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Compendium of
Unimplemented
Office of Inspector General
Recommendations

A Message From the Office of Inspector General

We are pleased to present the *Compendium of Unimplemented Office of Inspector General Recommendations* (Compendium).

The Compendium consolidates significant¹ unimplemented monetary and nonmonetary recommendations addressed to the Department of Health & Human Services (HHS) to provide information to interested parties about outstanding recommendations that, if implemented, have the potential to result in cost savings and improvements to program efficiency and effectiveness. These recommendations resulted from our audits and evaluations that were performed pursuant to the Inspector General Act of 1978, as amended. Our recommendations require one of, or a combination of, three types of actions: legislative, regulatory, or administrative. Some issues involve more than one type of action.

OIG performs routine followup with HHS and its operating and staff divisions to determine the status of actions being taken in response to our recommendations. This publication includes information about selected recommendations that had not been fully implemented as of September 30, 2009.

The Compendium mirrors HHS's organizational structure and related programs.

Centers for Medicare & Medicaid Services Programs

The programs of the Centers for Medicare & Medicaid Services (CMS), which include Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), account for most of HHS's budget. They variously provide medical care coverage for adults and children in certain statutorily defined categories.

Public Health and Human Service Programs and Departmentwide Issues

- Public Health. Agencies, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH); promote biomedical research; prevent and cure diseases; ensure the

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.

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 Services. The Administration on Aging (AoA) and the Administration for Children and Families (ACF) 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 dignity and quality of life.
- Departmentwide and cross-cutting issues. These include financial accounting, information systems management, oversight of grants and contracts, and selected initiatives involving more than one HHS organizational entity.

Priority Recommendations

The Office of Inspector General (OIG) relies on HHS management and governmentwide policymakers to decide which of its program recommendations are implemented.

Although many OIG recommendations are directly implemented by organizations within HHS, some are acted on by States that collaborate with HHS to administer, operate, and/or oversee designated programs such as Medicaid. HHS and the States sometimes do not immediately implement OIG’s recommendations for various reasons, including administrative complexities, the current policy environment, or a lack of statutory authority. In such cases, Congress often steps in to incorporate OIG’s recommendations into legislative actions, many of which result in substantial funds being made available for better use or in program improvements.

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 monetary and nonmonetary recommendations.

Medicare Priority Recommendations

Medicare Part A and Part B (Traditional Medicare)

- Hospitals—Modify Policy To Reduce or Eliminate Medicare Payments for Hospital Bad Debts. Estimated savings \$340 million. (p. 7)
- Nursing Homes—Ensure the Appropriate Processing of Denial of Medicare Payment Remedies for Noncompliant Nursing Homes. Nonmonetary. (p. 19)

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- Hospices—Ensure That Hospice Claims for Beneficiaries in Nursing Facilities Comply With Medicare Coverage Requirements. Nonmonetary. (p. 23)
 - Practitioners—Adjust Eye Global Surgery Fees To Reflect the Number of Evaluation and Management Services Actually Being Provided by Physicians. Estimated savings \$97.6 million. (p. 35)
 - Medical Equipment and Supplies—Ensure Medical Equipment Suppliers’ Compliance With Medicare Enrollment Standards. Estimated savings to be determined (TBD). (p. 57)
 - Medical Equipment and Supplies—Reduce the Rental Period for Medicare Home Oxygen Equipment. Estimated savings \$3.2 billion. (p. 61)
 - Medical Equipment and Supplies—Eliminate Medicare’s Vulnerability to Fraudulent or Excessive Inhalation Drug Claims in South Florida. Estimated savings TBD. (p. 75)

Medicare Part C (Medicare Advantage)

- Modify Payments to Medicare Advantage Organizations. Estimated savings \$1.97 billion. (p. 85)
- Place a Ceiling on Administration Costs Included in Medicare Advantage Organizations’ Bid Proposals. Estimated savings TBD. (p. 87)

Medicare Part D (Prescription Drug Benefit)

- Ensure Accuracy of Prescription Drug Plan Sponsors’ Bids and Prospective Payments. Estimated savings TBD. (p. 91)
- Implement Safeguards To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans. Nonmonetary. (p. 109)

Program Safeguard Contractors

- Improve the Performance Evaluation Process for Program Safeguard Contractors. Nonmonetary. (p. 119)

Medicaid Priority Recommendations

- Medicaid Federal and State Partnership—Limit Enhanced Payments to Costs and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share. Estimated savings \$120 million. (p. 123)

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- Medicaid Prescription Drugs—Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs. Estimated savings \$1.08 billion for brand-name drugs. (p. 135)
 - Medicaid Prescription Drugs—Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement. Estimated savings \$1 billion. (p. 141)
 - Medicaid Prescription Drugs—Extend Additional Rebate Payment Provisions to Generic Drugs. Estimated savings \$966 million. (p. 147)
 - Medicaid Managed Care—Enforce Federal Requirements for Submission of Medicaid Managed Care Encounter Data. Nonmonetary. (p. 151)

Public Health Priority Recommendations

- Centers for Disease Control and Prevention—Improve State and Localities’ Medical Surgical Preparedness for Pandemics. Nonmonetary. (p. 159)
- Food and Drug Administration—Update and Maintain an Accurate National Drug Code Directory. Nonmonetary. (p. 163)
- Food and Drug Administration—Improve and Strengthen Food Facilities’ Compliance With Records Requirements for Traceability of Food Products. Nonmonetary. (p. 167)
- Food and Drug Administration and National Institutes of Health—Ensure That Clinical Investigators Disclose All Financial Interests. Nonmonetary. (p. 169)
- National Institutes of Health—Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations. Nonmonetary. (p. 183)

If you have questions about this publication, please contact OIG’s Office of External Affairs at 202-619-1343.

To report potential instances of waste, fraud, or abuse related to HHS’s programs, you may contact the OIG Hotline by phone at 1-800-HHS-TIPS (1-800-447-8477) or by email at HHSTips@oig.hhs.gov. For information about mail, fax, and TTY options and the types of information needed in your report, please visit our Web site at <http://www.oig.hhs.gov/fraud/hotline>. An online version of the Compendium is located on OIG’s Web site at: <http://www.oig.hhs.gov/publications.asp>

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Part I: Medicare Program Recommendations

Medicare Part A and Part B (Traditional Medicare)

Medicare Part A and Part B

Hospitals:

Continue Mandated Reductions in Hospital Capital Costs

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

Recommendations: CMS should (1) seek legislative authority to continue mandated reductions in capital payments beyond fiscal year (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: To be determined (TBD*)

** The "TBD" designation is used in instances in which it is likely that implementation of the recommendation(s) would result in savings, but OIG has not estimated the savings, and estimates by third parties (e.g., in connection with a proposed rule or legislation) are not available.*

Management Response Summary: CMS did not concur with our recommendations. In its comments on the draft of our 1992 report, CMS said that it believed that the Social Security Act, § 1886(g)(1)(B)(iv), which states that the Secretary of the Department of Health & Human Services (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 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.

