching adjustment.

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

Medicare Hospitals

Revise Graduate Medical Education Payment Methodology

Background: Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 and section 9314 of the 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 within 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 the draft of our report that it believed that little 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

Medicare Hospitals

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, reimbursing PPS hospitals for bad debts only if the hospitals lost money on their Medicare operations, and including a bad debt factor in the DRG rates. CMS should seek legislative authority to further modify bad debt policies.

Savings: $340 million*

**Savings shown in the President's FY 2001 budget, proposing to eliminate bad debt payments to hospitals. Savings of $7.15 billion for FYs 2008-2012 was 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. Subsequently, 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 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

Medicare Hospitals

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 patients during the 3 days prior to the date of the patients' admission are not permitted under the OBRA of 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 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 prior to admissions during calendar year (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 prior to 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 prior 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 the draft of our 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

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 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 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 based on 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 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. The agency stated that it would consider incorporating interventions in the Ninth Statement of Work (SOW) for the QIO program. CMSindicated 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 request QIOs to categorize complaints by type to provide better data on lapses in continuity of care and to emphasize documentation. In April 2008, CMS informed us that the QIO 9th SOW, to begin August 1, 2008, will specifically address the issues of continuity-of care by developing the care transitions theme. We continue to monitor CMS's efforts to implement these actions.

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

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 continued to be 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. 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: $5 billion

Status: CMS concurred with our recommendations. With regard to the first recommendation, as of February 2008, Congress had a bill pending to reduce the monthly rental limit for oxygen from 36 to 13 months. Concerning the second and third recommendations, CMS posted a final rule on November 2, 2006, to address payments for nonroutine maintenance and servicing, as well as for portable oxygen after patients reach the 36-month cap on rental payments. The President's 2009 Budget proposal includes a provision further reducing the rental period for most oxygen equipment from 36 months to 13 months. We will continue to monitor this area as the new rental period is implemented.

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

End Stage Renal Disease

Reduce Medicare End Stage Renal Disease Payment Rates

Background: The OBRA of 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 $46 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 it 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. The OBRA of 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 payment amounts beginning in 1998, but the Benefits Improvement and Protection Act of 2000 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**	**$1.25 billion***
	Fee Schedule Adjustment	**TBD**

**The savings estimate is based on the 20-percent copay applied to FY 2005 Medicare payments for clinical laboratory services totaling $6.28 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. However, it did not concur with the 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. 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) 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. The MMA also set the laboratory fee schedule updates at 0 percent for 2004 through 2008. On October 17, 2007, CMS issued a notice (CMS-5045-N) to announce the first demonstration for the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. In April 2008, CMS informed us that the first site of the Competitive Bidding Demonstration Project was the San Diego-Carlsbad-San Marcos, California, metropolitan area. CMS indicated that it was currently evaluating the bids received and would announce the winning laboratories later, but noted that two laboratories in San Diego had filed a lawsuit to stop the Demonstration.

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. Although legislation over the years has reduced the prices for individual tests, we continue to recommend that CMS evaluate payments for laboratory services.

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

Medicare Reimbursement

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.

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 systematic controls on the home health benefit are warranted to prevent abuse.

Recommendation(s): Although Medicare regulations require physician certification for home health services, they do not explicitly require a physician to personally examine a beneficiary prior to making the certification. CMS should revise Medicare regulations to require that physicians examine patients before ordering home health care. As discussed below, other recommendations to correct abusive and wasteful practices are being addressed.

Savings: TBD

Status: In its comments on the draft of our July 1997 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 recertifications 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 was providing additional payments for physician plan care oversight and additional education for physicians and beneficiaries as incentives to encourage more physician involvement. 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**

Medicare Reimbursement

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 indicated that claim error rates for mental health services have exceeded 34 percent, suggesting widespread problems across a variety of provider types and care settings. Our 2007 study projected that 47 percent of the mental health services allowed by Medicare in 2003 did not meet program requirements. 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 that both underutilization and overutilization problems exist.

"Partial hospitalization" services, which may be provided by both hospitals and community mental health centers, have been particularly troublesome. These intensive services are designed to reduce the need for hospitalization of beneficiaries with serious mental illness. We have estimated that 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, miscoded and undocumented services accounted for 26 and 19 percent of all mental health services in 2003, respectively. Medically unnecessary services and services that violated the "incident to" rule each accounted for 4 percent of all mental health services 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" a 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 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, and $185 million in improper payments for other mental health services in 1998 and $718 million in improper payments in 2003.*

Status: In its comments on the draft of our October 1998 report, CMS concurred with the recommendations, 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 more accurate payment policy. CMS also concurred with our recommendations to our 2007 report 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). We continue to recommend that CMS reissue the 2003 Program Memorandum with the additional guidance cited in our recommendations.

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**

Other Medicare Reimbursement

Reduce Improper Medicare Payments for Allergen Immunotherapy

Background: In 2001, Medicare allowed approximately $130 million for allergen immunotherapy and related services. By 2003, this amount had grown to $171 million. Allergen immunotherapy, commonly known as allergy shots, is intended to reduce patients' reactions to particular allergens. Title XVIII of the SSA limits Medicare coverage to services that are medically necessary (section 1862(a)(1)(A)) and are supported by documentation (section 1833e).

Finding(s): Sixty-two percent of the allergen immunotherapy and related services allowed by Medicare in 2001 did not meet program requirements, resulting in $75 million in improper payments. In addition, in the absence of national guidance, carriers have implemented policies that are inconsistent with the standards of the Joint Task Force on Practice Parameters, which represents 95 percent of all allergists and immunologists. Care provided to approximately 70 percent of Medicare beneficiaries who received allergen immunotherapy in 2001 was inconsistent with professionally recognized standards of care.

Recommendation(s): CMS should require carriers to educate physicians who provide allergen immunotherapy to Medicare beneficiaries about coverage, coding, and documentation requirements and develop national coverage criteria for allergen immunotherapy based on professionally recognized standards of health care.