In the final rule that set FY 2008 hospital inpatient rates (which was published in the August 22, 2007, Federal Register), CMS said that it was monitoring current capital payment and cost data. The final rule also reduced capital payments by eliminating the large urban add-on adjustment. In December 2009, CMS stated that it believed the analysis it undertook in the FY 2010 rulemaking cycle appropriately reflects the current relationship between capital payments and costs.

Status: We continue to recommend that CMS review the need for capital payment reductions, and we are performing a followup audit of capital payments.

Related Reports:

1993 APR "Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, on Hospital Capital Costs, March 31, 1993." OAS-14-93-00380 [Report](#)

1992 APR *Analysis of Hospital Capital Costs.* OAS-09-91-00070 [Report](#)

Medicare Part A and Part B > Hospitals

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

Background: Under the Social Security Act, § 1886(d), Medicare pays for operating costs that are attributable to hospital inpatient services under the PPS. The system pays for care using a predetermined specific rate for each discharge. The Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) 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 steps to devise and implement an equitable PPS for capital costs, some future cost items had to be estimated. Subsequently, 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 of the forecasting estimates that CMS made 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.

Recommendations: 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 adjustments to the base rate.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: CMS agreed that the capital rate reflected an overestimation of base-year costs. Subsequently, the BBA provided for a reduction of 2.1 percent in capital payments for FYs 1998 through 2002. No more adjustments have been made. However, in the final rule that set FY 2008 hospital inpatient payment rates (published in the August 22, 2007, Federal Register), CMS said that it was continuing to monitor current capital payment and cost data to determine whether more adjustments were warranted. The final rule also reduced capital payments by eliminating the additional capital payments that hospitals in large urban areas previously qualified for. The President's FY 2009 budget included a legislative proposal to reduce hospital capital payments by 5 percent to ensure that they are appropriately aligned with capital costs. However, this proposal has not been enacted, and it was not included in the President's FY 2010 budget. In December 2009, CMS indicated that the analysis it undertook in the FY 2010 rulemaking cycle appropriately reflects the current relationship between capital payments and costs.

Status: We continue to monitor CMS's implementation of our recommendations.

Related Report:

1995 AUG *Review of Capital-Related Cost Prospective Payment System's Base Year 1992.*
OAS-07-95-01127 [Report](#)

Revise Graduate Medical Education Payment Methodology

Background: The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), § 9202, and the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986), § 9314, 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 Medicare will pay a disproportionate share of GME costs because of two factors in the methodology. Factor 1: the revised system allows hospital cost centers with little or no Medicare patient utilization to receive disproportionately high importance in the calculation of GME reimbursement. Factor 2: 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.

Recommendations: CMS should (1) address Factor 1 by revising the regulations to remove from a hospital’s allowable GME base-year costs any cost center with little or no Medicare utilization and (2) address Factor 2 by submitting 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.*

Management Response Summary: CMS did not concur with our recommendations, stating that it believed few Medicare savings would result from implementation of the first recommendation and that a legislative proposal to implement the second recommendation was not appropriate because of pending changes to GME programs. We note that the BBA and the Balanced Budget Refinement Act of 1999 (BBRA) contained provisions to slow the growth in Medicare spending on GME. In December 2009, CMS informed us that it is monitoring this area.

Status: We continue to recommend that CMS revise GME payment methodology to achieve further savings.

Related Report:

1994 APR *Nationwide Review of the Methodology for Identifying Medicare's Share of Graduate Medical Education Costs.* OAS-06-92-00020 [Report](#)

Modify Policy To Reduce or Eliminate Medicare Payments for 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 efforts to collect bad debts, such efforts often have 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.

Recommendations: CMS should consider various options, including (1) eliminating bad-debt payments, (2) reimbursing PPS hospitals for bad debts only if the hospitals lost money on their Medicare operations, and (3) seeking legislative authority to further modify bad-debt policies.

Savings: \$340 million*

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

Management Response Summary: CMS did not concur with our recommendations. In a February 10, 2003, proposed rule, CMS reiterated that it did not concur with the recommendations because the base period used to derive PPS rates did not include bad debts. Although the BBA provided for some reduction of bad-debt payments to providers, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) increased bad-debt reimbursement. The President's FY 2009 budget included a legislative proposal to eliminate Medicare bad-debt payments for providers over a 4-year period. However, this proposal has not been enacted, and it was not included in the President's FY 2010 budget.

Status: We continue to monitor CMS's implementation of our recommendations.

Related Reports:

- 2003 JAN *Review of Medicare Bad Debts Claimed by the Baystate Medical Center for Fiscal Year Ended September 30, 1999.* OAS-01-02-00515 [Report](#)
- 2003 JAN *Medicare Inpatient and Outpatient Bad Debts Claimed by Montefiore Medical Center for Fiscal Year Ended December 31, 1999.*
OAS-02-02-01031 [Report](#)
- 2003 JAN *Review of Medicare Bad Debts at Pitt County Memorial Hospital for the Fiscal Year Ended September 30, 1999.* OAS-04-02-02016 [Report](#)
- 2002 OCT *Review of Medicare Bad Debts for Florida Hospital for the Fiscal Year Ended December 31, 1999.* OAS-04-02-02011 [Report](#)
- 2002 OCT *Review of Medicare Inpatient Acute-Care Bad Debts at St. Joseph Hospital for Calendar Year 1999.* OAS-05-02-00039 [Report](#)
- 2002 OCT *Review of Medicare Inpatient Acute-Care Bad Debts at Ingalls Hospital for Fiscal Year 1999.* OAS-05-02-00052 [Report](#)
- 2002 OCT *Audit of Inpatient Bad Debts Claimed by Memorial Hermann Hospital in its Medicare Cost Report for the Fiscal Year Ended June 30, 2000.*
OAS-06-02-00027 [Report](#)
- 2002 SEP *Review of Medicare Bad Debts for Hospital Inpatient Services Claimed by St. Luke's-Roosevelt Hospital Center for Fiscal Year Ended December 31, 1999.*
OAS-02-02-01016 [Report](#)
- 2002 JUL *Review of Medicare Inpatient Bad Debts at United Hospital Center, Clarksburg, West Virginia, for Calendar Year 1999.* OAS-03-01-00022
[Report](#)
- 2002 JUL *Review of Medicare Bad Debts at the University of California, San Francisco Medical Center.* OAS-09-02-00057 [Report](#)
- 2002 JUN *Review of Medicare Inpatient Bad Debts at Mercy Catholic Medical Center, Conshohocken, Pennsylvania, for Calendar Year 1999.* OAS-03-02-00002
[Report](#)
- 2001 DEC *Review of Medicare Bad Debts at the University of Alabama at Birmingham Hospital.* OAS-04-00-06005 [Report](#)
- 1990 JUN *Options To Reform Payment for Medicare Bad Debts.* OAS-14-90-00339 [Report](#)

Expand the Diagnosis-Related Group Payment Window

Background: Under the PPS for inpatient hospital services, Medicare fiscal intermediaries (FI) 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, the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), § 4003, expanded the DRG payment window to preclude separate payment for nonphysician outpatient services up to 3 days immediately preceding the date of admission. This 3-day period is known as the DRG payment window.