Savings: $75 million*

**$75 million was improperly paid in 2001 based on a national projection of a sample of allergy services randomly selected from the Medicare 2001 National Claims History Data File.*

Status: In its comments on our report, CMS did not indicate whether it concurred or did not concur with our recommendations. In its comments, CMS stated that it was prepared to develop and disseminate educational materials and develop new coverage criteria for allergen immunotherapy services. The agency also commented that it had identified two options for developing national coverage criteria for allergen immunotherapy. In April 2008, CMS informed us that its Office of Clinical Standards and Quality was in the process of drafting language and recommendations that can be incorporated into the "Medicare Learning Network Matters" article. These articles are designed to inform physicians, providers, and suppliers about the latest changes to the Medicare Program.

Report(s): OEI-09-00-00531; issued 02/06

Other Medicare Reimbursement

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 carrier's 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. 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). However, CMS has not yet implemented an edit 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 Act also modified the payment methodology under the program to correct excess payments, reduce geographic variations in payments, and align payments to reflect beneficiaries' health status. The MMA of 2003 redesignated the M+C program as Medicare Advantage (MA) and increased payments.

Finding(s): Based on our previous reviews, studies by other agencies, and MA organization data, we concluded that 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 as 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 they 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 had the MA organizations been required to follow Medicare's general principle of paying only reasonable costs.

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 the draft of our January 2000 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 of 2003.

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

Medicaid Reimbursement

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 in 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 rise to $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, 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.

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**

Medicaid Reimbursement

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 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 assist the local education agencies in developing written policies and procedures that require service providers to document all health services and to retain those records for review.

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. However, under section 206 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, signed on December 29, 2007, there will be a 6-month delay in implementing these changes to ensure that 2007-2008 school-year budgets are not affected.

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**

Medicaid Reimbursement

Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments

Background: Section 1923 of the SSA, as amended by the OBRA of 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.

Finding(s): Nine of the ten States reviewed did not comply with the hospital-specific DSH limits imposed by section 1923(g) of the Act. As a result, payments exceeded the hospital-specific limits by about $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 about $223 million in excess payments because they included unallowable costs in their calculations of hospital-specific limits. In addition, three States required hospitals to return DSH payments totaling approximately $3.6 billion through intergovernmental transfers.

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 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 of 2003. CMS has informed us that it is reviewing comments on the proposed regulation and working on issuing the final regulation. The agency 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 Reimbursement

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 discount 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 more closely align pharmacy reimbursement with the actual acquisition cost of brand-name drugs paid by 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 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 the draft of our 2001 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 FYs 2007 or 2008 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

Medicaid Reimbursement

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

Background: Most States use the AWP minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for prescription drugs. For certain multiple source drugs, CMS sets FULs, which cap Medicaid reimbursement amounts for those drugs. We estimated the actual acquisition costs for 200 generic drugs with the highest Medicaid reimbursement for CY 1999.

Finding(s): State pharmacy reimbursement formulas discount 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. Using CY 1999 data, we estimated that the actual acquisition cost for generic drugs averaged 65.93 percent below the AWP. We estimated that changing the reimbursement policy to a tiered approach consistent with our recommendations could have saved the Medicaid program as much as $470 million for the 200 generic drugs with the highest Medicaid reimbursement for CY 1999.

Recommendation(s): CMS should encourage the States to more closely align pharmacy reimbursement with the actual acquisition costs of generic drugs paid by 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 drugs with FULs.

Savings: $470 million*

**Estimated savings are based on the 200 generic drugs with the highest Medicaid reimbursement for CY 1999.*

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. In April 2008, CMS informed us that it would follow up to ensure that States take OIG's findings into account. The Deficit Reduction Act of 2005 (DRA) changed the FUL calculation for generic drugs. For generic drugs with FULs, the Federal Government capped generic Medicaid drug payment at 250 percent of the lowest average manufacturer price (AMP) for a generic version of a drug. CMS promulgated a final rule pursuant to this change in July 2007 (72 Fed. Reg. 39142). As a result of litigation challenging the validity of this rule, a Federal court has issued an injunction in December 2007 against its implementation to the extent that the rule affects reimbursement rates. We plan to continue to monitor the pricing of Medicaid drug reimbursements for generic drugs.

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

Medicaid Drug Rebates

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

Background: The OBRA of 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. We calculated the rebates for the 100 brand-name drugs that had the highest Medicaid reimbursement for 1994 through 1996 using the AWP instead of the AMP.

Finding(s): Requiring manufacturers to pay Medicaid drug rebates using the same basis as reimbursements made 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 of 2005, 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. As a result of litigation challenging the validity of the new rule, however, a Federal court has issued an injunction in December 2007, prohibiting CMS from disseminating AMP data. 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

Medicaid Drug Rebates

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

Background: The OBRA of 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 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 Consumer Price Index for all urban consumers. To determine the potential effect that increases in best price (beyond the rate of inflation) had 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 Consumer Price Index-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 this 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. 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

Other Medicare and Medicaid Issues

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 existed 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 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. Subsequently, CMS decided not to do so, citing the uncertain but minimal savings potential and the administration's commitment to enhancing States' flexibility and, specifically, to avoiding the imposition of an unfunded mandate.

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

Public Health

Health Resources and Services

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 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 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.

Recommendation(s): HRSA should improve its oversight of the 340B 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 Discount program: (1) establish detailed standards for the calculation of 340B ceiling prices, (2) institute oversight mechanisms 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) obtain consistent unit of measure and package size data to accurately calculate 340B ceiling prices.

Savings: $46.8 million to federally supported covered entities*

**Estimated savings based on $3.9 million in overpayments by federally supported covered 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 more closely monitor 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. The agency 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 agency's ceiling prices. HRSA would then review the data that manufacturers and entities voluntarily submitted, to the extent that resources permitted. The agency also told us that it was assessing the need for

seeking 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, as well as 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.

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

Aging

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 the Older Americans Act.

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 the draft of our 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, it was in the process of 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

Departmentwide and Cross-Cutting Issues

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 and 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 assist State Medicaid agencies in coordinating 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 assist States in interfacing their Title IV-D and SCHIP databases and implementing 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 law and regulations prohibit States from accumulating additional medical support payments. As to our recommendations concerning SCHIP costs, CMS did not concur that issuing formal guidance 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 that it had provided guidance to States on the collection of Medicaid costs from available noncustodial employer-sponsored health care coverage and on their authority under Federal law to collect SCHIP costs from noncustodial parents during a series of Medical Support Collaboration meetings in 2005 sponsored by Administration for Children and Families (ACF). 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 administrative 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 also plan to perform follow-up work in FY 2009 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 Recommendation

Medicare and Medicaid

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, CMS policy requires hospice recertification every 6 years.

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 provided 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 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. 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 the frequency of hospice performance and enforcement remedies for poor hospice performance.

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

Other Medicare and Medicaid Issues

Increase Medicaid Fraud Referrals

Background: The passage of the DRA of 2005 focused attention on Medicaid program integrity. Within most States, two agencies share primary responsibility for protecting the integrity of the Medicaid program. The State Medicaid agency is responsible for ensuring proper payment, recovering misspent funds, identifying suspected Medicaid fraud, conducting a preliminary review to determine the extent of potential fraud, and making referrals to its Medicaid Fraud Control Unit (MFCU). Each MFCU is responsible for reviewing the referrals received from the State Medicaid agency and other sources to determine whether the issues involved merit criminal and/or civil investigation.

Finding(s): We found that 84 percent of MFCUs in this study reported receiving less than half of all suspected fraud referrals from their respective State Medicaid agencies. We also found that the percentage of MFCU-accepted referrals contributed by State Medicaid agencies remained constant during the 3-year study period at 33 percent; yet among the States, referrals from individual State Medicaid agencies to their respective MFCUs varied greatly.

Recommendation(s): CMS should establish fraud referral performance standards for State Medicaid agencies.

Status: CMS concurred with our recommendation to work toward the establishment of fraud referral performance standards. CMS has been working with OIG, State Medicaid agencies, and MFCUs in a collaborative effort to develop a common definition of referral and minimum criteria set. In November 2007, representatives of these organizations met and drafted a criteria set for consensus. Subsequently, the draft criteria were presented to stakeholders for comments which CMS received in February 2008. As of February 2008, CMS and OIG were reviewing the comments and were working toward incorporating them into the proposed referral standard definition. In April 2008, CMS informed us that it plans to finalize the fraud referral standards by September 2008.

Report(s): OEI-07-04-00181; issued 01/07

Medicaid Drugs

Review Impact of New Federal Upper Limit Calculations

Background: Pursuant to section 1927(e) of the SSA, CMS is required to establish FUL to reduce the amount that Medicaid reimburses for multiple-source drugs. Prior to 2007, Federal regulations set the FUL amount at 150 percent of the 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 lowest price published in the national compendia. 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 the FUL drugs by $3.6 billion over 5 years.

Finding(s): 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. Six of twenty-five selected high-expenditure drugs had estimated average pharmacy acquisition costs that would be below the new FUL amounts. Among the 25 selected high-expenditure drugs, examining the volume-weighted AMPs helped identify instances in which pharmacy acquisition costs may exceed the new FUL amounts. Under the new calculation method established by the DRA, FUL amounts are likely to decrease substantially. Furthermore, we found that the AMPs used to set a new FUL amounts 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 FUL drugs and calculated prices. The DRA drug provisions and this report supersede previous OIG reports (OEI-03-02-00067 and OEI-03-04-00320) issued in 2004 with regard to the FUL. On July 6, 2007, CMS published a final rule with comment period detailing how AMP-based FUL amounts would be calculated under the new guidelines established by the DRA. In December 2007, as a result of litigation challenging the validity of the new rule, a Federal court has issued an injunction prohibiting CMS from implementing it to the extent that the rule affects reimbursement rates. OIG continues to monitor the appropriateness of FULs.

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

Medicaid Drugs

Assess the Use of New Drug Pricing Data in the Medicaid Program

Background: The DRA of 2005 required CMS to provide States monthly with AMP data for prescription drugs covered by Medicaid starting in July 2006. The DRA also permits CMS to collect and disseminate retail sales price (RSP) data for Medicaid-covered drugs to States. Our recent studies have found that published prices, such as AWP and wholesale acquisition cost used by States to estimate drug acquisition costs, are higher than prices based on actual sales transactions. States are not required to use AMP or RSP data for Medicaid drug reimbursement.

Finding(s): As of July 2007, most States had not decided whether to use AMP and/or RSP data for Medicaid drug reimbursement. Thirty-nine States had not decided whether to use AMP data for Medicaid drug reimbursement. States raised concerns about the AMP data files that they received from CMS, indicating that the AMP units appeared to be inconsistent with typical unit definitions of drug products and requesting that the drug unit definition be included in the data files. Forty-three States had not decided whether to use RSP data. States reported that they wanted to know how RSP data would be determined and defined before deciding to use RSP data.

Recommendation(s): CMS should explicitly detail AMPs' definition and calculation, including the definition of retail pharmacy class of trade, when promulgating new AMP regulations. It should also provide unit definitions in AMP data files and furnish States with interim guidance and/or information regarding AMP data before the final regulations are published. Finally, CMS should explicitly detail RSPs' definition, calculation, and method of collection when distributing RSP data to States.

Status: Although it questioned the timing of our study, CMS generally concurred with our recommendations and stated that it recognized that most States had not decided whether to use AMP or RSP data for Medicaid drug reimbursement. CMS addressed the definition, calculation, and method of collection of AMP in a final rule with comment, released July 6, 2007, that includes revisions to the definition of the determination of AMP. In December 2007, a Federal court issued a preliminary injunction prohibiting CMS from sharing AMP data with the States. We will continue to monitor implementation of States' use of AMP and/or RSP data for drug reimbursement.