Finding(s): For the period November 1990 through December 1991, our review identified about \$83.5 million in admission-related nonphysician outpatient services rendered 4 to 7 days immediately before inpatient admissions. A subsequent review identified \$37 million in preadmission services provided to patients for 10 selected DRGs 4 to 14 days before admissions during 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.

Recommendations: 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 from November 1990 through December 1991. **The savings estimate is based on the 10 selected DRGs associated with nonphysician outpatient services rendered 4 to 14 days before inpatient admissions during CY 2000.*

Management Response Summary: CMS concurred with the recommendation in our 2003 report; however, it noted that it would need to consider the impact on admission-related outpatient services provided to beneficiaries before a legislative change could be advanced. In December 2009, CMS stated that it did not believe that it was appropriate to include all diagnostic services 4 to 7 days prior to admission unless it was shown that hospitals were pre-ordering diagnostic tests to avoid bundling the tests.

Status: We continue to recommend expanding the DRG payment window.

Related Reports:

2003 AUG *Expansion of the Diagnosis Related Group Payment Window.*
OAS-01-02-00503 [Report](#)

1994 JUL *Expansion of the Diagnosis Related Group Payment Window.*
OAS-01-92-00521 [Report](#)

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

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

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

Recommendations: CMS should, in conjunction with the Office of Inspector General (OIG), (1) further examine the extent to which the base-period costs used in the outpatient prospective payment rate calculations included unallowable costs and improper payments, and (2) if this work reveals that excessive unallowable costs and improper payments were included in the calculations, make appropriate adjustments.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: In its comments on our draft report, CMS concurred with our recommendation. However, no more analysis has been performed to examine the adequacy of base-year costs. CMS subsequently said that introducing an adjustment to the base year rates would now be difficult because the base rates were established over a decade ago.

Status: We continue to recommend that the rates be examined and adjusted if appropriate.

Related Report:

1998 NOV *Review of the Health Care Financing Administration's Development of Medicare's Prospective Payment System for Hospital Outpatient Department Services.* OAS-14-98-00400 [Report](#)

Monitor the Quality and Appropriateness of Hospital and Nursing Home Consecutive Stays

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

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

Recommendations: CMS should (1) direct QIOs to monitor for fragmentation and quality of care across consecutive-stay sequences; (2) encourage FIs and QIOs, as appropriate, to monitor the medical necessity and appropriateness of services provided; (3) collaborate with providers to improve systems of care on the basis of review results; and (4) 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*

**Savings not estimated.*

Management Response Summary: CMS concurred with our recommendations in 2007, noting that it would place greater emphasis on continuity-of-care issues in all consecutive-stay settings and on measuring the rate of events, such as hospital readmissions. CMS said that it would consider incorporating interventions in the Ninth Statement of Work (SOW) for the QIO program. CMS indicated that it was working with physician groups to increase the understanding of the “medical home” concept, in which care is coordinated for a patient through a single site, and would ask QIOs to categorize complaints by type to provide better data on lapses in continuity of care and to emphasize documentation.

In August 2008, CMS awarded contracts for the QIO program’s Ninth SOW, which extends through July 31, 2011. As part of a “subnational” task, QIOs in 14 States (Alabama, Colorado, Florida, Georgia, Indiana, Louisiana, Michigan, Nebraska, New Jersey, New York, Pennsylvania, Rhode Island, Texas, and Washington) are participating in the Care Transitions Project, which aims to promote continuity of care and coordination of services across settings (e.g., hospital to home). As part of the project, QIOs will attempt to reduce unnecessary readmissions to hospitals. In September 2009, the Secretary of HHS announced the “Medicare-Medicaid Advanced Primary Care Demonstration Initiative,” which will provide funds to States that have Advanced Primary Care (APC) projects for Medicaid beneficiaries. The APC model, also known as the patient-centered medical home, requires a practice to link multiple points of health delivery by using a team approach to improve patient outcomes, increase coordination of care, and reduce unnecessary hospitalizations. The new demonstration is expected to begin in 2010 and will provide States’ funds to extend APC projects involving Medicaid and private payers to Medicare beneficiaries.

Status: We will continue to monitor CMS’s oversight of the implementation of the Ninth SOW and the APC demonstration project.

Related Reports:

2007 JUN *Consecutive Medicare Stays Involving Inpatient and Skilled Nursing Facilities.*
OEI-07-05-00340 [Report](#)

2005 JUN *Consecutive Medicare Inpatient Stays.* OEI-03-01-00430 [Report](#)

Medicare Part A and Part B

Nursing Homes:

Ensure That States Properly Maintain Nurse Aide Registries

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

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

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

Management Response Summary: CMS concurred with our recommendations. CMS indicated that it had developed and disseminated the *Abuse and Neglect Detection*

and Prevention Training Manual to provide surveyors and other reviewers with more 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 (S&C) letter (S&C 05-46) to State survey agency directors requesting that they review the Federal requirements related to the operation and maintenance of the nurse aide registry. In 2005, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), CMS implemented a 2-year Criminal Background Check Demonstration for nurse aides in seven States. CMS released the final evaluation report on the results of the Criminal Background Check Demonstration in September 2008. In April 2009, CMS informed OIG that it planned to issue an S&C letter detailing the Background Check Pilot States' lessons learned. However, as of November 2009, CMS indicated that it will not issue such a letter. If the elements of the national background check expansion program included in the proposed health reform legislation are passed, CMS may then issue a memorandum.

Status: We are continuing to monitor CMS's actions to ensure that States are in compliance with Federal nurse aide registry regulations and will conduct more work in the area of nursing home background checks. We will reevaluate the status of this item when the work is complete.

Related Reports:

- 2005 JUL *Nurse Aide Registries: Long Term Care Facility Compliance and Practices.*
OEI-07-04-00140 [Report](#)
- 2005 FEB *Nurse Aide Registries: State Compliance and Practices.*
OEI-07-03-00380 [Report](#)
- 1998 SEP *Safeguarding Long Term Care Residents.* OAS-12-97-00003 [Report](#)

See Also:

- 2008 MAY OIG Testimony Before the House Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations: "Nursing Home
Safeguards." [Testimony](#)

Update Nurse Aide Training Curriculum

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

Finding(s): As of July 2001, 90 percent of surveyed nursing home experts reported that the medical and personal care needs of today's nursing home residents have changed since the implementation of OBRA 1987. 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 meet Federal requirements.

Recommendations: CMS should (1) improve nurse aide training and competency program requirements to ensure that the content of the training curriculum and testing remain relevant to complex resident care needs, and (2) continue to work with States to ensure that training is effective and efficient and that nursing homes comply with in-service training requirements.

Management Response Summary: CMS concurred with our draft recommendations. After our report was issued, CMS told us that it intended to use a contractor to document the problem more extensively and develop specific policy and program options for improvement. In April 2009, CMS said that its final report on improving nurse aide training, completed in September 2008, contained a conclusion that statutory change is necessary to address improvements in nurse aide training requirements.

Status: We encourage CMS to work with Congress to ensure the necessary statutory changes are made.

Related Report:

2002 NOV *Nurse Aide Training*. OEI-05-01-00030 [Report](#)

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

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

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

Recommendations: CMS should (1) manage DPNA cases to ensure that DPNA instructions are sent promptly and that FIs and MACs retrospectively review cases that are processed late to correct any payment errors, (2) address communication breakdowns by implementing a standard format to notify FIs or MACs that a DPNA remedy will be in effect, (3) require confirmation that instructions are received and understood, and (4) update guidance on coding readmissions and verifying readmission status for DPNA claims.

Management Response Summary: CMS agreed with our recommendations and outlined specific actions to address each recommendation. The agency indicated that it would develop internal procedures to effectively communicate DPNA instructions to FIs and MACs, create a protocol so contractors could notify CMS that a DPNA had been implemented as requested, and update manual instructions to clarify coding and verification requirements for DPNA readmissions. In July 2008, CMS issued CMS Manual System Transmittal 1555 Change Request 6116, which implemented new coding requirements for SNF provider billing services during a DPNA period. This action implemented our recommendation to update guidance on coding and billing for

admissions. In April 2009, CMS told OIG that it had established a workgroup to improve practices to reduce improper payments to nursing homes subject to DPNAs. According to CMS, the workgroup is developing a formal administrative policy guidance memorandum for internal use by CMS and MACs about consistency in effectuating DPNAs. The guidance was scheduled to be issued in summer 2009; however, as of November 2009, this guidance had not been issued.

Status: We continue to monitor CMS's progress in implementing its guidance concerning DPNA instructions and protocols with contractors.

Related Report:

2008 MAY *Nursing Home Enforcement: Processing Denials Of Medicare Payment.*
OEI-06-03-00390 [Report](#)

See Also:

2007 JUL OIG Testimony Before the Senate Special Committee on Aging:
"Elder Abuse and Noncompliant Nursing Homes." [Testimony](#)

Medicare Part A and Part B

Hospices:

Improve Oversight of Medicare Hospices

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

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

Recommendations: CMS should (1) provide guidance to State agencies and CMS regional offices about analysis of data and identification of at-risk hospices, including hospices in Federal comparative surveys and annual State performance reviews; (2) seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification; and (3) seek legislation to establish more enforcement remedies for poor hospice performance.

Management Response Summary: CMS partially concurred with our recommendations. CMS indicated that it had developed reports to support the oversight efforts of the regional offices and was exploring and implementing methods to become more efficient in targeting its resources toward providers most in need of closer

oversight. CMS stated that its management challenge was to make the most effective use of appropriated resources. On June 5, 2008, CMS promulgated the hospice final rule to revise the conditions of participation (CoP), which had been last amended in 1990. This final rule became effective on December 2, 2008. It focuses on the care delivered to patients and their families by hospices and the outcome of care. CMS did not concur with the recommendation to include hospices 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.

Status: We continue to recommend that CMS seek regulatory or statutory changes to establish specific requirements for (1) the frequency of hospice performance certification and (2) enforcement remedies for poor hospice performance.

Related Report:

2007 APR *Medicare Hospices: Certification and Centers for Medicare & Medicaid Services Oversight.* OEI-06-05-00260 [Report](#)

Ensure That Hospice Claims for Beneficiaries in Nursing Facilities Comply With Medicare Coverage Requirements (New)

Background: The Medicare hospice benefit allows a beneficiary with a terminal illness to forgo curative treatment for the illness and instead receive palliative care. The number of beneficiaries receiving hospice care has significantly increased in recent years, and some studies suggest that the use of hospice care has grown most rapidly in nursing facilities. Hospice benefit coverage requirements described at 42 CFR § 418 require an election statement, a plan of care, and a certification of terminal illness for patients receiving hospice services.

Finding(s): We found that 82 percent of hospice claims for beneficiaries in nursing facilities did not meet at least one Medicare coverage requirement, based on a medical record review of a stratified random sample of hospice claims for beneficiaries in nursing facilities in 2006. Medicare paid about \$1.8 billion for these claims. Thirty-three percent of claims did not meet election requirements, and 63 percent did not meet plan-of-care requirements. For 31 percent of claims, hospices provided fewer services than outlined in beneficiaries' plans of care. In addition, 4 percent of claims did not meet certification of terminal illness requirements.

Recommendations: CMS should (1) educate hospices about coverage requirements and their importance in ensuring quality of care, (2) provide hospices with tools and guidance to help them properly demonstrate that coverage requirements are met, and (3) strengthen monitoring practices for hospice claims.

Management Response Summary: CMS concurred with our recommendations. CMS said that it has (1) made presentations at industry conferences and participated in other events with hospice associations; (2) updated its Web site with a training broadcast for State surveyors that is available to hospice providers; and (3) educated providers about the requirements of the new CoP, issued June 5, 2008. The CoP provisions, which relate to providers' eligibility for participation in the Medicare program, address patient care planning and the care of patients in nursing facilities. The agency issued *Hospice Program Interpretive Guidance*, a tool used by providers and State Survey agencies to determine compliance with the CoP provisions. CMS also said that it held three satellite training sessions to educate stakeholders on the new CoP requirements. CMS said that it will instruct Medicare contractors to consider the coverage requirements issues in our report when prioritizing its medical review strategies or other interventions.

Status: We continue to recommend that CMS strengthen its monitoring practices for hospice claims.

Related Report:

2009 SEP *Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements.* OEI-02-06-00221 [Report](#)

Medicare Part A and Part B

Home Health Agencies:

Require Physician Examination Before Ordering Home Health Services

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

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

Recommendations: CMS should revise Medicare regulations to require that physicians (1) examine patients before ordering home health care and (2) see the patient at least every 60 days. As discussed below, other recommendations to correct abusive and wasteful practices are being addressed.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: In its comments on our July 1997 draft report, CMS partially concurred with our recommendation, stating that it agreed in principle that physicians should certify home health care only on the basis of personal knowledge of patients' conditions and that recertification should be made only when that knowledge is updated. However, CMS said that it did not support imposing specific service requirements or timeframes until it had examined coverage rules and CoP to develop requirements necessary for ensuring proper certification. In the final physician fee schedule rule published in the November 15, 2004, Federal Register, CMS provided additional payments for physician plan care oversight. CMS also told us it was considering additional education for physicians and beneficiaries as incentives to encourage more physician involvement. However, our four-State review of services provided in 1998 identified unallowable services because of inadequate physician involvement.