Report(s): OEI-03-06-00490; issued 06/07

Improve U.S. Public Health Service Commissioned Corps Response Operations for Future Public Health Emergencies

Background: Agencies within and outside of HHS employ U.S. Public Health Service Commissioned Corps (CC) officers to provide health care and related services in health professional shortage areas. In addition, the Secretary of HHS has the authority to deploy the CC in response to public health emergencies. Hence, CC officers must simultaneously fulfill their responsibilities to their employer agencies and to the Corps. In August and September 2005, respectively, Hurricanes Katrina and Rita struck the Gulf Coast. In response to health care and public health needs in the affected areas, the Corps carried out the largest deployment in its 209-year history. More than 2,100 officers worked with State, local, and private agencies in response to the hurricanes.

Finding(s): We found that the CC provided valuable support to States, but more officers—especially nurses, mental health professionals, and dentists—were needed. Although most deployed officers met the CCs readiness standards, many lacked experience, effective training, and familiarity with response plans. We also found that agencies were unwilling or unable to allow some officers to deploy, while logistical difficulties delayed others' arrival in the field. Most officers were equipped adequately, but some lacked working communications devices and other basic tools. We found that many officers personally incurred mission-related expenses and some were not reimbursed promptly, which could affect their ability to deploy in future public health emergencies.

Recommendation(s): The CC should institute more effective training for its officers, improve the system used to contact officers for deployment, work with the Office of the Assistant Secretary for Preparedness and Response (ASPR, formerly the Office of Public Health Emergency Preparedness) to streamline deployment-related travel, stagger deployments to ensure continuity of operations, improve its ability to coordinate mission assignments and communications in the field, and ensure that all deployable officers have Federal Government travel credit cards.

Status: The Assistant Secretary for Health concurred with our recommendations for improving the CC's response to public health emergencies and noted that our recommendations were being addressed as part of the CCs comprehensive transformation process. In March 2008, the CC reported to us that it had made progress in implementing the report recommendations by instituting more effective deployment-related training and improving contact and communication mechanisms for officers, staggering deployments to ensure continuity of operations, and improving its ability to coordinate mission assignments and communications in the field. We concur that the CC has implemented five of the six recommendations in our report; however, we continue to support our recommendation that the Corps ensure that all deployable officers have Federal Government travel cards and that the CC continue to work with ASPR to refine procedures for reimbursement.

Report(s): OEI-09-06-00030; issued 02/07

Strengthen Oversight and Guidance for Use of Government Purchase Cards During Emergencies

Background: The Government purchase card program was designed to save the Government money by avoiding costly paperwork and to expedite the process of making purchases. In response to Hurricane Katrina, P.L. No. 109-62 authorized agencies to streamline certain purchasing requirements for procurement of supplies or services to support rescue and relief operations. This law also raised the micropurchase threshold from $2,500 to $250,000 for procurement of supplies or services to support Hurricane Katrina rescue and relief operations.

Finding(s): Fifteen percent of purchases made in response to Hurricane Katrina did not comply with HHS guidelines and agency procedures related to three key elements. The elements of noncompliance are lack of approving official review, use of Government purchase cards by unauthorized persons, and insufficient purchase documentation. Additionally, cardholders had concerns regarding the legality and complexity of some purchases and over half of cardholders expressed the need for additional written guidance regarding emergency purchasing procedures. Lastly, the Hurricane Katrina purchase data contained inaccuracies that could represent challenges for oversight and tracking purposes.

Recommendation(s): The Assistant Secretary for Administration and Management (ASAM) should provide additional written guidance on emergency purchasing procedures. This guidance should include (1) examples of allowable and unallowable purchases in an emergency, (2) the way to ensure delivery to a location other than the cardholder's office, and (3) advice on locating and communicating with vendors during an emergency. ASAM should also require training on emergency purchasing procedures. Finally, ASAM should develop a tracking system for monitoring Government purchase card purchases during emergency situations.

Status: ASAM concurred with these recommendations and stated that action had been taken to implement them. In July 2007 correspondence, ASAM provided us with an updated Purchase Guide Version 4.0 and Quick Reference Guide; ASAM stated that it had updated its training class to reflect Version 4.0 enhancements and was exploring the feasibility of an automated, enterprisewide purchase card system that could be used in all situations, including emergencies. In March 2008, ASAM informed us that it had added a requirement to a task order to develop an automated system to capture, track, and report on emergency purchase card transactions that will be effective in November 2008. We continue to recommend that ASAM implement an automated tracking system for monitoring Government purchase card purchases during emergency situations.

Report(s): **OEI-07-06-00150; issued 05/07**
OEI-07-07-00430; issued 06/07

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. States may structure their 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 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. Lastly, 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. CMS noted that it had assisted States in strengthening fraud and abuse efforts, which included assessment of its mechanisms and revision of the SCHIP annual report template to collect information from States about their fraud and abuse safeguards. We continue to recommend that CMS implement measures to ensure that noncompliant States institute procedures for investigating and referring fraud and abuse cases.

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

Previous Nonmonetary Recommendations

Medicare and Medicaid

Medicare Hospitals

Improve Carrier Determination of Copayments for Medicare Mental Health Services

Background: The Medicare Supplementary Medical Insurance benefit program (Part B) covers physician services, outpatient care, and some other services not covered by Medicare's Hospital Insurance benefit program (Part A). In general, beneficiaries are responsible for copayments of 20 percent of the approved amount for most Part B services. Outpatient mental health services are covered under Part B. However, section 1833(c) of the SSA limits Medicare payment to 62.5 percent of the expenses (Medicare-approved amount) for services in connection with the treatment of mental disorders. The limitation applies to services that are furnished in connection with the treatment of mental, psychoneurotic, or personality disorders. Thus, for these services, beneficiaries have greater cost-sharing liability.

Finding(s): We found that in 2003, beneficiary copayments could have been more than double for the same mental health services based on the beneficiaries' geographic locations. Carriers inconsistently applied the "outpatient mental health treatment limitation" (the limitation), causing these disparities in copayments. In addition, some carriers had incorrectly applied the limitation to claims for medical management services for beneficiaries diagnosed with Alzheimer's disease and related disorders. Over a 4-year period, Medicare carriers overstated copayments for beneficiaries with Alzheimer's disease and related disorders by approximately $27 million.