Status: Although the BBA, enacted in 1997, included some provisions to restructure home health benefits, we continue to recommend that there is a need for CMS to revise regulations to require that physicians examine Medicare patients before ordering home health services.

Related Reports:

- 2001 MAR *Review of Medicare Home Health Services in Florida.*
OAS-04-99-01195 [Report](#)
- 1999 NOV *Review of Medicare Home Health Services in California, Illinois, New York, and Texas.* OAS-04-99-01194 [Report](#)
- 1999 SEP *Review of Costs Claimed by Dr. Pila Foundation Home Care Program in Ponce, Puerto Rico.* OAS-02-97-01034 [Report](#)
- 1999 SEP *Review of Costs Claimed by Homebound Medical Care, Inc.*
OAS-04-98-01184 [Report](#)
- 1999 APR *Review of Costs Claimed by MedCare Home Health Services, Inc.*
OAS-04-97-01170 [Report](#)
- 1999 APR *Review of Costs Claimed by Staff Builders Home Health Care, Inc.*
OAS-04-97-01166 [Report](#)
- 1997 SEP *Review of Costs Claimed by Eddy Visiting Nurse Association of the Capital Region.* OAS-02-97-01026. [Report](#)
- 1997 JUL *Operation Restore Trust: Audit of Medicare Home Health Services in California, Illinois, New York and Texas.* OAS-04-96-02121 [Report](#)
- 1996 NOV *Operation Restore Trust: Review of Home Health Claims Submitted by First American Health Care, Inc., Pennsylvania.* OAS-03-95-00011 [Report](#)
- 1996 SEP *Operation Restore Trust: Review of Costs Claimed by Home Health Services of South Florida Inc., d/b/a USA Home Health Services.*
OAS-04-95-01105 [Report](#)
- 1996 SEP *Review of Costs Claimed by Home Health Care Inc.* OAS-04-95-01107 [Report](#)
- 1996 JUN *Review of Costs Claimed by American Health Care Services.*
OAS-04-95-01104 [Report](#)
- 1996 MAR *Review of Costs Claimed by Visiting Nurses Association of Dade County, Inc.*
OAS-04-95-01103 [Report](#)

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- 1996 MAR *Review of Costs Claimed by Pro-Med Home Health, Inc.*
OAS-04-95-01106 [Report](#)
- 1995 JUN *Results of the Audit of Medicare Home Health Services in Florida.*
OAS-04-02087 Report
- 1995 FEB *Review of Costs Claimed by St. Johns Home Health Agency.*
OAS-04-94-02078 [Report](#)

Consider Intermediate Sanctions for Deficiency History in Medicare Recertifications of Home Health Agencies (New)

Background: The Social Security Act, § 1891(c)(2)(A), requires that CMS survey the quality of care and services furnished by HHAs at least every 36 months. HHAs participating in the Medicare program must comply with 15 Medicare CoP and 69 standards. CMS contracts with State agencies to conduct initial HHA certification and recertification surveys to determine CoP compliance. State agencies annually survey a 5-percent targeted sample of at-risk HHAs. Noncompliance with one or more CoP is cause for termination of participation. Termination is the only sanction available to CMS in response to HHA noncompliance.

Finding(s): We found that 15 percent of HHAs repeated the same deficiency citation on three consecutive surveys. In HHAs with repeat citations, the most frequently repeated deficiency citation related to patient plans of care. On the three most recent surveys, these HHAs received, on average, twice as many deficiency citations per survey compared with HHAs without repeated citations. Most HHAs with repeat citations are located in six States and tend to be concentrated in highly populated areas. We also found that CMS does not use all of the available deficiency history information in its oversight of HHAs; deficiency history beyond the most recent survey can be an important indicator of performance on the next survey and can improve CMS's identification of at-risk HHAs. For HHAs with one or more condition-level deficiency, CMS has no sanction other than initiating a termination.

Recommendations: CMS should (1) use existing survey data to identify patterns of deficiency citations and at-risk HHAs, (2) require surveyors to review all of the available survey data before each survey, (3) include multiple survey results in its algorithm to identify HHAs at risk of providing poor quality of care, and (4) implement intermediate sanctions as directed by OBRA 1987. There are no intermediate sanctions for poor-performing HHAs, and the only sanction available is termination from the Medicare program.

Management Response Summary: In response to our 2008 draft report, CMS partially concurred with our recommendations and said that during the last several years, it has taken steps to improve oversight of HHAs, many of which address the issue of repeated deficiencies. CMS concurred, in part, with the recommendation that the State survey agency use all survey data to identify patterns of deficiency citations and at-risk HHAs before conducting each survey. CMS did not concur with the second part of the recommendation to include multiple survey results in its algorithm to identify a targeted sample of HHAs that are at risk of providing poor quality of care. CMS explained that including an algorithm of three standard surveys would result in HHAs,

particularly newer ones, not being considered in the targeting process because these HHAs lack historical survey data. CMS concurred with the recommendation to implement intermediate sanctions as directed by OBRA 1987 and said that it had initiated the rulemaking process numerous times but that other demands had impeded promulgation of a final rule. In December 2009, CMS stated that it had drafted an alternative sanction that is under review.

Status: We continue to recommend that CMS promulgate a rule to implement alternative sanctions.

Related Report:

2008 JUL *Deficiency History and Recertification of Medicare Home Health Agencies.*
OEI-09-06-00040 [Report](#)

Medicare Part A and Part B

Ambulatory Surgical Centers:

Improve Quality Oversight of Ambulatory Surgical Centers

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

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

Recommendations: CMS should (1) determine an appropriate minimum cycle for surveying ASCs certified by State agencies, (2) hold State agencies and accreditors fully accountable to the Medicare program for their performance in overseeing ASCs, (3) ensure that State agency certification and accreditation strike an appropriate balance between compliance and continuous quality improvement, and (4) update its regulations for ASCs by adding sections that deal with patients' rights, continuous quality improvement, and making the conditions adjustable to match the levels of surgery performed by different ASCs.

Management Response Summary: CMS generally concurred with our recommendations. CMS updated its *State Operations Manual* (section 2008F) on May 21, 2004, to state that "resurveys are generally conducted annually, but depending on national initiatives and budget constraints, the cycle may vary." CMS has not mandated a minimum cycle for surveying ASCs certified by State agencies, but American Recovery and Reinvestment Act of 2009 (Recovery Act) funds will allow States to survey one-third of all nonaccredited ASCs in FY 2010. Since 2006, CMS has published Medicare payment information for procedures commonly performed in ASCs on a State and county, but not individual facility, basis. CMS indicated that this information would "help patients

undergoing surgical procedures select the most appropriate setting for the delivery of high quality, efficient care.”

In April 2009, CMS informed OIG that, because of budgetary constraints, it had deferred reporting of ASC quality data for CY 2010 in the CY 2009 Outpatient Prospective Payment System (OPPS) final rule. As of November 2009, the ASC proposed rule did not include quality reporting requirements. CMS revised the CFCs for ASCs, effective May 18, 2009, to add requirements concerning patients’ rights and replace the Evaluation of Quality CFC with a quality assurance/performance improvement (QAPI) (i.e. continuous quality improvement) CFC. CMS noted in its August 2007 proposed rule that the revisions were the result of the February 2002 OIG report. Also, in the preamble to the proposed rule, CMS stated that, from a policy and operational perspective, it was unable to adjust the CFCs to match the levels of surgical services performed by ASCs, but that it “would expect each ASC’s QAPI program to reflect the scope and severity of the surgical services they perform.”

Status: We continue to recommend the implementation of a minimum cycle for the survey of ASCs certified by State agencies. We will continue to monitor the implementation of our recommendations.

Related Report:

2002 FEB *Quality Oversight of Ambulatory Surgical Centers: a System in Neglect.*
OEI-01-00-00450 [Report](#)

Medicare Part A and Part B

Rural Health Clinics:

Improve Oversight of Rural Health Clinics

Background: The Rural Health Clinic (RHC) program, created in 1977 by the Rural Health Clinic Services Act of 1977, is intended to increase access to health care in rural, medically underserved areas and to expand the use of midlevel practitioners in rural communities. In 1996, OIG and the Government Accountability Office (GAO) issued reports that raised concerns about the inappropriate growth and locations of RHCs. Both organizations recommended changes to ensure that RHCs are in areas that would otherwise be underserved. OIG re-examined this program and issued a followup report in 2005.

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

Recommendations: CMS should, (1) in conjunction with the Health Resources and Services Administration (HRSA), modify the certification process to increase State involvement and ensure more strategic placement of RHCs; (2) expedite the issuance of the regulations under development, and (3) take immediate steps to improve the oversight and functioning of the cost reimbursement system, with a long-term goal of implementing an improved method of reimbursement.

Management Response Summary: 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 about provider-based and freestanding designation conditions. CMS published a notice of proposed rulemaking, *Medicare Program: Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers* (73 Fed. Reg. 36696, June 27, 2008), which addressed several of OIG's recommendations. CMS has indicated that the final rule is in the clearance process.

HHS published a notice of proposed rulemaking, *Designation of Medically Underserved Populations and Health Professional Shortage Areas* (73 Fed. Reg. 11232, February 29, 2008),

to revise and consolidate the criteria and processes for designating these shortage areas. On July 23, 2008, HRSA published a notice in the Federal Register indicating that it had received many substantive comments on the proposed rule, and, based on a preliminary review of the comments, it may need to make a number of changes. In HRSA's March 2009 status update of the Compendium, it indicated that, instead of issuing a final regulation as the next step, HHS planned to issue a new notice of proposed rulemaking for further review and public comment before issuing a final rule. As of December 2009, HRSA reported postponing publication to consider the impact of pending health care reform legislation.

Status: We will continue to monitor CMS's and HRSA's efforts to modify certification process requirements.

Related Reports:

2008 MAY *Status of the Rural Health Clinic Program.*
OEI-05-03-00170 [Report](#)

1996 JUL *Rural Health Clinics: Growth, Access, and Payment.*
OEI-05-94-00040 [Report](#)

Medicare Part A and Part B

Practitioners:

Adjust Eye Global Surgery Fees to Reflect the Number of Evaluation and Management Services Actually Being Provided by Physicians (New)

Background: The Medicare program pays for physicians' services furnished on or after January 1, 1992, based on a fee schedule that is updated annually. Fee schedule amounts are based on resources such as physicians' time and intensity of the work (measured in relative value units (RVU) that are involved with furnishing services). CMS must review RVUs at least every 5 years and adjust them as it deems necessary to account for developments such as medical practice or coding changes, new data, or new procedures.

Global surgery fees on the fee schedule include payments for surgical services and the related pre- and post-operative evaluation and management (E&M) services that are provided during the global surgery period. These global fees are based, in part, on CMS's estimates of the number of pre- and post-operative E&M services that physicians typically provide to beneficiaries. CMS compensates physicians for surgical services and the related E&M services included in the fee regardless of the E&M services actually provided during the global surgery period.

Finding(s): Eye global surgery fees often did not reflect the number of E&M services that physicians provided to beneficiaries during the global surgery periods because CMS had not adjusted or only recently adjusted the RVUs for most of the global surgery codes in our sample. The fees reflected the number of E&M services provided during the global surgery periods for 60 of the 300 global surgeries that we sampled. The fees for the remaining 240 global surgeries did not reflect the number of E&M services provided. Physicians provided fewer E&M services than were included in 201 global surgery fees and provided more E&M services than were included in 39 global surgery fees. We estimated that Medicare paid \$97.6 million for E&M services that were included in eye global surgery fees but were not provided during the global surgery periods in CY 2005.

Recommendations: CMS should consider (1) adjusting the estimated number of E&M services within eye global surgery fees to reflect the number of E&M services actually being provided to beneficiaries or (2) using the financial results of the audit, in conjunction with other information, during the annual update of the physician fee schedule.

Savings: \$97.6 million*

**This represents the estimated amount Medicare paid for E&M services that were included in eye global surgery fees but were not provided during the global surgery periods in CY 2005.*

Management Response Summary: In its comments on our 2009 draft report, CMS acknowledged the merit of our findings and said that it will work with the American Medical Association Relative Value Update Committee and the relevant physician specialty societies to identify and correct those services in which the number of E&M services has changed during the global period. CMS noted that OIG did not look at the intensity level of the E&M services that were actually performed. CMS believes it would be prudent to conduct further analysis before proposing any changes in the current number of E&M services assigned to eye surgeries.

Status: We will monitor CMS's actions to address our recommendations.

Related Report:

2009 APR *Nationwide Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005.*
OAS-05-07-00077 [Report](#)

Strengthen Program Safeguards to Prevent Improper Medicare Payments for Facet Joints Injection (New)

Background: Facet joints aid stability, and facet joint injections, an interventional pain management technique, are used to diagnose or treat back pain. Pursuant to the Social Security Act, Medicare will cover these procedures if they are “reasonable and necessary” and only when physicians have furnished appropriate information. Medicare Part B carriers are responsible for implementing program safeguards for these services. Medicare Part B payments for facet joint injections have increased from \$141 million in 2003 to \$307 million in 2006. Over the same period, the number of Medicare claims for facet joint injections increased by 76 percent.