Recommendation(s): CMS should (1) issue new guidance to carriers regarding the outpatient mental health treatment limitation and ensure that the limitation is consistently applied among all carriers and (2) require its carriers to adjust the copayments for beneficiaries who had been overcharged.

Status: CMS concurred with our recommendations. In response on our 2006 report, CMS informed us that it planned to issue more precise guidance that would establish policy for application of the outpatient mental health treatment limitation; create and post educational material on its Web sites; and, to the extent operationally feasible, require carriers to reopen and adjust incorrectly processed claims for patients with Alzheimer's disease and related disorders. In April 2007, CMS noted that significant information on medical documentation requirements had been added to its Web site. It also indicated plans to consolidate Web site information for providers of mental health services with the expectation that providers of mental health services would meet all applicable requirements. We continue to recommend that CMS implement these actions.

Report(s): **OEI-09-04-00221; issued 10/06**
OEI-09-04-00220; issued 04/07

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 (Networks). This study assessed the extent to which data were available to assist Networks in identifying 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 had limitations in assisting Networks to identify facilities with quality improvement needs. Limitations included lack of facility-specific, comprehensive, or current clinical performances measures (CPM). CMS had taken action toward providing a streamlined source of data that could assist Networks in identifying facilities with quality improvement needs; however, it had not yet been implemented. In 2000, CMS stated that it was developing a Core Data Set project that would regularly collect facility-specific data on a comprehensive set of CPMs. CMS faced technical and resource challenges, and the implementation of the Core Data Set is not complete.

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 whether it concurred or did not concur with our recommendations. CMS stated that it had made progress in collecting data to improve the quality of care in the ESRD program and indicated that there were still opportunities for improvement. 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 electronic 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 data and the CPM data annually for all eligible ESRD patients via CROWNWeb.

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

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. The quality of oversight is determined by how well an ASC meets Medicare's Conditions of Coverage, an established set of minimum health and safety standards with which ASCs must comply to qualify for Medicare reimbursement. ASCs must become Medicare certified by a State survey and certification agency or be privately accredited to show that they meet the Conditions of Coverage. ASCs are free to choose either a State agency or a private agency through which to become certified.

Finding(s): We found that the number of Medicare ASCs more than doubled from 1990 to 2000 and that major procedures performed within 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 this 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 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. The MMA directed that a new payment system for ASC services be implemented no later than January 1, 2008. One purpose of this statute is to encourage quality and efficient care in the most appropriate outpatient setting, given the rapid spending growth for services and the large variations in the use of services. A Proposed Rule on the conditions of participation for ASCs, which addresses quality matters, was published on August 31, 2007. We continue to monitor the status of the rule.

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

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 mid-level 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: providing access to care, reimbursement, managed care, and 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 urbanized 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 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. Additionally, 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 medically underserved populations and health professional shortage areas. 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. The proposed rule is undergoing departmental review.

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

Nursing Homes

Ensure That States Cease Imposing Fees on Nurse Aide Registration

Background: Sections 4201 and 4211 of the OBRA of 1987 include numerous provisions intended to improve the quality of care in long term care (LTC) facilities, amending sections 1819 and 1919 of the SSA. The OBRA requires that each State establish and maintain a nurse aide registry. Sections 1819(e)(2) and 1919(e)(2) prohibit States from imposing on individuals any charges related to registration in the registry.

Finding(s): Based in a 2005 survey of State fees, we found that 24 of the States had imposed fees related to nurse aide registries, including fees that may be required for initial or continued placement in the registries. Four States required aides to pay for placement on nurse aide registries, and others imposed fees on nurse aides as a requirement to work in LTC facilities. We found that CMS had provided guidance to only the States that had requested it and conducted limited oversight of States regarding registry fees.

Recommendation(s): CMS should clarify the prohibition on charging fees related to nurse aide registries, conduct appropriate oversight to prevent States from charging inappropriate fees, and ensure that States cease imposing on nurse aides fees that violate Federal requirements.

Status: CMS concurred with our recommendations. It indicated that it would work through its regional offices to notify States found to impose fees in violation of Federal requirements that such practices must cease and to ensure that proper revenue offset is made to claims for Federal financial participation. CMS also indicated that it would ensure that all State Medicaid agencies review a written reminder of the statutory and regulatory provisions that prohibit the imposition of any charges relating to the nurse aide registry on nurse aides. In February 2006, CMS issued a Survey and Certification State Medicaid Director Letter in which it stated that States are prohibited from charging for nurse aide registration. However, during our ongoing work in this area, we have noted that some States continue to charge fees for nurse aide registration. We continue to recommend that CMS monitor and act on States' noncompliance.

Report(s): OEI-07-05-00070; issued 12/05

Ensure That Only Registered Nurse Aides Without Substantiated Findings Are Registered

Background: Amending sections 1819 and 1919 of the SSA, sections 4201 and 4211 of the OBRA of 1987 include numerous provisions intended to improve the quality of care in 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 September 2003 data, 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 timely 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) utilize 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 will contain information about individuals and to not employ individuals as nurse aides for more than 4 months without registration, and (4) ensure in other States that LTC facilities use available resources to ensure that nurse aides with substantiated adverse findings or criminal backgrounds are not employed.

Status: CMS concurred with our recommendations. In commenting on our 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. Pursuant to the MMA, in 2005 CMS implemented a 2-year Criminal Background Check Demonstration for nurse aides in seven States. CMS also informed us that the background check pilot final evaluation study is targeted for issuance in summer 2008. We continue to monitor CMS's actions to ensure that States are in compliance with Federal nurse aide registry regulations.

Report(s): **OEI-07-03-00380; issued 02/05**
OEI-07-04-00140; issued 07/05

Nursing Homes

Update Nursing Home Nurse Aide Training Curriculum

Background: The OBRA of 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 the 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 indicated to us that it intended to use a contractor to more extensively document the problem and develop specific policy and program options for improvement. CMS also indicated that it had planned to propose adding a requirement to the conditions of participation that nursing homes document when in-service training is conducted to address the weaknesses identified in nurse aides' performance reviews. CMS informed us in April 2008 that it had drafted a report addressing several areas that the agency had identified for policy improvement and development. We will continue to monitor CMS's efforts for improvement in this area.