Finding(s): We found that 63 percent of facet joint injection services allowed by Medicare in 2006 did not meet Medicare program requirements, resulting in about \$96 million in improper payments for physician services. Medicare allowed an additional \$33 million in improper payments for associated facility claims. Services provided in an office setting were more likely to have a payment error than those provided in an ambulatory surgical center or a hospital outpatient department. We also found that, in 2006, most carriers had policies and safeguards for facet joint injection services. However, carriers identified limits to using these safeguards. One of those limits is a lack of consensus in the medical community about the frequency with which injections may be administered, which is a barrier to creating frequency limits in local coverage determinations (LCD). Also, edits for facet joint injections are difficult to automate because many require information that is not available on Medicare claims.

Recommendations: CMS should (1) strengthen program safeguards to prevent improper payment for facet joint injection services; (2) clarify billing instructions for bilateral services; and (3) act to resolve the undocumented, medically unnecessary, and miscoded services that we found.

Savings: TBD*

**Study findings estimate \$129 million in potential improper payments. However, because some of the services that were provided may have been covered by Medicare, we are unable to determine savings.*

Management Response Summary: CMS agreed with our recommendations about clarifying billing instructions for bilateral services and taking action on services paid in error in our sample. CMS indicated that it plans to take steps to address the recommendation to strengthen program safeguards, including encouraging carriers to consider automated edits for radiographic imaging where such imaging is already required in their LCDs, and CMS expects that frequency limits will be addressed by the

MACs' annual review of LCDs. CMS provided instructions and educational context regarding the appropriate use of Modifier 59 and add-on codes for facet joint injection services through Change Request 6518 and Medicare Learning Network (MLN) Matters article (Number MM6518), July 2009.

Status: Because of the lack of medical consensus on the frequency issue, OIG is concerned that the MAC will default to the least restrictive requirement, which in some cases could be no limit.

Related Report:

2008 SEP *Medicare Payments for Facet Joint Injection Services.*
OEI-05-07-00200 [Report](#)

Identify and Monitor the Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services (New)

Background: Medicare Part B pays for services that are billed by physicians but are performed by nonphysician practitioners. These services often are called “incident to” services, or services provided under the “incident to” rule and typically are performed in a physician’s office. The “incident to” rule allows physicians to bill for services performed by any personnel, licensed or unlicensed. “Incident to” services must meet Medicare’s general criteria for medical necessity, documentation, and quality of care. Medicare does not require identifiers on claims indicating that the service was furnished “incident to.” Therefore, based on claims data analysis, it is not possible to determine the extent to which physicians are billing for services under “incident to.”

Finding(s): In the first quarter of 2007, we found that, when Medicare allowed physicians more than 24 hours of services in a day, half of the services were not performed personally by a physician. Nonphysicians performed the remaining services, which physicians may have billed as “incident to” services. Medicare allowed \$105 million for services that the physicians personally performed and approximately \$85 million for services that nonphysicians personally performed. Unqualified nonphysicians performed 21 percent of the services that physicians did not perform personally. These nonphysicians did not possess the necessary licenses or certifications, had no verifiable credentials, or lacked the training to perform the service.

Recommendations: (1) CMS should seek revisions to the “incident to” rule. The rule should require that physicians who do not personally perform the services that they bill to Medicare ensure that no one except licensed physicians perform the services or nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations perform the services under the direct supervision of a licensed physician. (2) CMS should require physicians who bill services to Medicare that they do not perform to identify the services on their Medicare claims using a service code modifier. The modifier would allow CMS to monitor claims to ensure that physicians are billing for services performed by nonphysicians with appropriate qualifications. (3) CMS should act to address claims for services that we detected that were billed by physicians and performed by nonphysicians that were, by definition, not “incident to” services and were for rehabilitation therapy services performed by nonphysicians who did not have the training of therapists.

Management Response Summary: CMS concurred with two of our three recommendations. In reference to our first recommendation, CMS is clarifying the manual policies relative to services “incident to” physicians’ services. CMS will provide improved guidance for documenting the qualifications of the persons performing the services. CMS did not concur with our second recommendation to create a service code modifier to identify physicians’ claims for services that physicians do not personally perform. To implement our third recommendation, CMS issued Transmittal 574 (Change Request 6655) to the MACs, instructing them to review claims data for “incident to” services. CMS requested contractors to consider information contained in this report when prioritizing their review strategies.

Status: We continue to recommend that CMS acquire the ability to identify and monitor claims for services that physicians do not personally perform, and we will continue to monitor CMS’s implementation of the recommendations associated with this review.

Related Report:

2009 SEP *Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services.* OEI-09-06-00430 [Report](#)

Prevent, Detect, and Resolve Improper Payments For Noncovered Chiropractic Services (New)

Background: Medicare pays only for medically necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. When submitting claims, chiropractors must use the acute treatment modifier to identify services that are active/corrective treatment and must document services pursuant to CMS's *Medicare Benefit Policy Manual*. When further improvement cannot reasonably be expected from continuing care, the services are then considered maintenance therapy, which is not medically necessary and therefore not payable under Medicare. Previous OIG work found significant vulnerabilities existed in connection with chiropractic claims, particularly concerning Medicare payments for maintenance therapy.

Finding(s): We found that (1) Medicare inappropriately paid \$178 million for chiropractic claims in 2006, representing 47 percent of claims meeting our study criteria; (2) efforts to stop payments for maintenance therapy have been largely ineffective; (3) claims data lack initial visit dates for treatment episodes, hindering the identification of maintenance therapy; and (4) chiropractors often do not comply with documentation requirements.

Recommendations: CMS should (1) implement and enforce policies, such as a cap on allowed chiropractic claims, to prevent payments for maintenance therapy; (2) review treatment episodes rather than individual chiropractic claims to strengthen the ability of the Comprehensive Error Rate Testing program (CERT) to detect errors in chiropractic claims; (3) ensure that chiropractic claims are not paid unless documentation requirements are met; and (4) act to resolve the undocumented, medically unnecessary, and miscoded claims that we found in our sample.

Savings: \$178 million*

**Based on OIG's medical review of 2006 chiropractic claims.*

Management Response Summary: CMS did not indicate agreement or disagreement with the first recommendation. However, it agreed with the second recommendation and described actions it would take to address the third and fourth recommendations. In response to the first recommendation, CMS said that the objective data required to impose a national cap on the number of chiropractic services does not exist. In response to the second recommendation, CMS indicated that it would have to conduct a cost-benefit analysis to determine the utility of expanding this review to

include claims beginning with the first claim of the treatment episode. In response to the third and fourth recommendations, CMS issued Transmittal 574 (Change Request 6655) in October 2009, instructing the MACs to review claims data, particularly for chiropractic services. The transmittal also instructs MACs to take appropriate action consistent with their individual prioritized strategy, such as establishing automated prepayment reviews, developing postpayment reviews, and educating physicians and suppliers if the data warrant any action. CMS recently indicated that it will determine if additional policies are needed to prevent improper payments. CMS will explore the feasibility of requiring that all documentation requirements be met before chiropractic claims are paid.