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

Strengthen Managed Care (Part C) and Prescription Drug (Part D) Benefit Payment Cycles

Background: Medicare managed care (i.e., Part C) and outpatient prescription drug (i.e., Part D) expenditures are processed and paid for by CMS's central office. In January 2006, CMS completed a system conversion to the Medicare Advantage Prescription Drug System for payments to the managed care organizations and for the Medicare prescription drug program. The Part D program commenced operations in January 2006, and reconciliation of payments is scheduled to occur 6 months after the close of the plan year. Therefore, FY 2007 ending September 2007 was the first year of Part D reconciliation. An accrual as of September 2007, totaling more than $8 billion, was recorded on CMS's general ledger that included the contract year reconciliation (CY 2006) and an estimated account receivable covering the FY under audit.

Finding(s): The FY 2007 financial statement audit for the Part D reconciliation process noted that CMS had not fully developed the new reconciliation process and lacked monitoring controls to ensure the accuracy of the prescription drug data and drug rebate data submitted by the plans. The lack of a timely calculation of the estimate resulted in inaccurate reporting within the interim financial statements. CMS lacked the documentation (policies and procedures) to develop the FY 2007 Part D estimate, including the estimate related to invalidly rejected prescription drug data.

For Part C, the audit noted recurring issues with CMS's oversight of the MAs. Because of the significant increase in MAs and limited oversight resources, CMS did not readily provide a complete set of monitoring policies and procedures or properly document the rationale and sampling approach for the population selected for review. In addition, CMS did not provide sufficient documentation to evidence ongoing monitoring of MAs, and the Health Plan Management System used by CMS to monitor MA oversight contained inaccurate information, which weakened CMS's ability to properly monitor the MAs.

Recommendation(s): CMS should (1) continue to develop its policies and procedures related to the development, documentation, and validation of the Part D accrual process; (2) establish policies for regional office monitoring of the various organizations (MAs, Medicare Advantage-Prescription Drug, Prescription Drug Plan, etc.) that include tailored procedures to address the unique requirements or risks of each organization; (3) ensure that policies and procedures for the monitoring of organizations within the managed care program are consistently implemented and that monitoring of these organizations is documented in accordance with appropriate standards and guidelines; (4) develop detailed policies and procedures outlining the minimum documentation requirements that must be met as part of the monitoring reviews to appropriately support the review outcome; (5) document the compliance with regulations for the monitoring of specific chapters and/or elements for organizations; (6) ensure that findings, corrective action plans, and acceptance of providers' corrective action plans are provided, reviewed, and released within the proposed time; and (7) ensure that relevant data are updated timely to provide the information necessary for adequate management oversight.

Status: CMS concurred with the recommendations made in the FY 2007 financial statement audit report. The report noted that, during FY 2007, CMS had enhanced the procedures used to validate and authorize payments for Medicare Part C and the Part D benefits. Enhancements were made to a number of validation functions, including the Beneficiary Payment Validation, the Plan Payment Validation, and the monitoring and tracking of payment issues. The report also noted that CMS had made significant improvements in documenting its determination of eligibility of organizations during the initial application review.

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

Other Medicare and Medicaid Issues

Improve Medicare Information Systems Controls

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.

Finding(s): In FY 2007, CMS continued to make progress in identifying and addressing weaknesses in its automated Medicare processing systems. Although our review disclosed no exploitation of any identified vulnerability, the weaknesses noted could result in direct update access to Medicare claims data without consistent logging and review. For controls over edit settings in the Fiscal Intermediary Shared System (FISS), Viable Information Processing Medicare System (VMS), and Multiple Carrier System (MCS) application systems, the audit noted exceptions at certain contractors; and workgroup settings for MCS were not correct for numerous edits resulting in incorrect edit settings at some contractors. The audit noted a lack of controls with respect to software supplementing the FISS, MCS, and VMS systems. The use of such programs without the enforcement of strong controls could result in inconsistent and uncertain claims processing, leading to payment inaccuracies. For the areas of direct update access to Medicare claims data, control over edit settings in the FISS, VMS, and MCS systems and controls over the use of supplemental software used to process claims, the audit noted instances in which CMS's central office issued guidance and requirements to address internal control concerns, but the contractors had not implemented the needed controls. Effective management controls over the use of direct update access to claims, changes to edits within the three major Medicare application processing systems, and supplemental software programs are imperative to establishing a reasonable range of assurance over the accuracy of Medicare claims processing.

Recommendation(s): CMS should (1) establish a process to periodically review and test contractor reports of employees with direct update access to Medicare claims data; (2) establish ongoing workgroups to review FISS, MCS, and VMS edits that should be turned on or off; (3) establish a formal review process to, on a selected and unannounced basis, obtain and review actual in-use edit settings for the FISS, VMS, and MCS systems running at the contractor sites; (4) use the results obtained through the review process to identify edit settings not in compliance with the recommended edit settings suggested by the workgroups; (5) establish reports to determine the volume of and reasons for claims bypassing the Common Working File (CWF) application; (6) work with contractors and maintainers of the FISS, MCS, and VMS systems to ensure that automated adjudication system programs, such as SuperOps and SCF, maintain complete audit trails; and (7) continue to enhance processes for the recertification of contractor employee access and the review of violation reports for the FISS, MCS, and VMS.

Status: CMS concurred with the recommendations in the FY 2007 financial statement audit report. The report noted that, during FY 2007, CMS had worked to establish and document consistent controls over the use of direct update access to claims data; edits within the FISS,

MCS, and VMS; and the use and control of supplemental software programs. However, we noted the challenges involved in consistently enforcing these controls over 28 contractor and 13 data center locations, and we encourage CMS to continue its efforts to gain contractor support for full implementation of these controls.

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

Other Medicare and Medicaid Issues

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 then 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 be 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 report, CMS partially concurred with our recommendations. CMS disagreed with our first two recommendations regarding what should be addressed in PSC performance evaluation reports. With regard to the first recommendation, CMS stated that quantifying results may compromise investigations and create perverse incentives. We note, however, that our recommendation was not to establish a quota system for performance; rather, we recommended that CMS include a combination of qualitative and quantitative results information in the PSC evaluation report. Without this information, it would be difficult to determine PSC effectiveness. With regard to the second recommendation, CMS stated that resources sometimes prevented addressing all PSC activities in the evaluation reports. With regard to the third recommendation, CMS has reevaluated its use of the term "finalized" in the performance evaluation criteria and the contract renewal process timetable. In reference to the fourth recommendation, CMS has enhanced its tracking system to track milestone dates that are not captured by the National Institutes of Health (NIH) database. We continue to recommend that activities required in PSC task orders be addressed in evaluation reports.

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

Laboratories

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. The CLIA waives the standards for laboratories that use only tests that the Secretary of HHS has determined have insignificant risk of erroneous results. 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 manufacturer's 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 certificates 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 certificates of waiver or provider-performed microscopy to identify which test systems they use, and each year conduct inspections 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 the Centers for Disease Control and Prevention (CDC) on developing a document outlining laboratory practices for waived testing, which was published in November 2005 in the "Morbidity and Mortality Report." We recommend that CMS implement all of 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

Prescription Drugs

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 agreements with drug manufacturers directly. In accordance with section 1927 of the SSA, 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 manner in which, AMPs are determined under section 1927 of the SSA and 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 primarily focused on how manufacturers calculate 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 in regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and 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 encourage States to analyze the relationship between AMP and pharmacy acquisition cost 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. However, as a result of litigation challenging the validity of the new rule, a Federal court in December 2007 issued an injunction prohibiting CMS from implementing it to the extent that the rule affects reimbursement rates. Given that OIG audits continue to identify variation among calculation methods, we continue to recommend that CMS provide oversight to determine whether 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

Public Health

Health Resources and Services

Improve Health Resources and Services Administration Alert List Practices

Background: The purpose of the Alert List is to safeguard HHS funds by alerting other agencies to potential risks in awarding grants. The Alert List is posted on the HHS Intranet site for all agencies that award grants. If an awarding agency has concerns about a grantee because of 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 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 comments on our report, HRSA did not indicate whether it concurred or did not concur 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 the report. Subsequent to our report, HRSA indicated that it intended to adhere to departmental guidance on the Alert List and was working closely with grants officers to ensure that Alert List procedures are followed. However, in July 2007, HRSA was informed that the Department had suspended the alert system pending a major redesign projected for FY 2008.

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

Report Medical Malpractice Cases to the National Practitioner Data Bank

Background: According 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 a corrective action process that would 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 where the standard of care was not met. HRSA started reporting such cases soon thereafter. At the time of the 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, and NIH had not submitted any reports. All cases submitted by IHS and HRSA involved practitioners who did not meet the standard of care. Neither agency had submitted cases where the standard of care was met. NIH indicated that it would not submit reports until a revised departmental policy is issued.

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 (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 NPDB 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. According to HRSA, it has studied the compliance with the NPDB reporting requirements and found that the vast majority of hospitals and other health care entities, specifically managed care entities, would not release the professional review materials supporting their actions in the absence of clear legal authority requiring them to do so. HRSA has acknowledged that the existing legislation is inadequate to force NPDB reporters to reveal information needed to enable audits of reporting compliance. In December 2007, HRSA informed us that the legislative proposal that it had developed to establish a civil monetary penalty for each instance of a hospital's failure to report was proceeding through Department clearance.

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, $597.3 million was provided 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, or 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, or 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. According to information from HRSA, it had consolidated its grants management offices, relocated most Title II monitoring responsibilities from regional offices to headquarters, and redefined the Office of Field Operations as the Office of Performance Review. In March 2008, HRSA reported that it had taken steps to implement our recommendations, including enhanced training for project officers, development of a site visit protocol for onsite monitoring, and increasing the number of grantee site visits. While recognizing these efforts, we continue to recommend that HRSA implement the remaining recommendations, including improving project officer continuity and coordination and standardizing the corrective action process for grantee oversight.

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 agency'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 report, FDA did not indicate whether it concurred or did not concur with our recommendations. Subsequent to the issuance of 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 which conduct the studies and field investigations in FDA's Office of Regulatory Affairs. FDA also indicated that it had developed several 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, requiring drug firms engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to Food and Drug Administration (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. It inputs 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. As 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 report, FDA delineated a number of planned 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 referenced 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. In April 2008, FDA informed us that the proposed rule is expected to be published in late 2008 or early 2009. The agency also indicated that it had made progress in developing the new electronic registration and listing system and expected to begin fielding it in late 2008. We will continue to monitor the status of the proposed rulemaking.

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

Improve FDA's Postmarketing Oversight of Drugs

Background: FDA requires all new drugs to undergo clinical testing to demonstrate their safety and efficacy prior to 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 FYs 1990 and 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 timely 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 agency 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 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 ASRs were validated. Subsequent to our report, FDA informed us that it had efforts underway to enhance its postmarketing study commitment database and reporting capabilities; trained its review division staff on ASR validation procedures; standardized the process by which postmarketing study commitments were requested and reviewed; and hired contractors to conduct a thorough analysis of the postmarking commitment process to gain greater internal consistency regarding how the agency requires, requests, facilitates, and reviews postmarketing study commitments. FDA also informed us that in February 2006, it had issued industry guidance to describe in greater detail the content, form, and timing of postmarketing reports and in July 2006 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 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 did indicate that States varied in their reporting of data. Given that these data are essential for cost sharing and agency performance measurements, we continue to recommend that AoA improve the quality of participation data.

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

Improve Methods of Recruiting Foster Parents

Background: ACF has regulatory oversight of the Title IV-E Foster Care program, an entitlement program designed to assist States in covering 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 in nature 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 assist States in improving 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

Departmentwide and Cross-Cutting Issues

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 Office of Management and Budget (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 2007 financial statement audit noted that HHS continued to have serious internal control weaknesses in its financial management systems and reporting processes. Substantial manual procedures, numerous adjusting entries, and untimely and incomplete reconciliations and accrual processes hindered the Department's ability to produce timely and reliable financial statements. HHS's financial management systems did not substantially comply with Federal financial management systems requirements or the U.S. Government standard General Ledger at the transaction level.

In addition, HHS lacked sufficient controls over its accounting and business processes to ensure that budgetary transactions were properly recorded, monitored, and reported. Management routinely used high-level analysis to develop adjustments and to derive budgetary balances for financial reporting purposes. Improved procedures are needed to ensure accurate reporting of the status of budgetary resources.

Furthermore, information technology general control weaknesses in both the design and the operation of key controls were noted. Of particular concern was the lack of pervasive information technology security standards for areas such as security settings on platforms, policies regarding the control and use of passwords, and policies regarding control over changes to applications.

Recommendation(s): HHS should continue to develop and refine its financial reporting systems and processes. HHS should fully utilize the built-in system functionality designed to perform complete transaction processing and financial reporting in compliance with Federal financial reporting requirements. HHS should also update the documentation of policies and procedures for the preparation of the financial statements and ensure compliance through a monitoring process. In addition, HHS should establish appropriate reconciliation policies and procedures.

HHS should implement departmentwide procedures requiring the periodic review of undelivered orders and requiring the recording of recoveries in accordance with Federal accounting standards. HHS should also implement a commitment accounting function within the current General Ledger system to enable automated reconciliation of obligations and implement the projects module of the Unified Financial Management System (UFMS) across HHS to ensure that obligations are recorded in a timely manner through automated processes.

HHS should develop overall HHS platform configuration security standards for all operating platforms and databases, following the guidance issued by the National Institute of Standards and Technology, for all components and ensure the acceptance and implementation of the standards. HHS should also enhance policies and procedures to ensure that system administrators perform periodic reviews of access authorizations for all applications and that a process exists for communicating the names of terminated employees to administrators for their timely removal. Additionally, HHS should maintain effective program change controls processes for all applications to limit the risk of unauthorized changes to the production systems.

Status: In the FY 2007 Agency Financial Report (AFR), issued in November 2007, HHS acknowledged that it continued to have internal control weaknesses in its financial systems and processes, budgetary accounting, and financial management information technology systems. To facilitate resolution of financial systems and processes and budgetary accounting weaknesses, HHS indicated that it planned to continue efforts to improve financial management processes and to fully utilize the UFMS functionality and control capabilities. In the Management's Discussion and Analysis section of the FY 2007 AFR, HHS stated that the NIH Business System was fully implemented in June 2007, UFMS global would be fully implemented in 2008, and the CMS implementation would be fully operational by 2011. In addition, HHS indicated that it would be formulating entitywide goals for correcting the information technology weakness.

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

Departmentwide and Cross-Cutting Issues

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 intermediate care facilities for persons with mental retardation, nursing homes, and psychiatric facilities, 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 occurred during the use of restraints.

Finding(s): We found that, between 1999 and 2000, approximately 90 percent of persons with disabilities resided 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 varied 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 settings in which State systems were 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 that would (1) improve the reporting of potential abuse or neglect of persons with disabilities, (2) strengthen investigative and resolution processes, (3) assist in analyzing incident data to identify trends indicative of 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 in FY 2009 to determine whether appropriate action has been taken on our recommendations.

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

Improve Safeguards for Long Term Care Residents

Background: Under Federal regulations, residents of nursing homes and other LTC facilities have the right to reside in safe and secure environments, free from abuse and neglect. There is no Federal requirement to conduct criminal background checks of current or prospective employees of nursing facilities apart from those specifically addressing nurse aides.

Finding(s): We found that, between 1996 and 1998, there was no assurance that nursing home staff who could place elderly residents at risk of abuse or neglect were systematically identified and excluded from employment. Not all States required criminal background checks of applicants or onboard staff; however, the States requiring background checks believed that they had reduced the instances of abuse. Screening nurse aide registries can also be an effective tool in identifying known abusers, but in one State reviewed, the registry did not always record findings of abuse and convictions. Additionally, although use of the OIG exclusion list could make screening more effective, none of the nursing homes surveyed in six States was aware of this database or its availability on the Internet.

Recommendation(s): CMS should consider establishing Federal requirements and criteria for performing criminal checks and developing a national abuse registry or expanding the current State registries to include all workers in facilities receiving Federal reimbursement.

Status: CMS concurred with our recommendations and stated in its comments that it planned or had taken some actions to improve safeguards for LTC residents in nursing homes. We note that the MMA of 2003 established the framework for a program to evaluate national and State background checks on direct patient access employees of LTC facilities or providers; the program, which was to include up to 10 States, will identify efficient, effective, and economical procedures with which LTC facilities or providers can conduct background checks. In April 2008, CMS informed us that seven States, representing a mix of rural and urban areas and including diverse populations, had participated in its background check pilot program. CMS informed us that the background check pilot final evaluation study is targeted for issuance in summer 2008. We will monitor how CMS uses the study results in its efforts to implement our recommendation.

Report(s): OAS-12-97-00003; issued 09/98

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 of 1997
BBRA	Balanced Budget Refinement Act of 1999
CC	Commissioned Corps
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 Payment 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
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 of 1981
OBRA	Omnibus Budget Reconciliation Act of 1986
OBRA	Omnibus Budget Reconciliation Act of 1987
OBRA	Omnibus Budget Reconciliation Act of 1989
OBRA	Omnibus Budget Reconciliation Act of 1990
OBRA	Omnibus Budget Reconciliation Act of 1993
OIG	Office of Inspector General
P.L.	Public Law
PPS	Prospective Payment System
SCHIP	State Children's Health Insurance Program
SSA	Social Security Act
TBD	To Be Determined
UPL	Upper Payment Limit

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