Status: We continue to recommend that CMS implement and enforce policies to prevent future payments for maintenance therapy and that CMS ensure that chiropractic claims are not paid unless documentation requirements are met.

Related Report:

2009 MAY *Inappropriate Medicare Payments for Chiropractic Services.*
OEI-07-07-00390 [Report](#)

Medicare Part A and Part B

Laboratory and Imaging Services:

Review Payment Levels and Reinstate Beneficiary Cost Sharing for Laboratory Services

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

Finding(s): Our 1996 report found that Medicare paid clinical laboratories more than was paid to physicians for the same tests. Our 1990 report found that clinical laboratories marketed customized panels to physicians at less than the amount paid by Medicare for the same tests, contributing to a significant increase in the use of laboratory services.

Recommendations: CMS should (1) review payment levels for lab tests and (2) reinstate the beneficiary coinsurance and deductible provisions for lab tests as a means of controlling utilization.

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

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

Management Response Summary: In its comments on the draft of our 1996 report, CMS partially concurred with our recommendations and noted that it had taken steps to reduce payments for lab tests. The BBA required the Secretary of HHS to request that the Institute of Medicine (IOM) conduct a study of Part B lab test payments. As a result of the IOM’s recommendations, section 302(b) of the MMA mandated that CMS conduct a demonstration that applies competitive bidding to clinical laboratory tests that would otherwise be paid under the Medicare Part B fee schedule.

In December 2005, CMS submitted to Congress the initial report on the demonstration. However, before CMS could complete the demonstration, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 145(a), repealed the project for Medicare clinical laboratory tests paid under the Medicare Part B fee schedule. In addition, section 145(b) of MIPPA specifies that the annual clinical laboratory fee schedule update will be reduced each year from 2009 through 2013 by 0.5 percentage points. The update for 2009 equals a 4.5-percent increase for payments made under the Medicare Part B Clinical Laboratory Fee Schedule.

CMS did not concur with our 1996 recommendation to reinstate beneficiary coinsurance and deductible provisions for laboratory services, noting that the President's 1996 budget statement did not include such a proposal.

Status: Although legislation has reduced the prices for individuals' tests, we continue to recommend that CMS evaluate payments for lab tests. 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 lab tests.

Related Reports:

- 1996 JAN *Follow-up to Report on Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests.* OAS-09-93-00056 [Report](#)
- 1990 JAN *Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests.* OAS-09-89-00031 [Report](#)

Establish a New Payment Rate-Setting Process for Laboratory Tests (New)

Background: Medicare Part B covers most outpatient clinical diagnostic lab tests and pays 100 percent of their costs because there are no beneficiary copayments or deductibles for lab tests. In 2007, lab tests accounted for 3 percent of all Medicare Part B payments. Payments are determined by the Clinical Laboratory Fee Schedule, which comprises rates established by each regional carrier, subject to the National Limit Amount (NLA) cap mandated by COBRA. At the time of this report, the NLA was set at 74 percent of the median carrier rate. Carriers pay laboratories the lower of the laboratories' charges or the carrier rate as capped by the NLA.

Finding(s): We found that carrier rates for nearly all lab tests varied. Eighty-three percent of carrier rates were at the NLA, and 89 percent of lab test claims were paid at the NLA. Variation from the NLA was inconsistent within each carrier and thus did not appear to reflect geographic differences in costs. Carriers pay different rates for the same lab test, so Medicare payments also vary. Medicare paid more than \$3.4 billion for lab tests in 2007. Finally, Medicare payments would have been \$3.5 billion if all of the tests had been paid at the NLA. Setting all carrier rates at 73 percent of the median carrier rate would have eliminated variation without a change in overall Medicare payments.

Recommendation: CMS should seek legislative authority to establish a new process for setting accurate and reasonable payment rates for lab tests.

Savings: Budget neutral to \$1 billion*

**If CMS were able to set payment rates at 50 percent of the median carrier rate, Medicare payments would have been reduced to \$2.4 billion, a reduction of \$1 billion. If CMS were able to set payment rates at 73 percent of the median carrier rate, overall payments would remain the same, but variations would be eliminated.*

Management Response Summary: CMS did not agree with our recommendation to seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. CMS said it would take our recommendation into consideration as it continues to monitor the effects of its payment policies.

Status: We continue to encourage CMS to pursue legislation that would set accurate and reasonable payment rates for lab tests.

Related Report:

2009 JUL *Variation in the Clinical Laboratory Fee Schedule.* OEI-05-08-00400 [Report](#)

Monitor Medicare Part B Billing for Ultrasound (New)

Background: Medicare covers ultrasound as a diagnostic service under the Social Security Act, § 1861(s)(3). Medicare generally covers specified ultrasound procedures and will cover additional procedures if they are clinically effective and medically justified. Medicare divides imaging services into two components: the technical component, which is the taking of the image, and the professional component, which is the doctor interpreting the image. The technical component of ultrasound services provided in ambulatory settings, such as doctors' offices and Independent Diagnostic Testing Facilities, is covered under Part B. The technical component of services provided in institutional settings, such as hospitals and hospital outpatient departments, is covered under Part A. The professional component of ultrasound is always covered under Part B, regardless of setting.

Finding(s): We found that in 2007, 20 high-use counties accounted for 16 percent of Part B spending on ultrasound services despite having only 6 percent of Medicare beneficiaries. We also found that 3.2 million claims, or nearly one in five ultrasound claims nationwide, had characteristics that raise concern about whether the claims were appropriate. These claims represent \$403 million in Part B charges. Finally, we found that certain suppliers billed for a large number of ultrasound claims with questionable characteristics.

Recommendations: CMS should (1) monitor ultrasound claims data to detect questionable claims and (2) take action when suppliers bill for high numbers of questionable claims for ultrasound services.

Savings: TBD*

**Based on a review of 2007 Part B claims data.*

Management Response Summary: CMS concurred with both recommendations. In October 2009, CMS issued Transmittal 574 (Change Request 6655), instructing the MACs to review claims data, particularly for ultrasound services. In addition, the transmittal also instructs MACs to take appropriate action consistent with their individual prioritized strategy, such as establishing automated prepayment reviews, developing postpayment reviews, and educating physicians/suppliers if the data warrant any action. CMS stated that it would take appropriate action to forward the listing of questionable claims, identified by OIG, to the Recovery Audit Contractors (RAC) and MACs. It also indicated that it had shared this report with its program integrity contractors.

Status: We continue to monitor CMS's efforts to reduce Medicare's vulnerability to questionable claims for ultrasound services including CMS actions with regard to providers identified by OIG that may have been inappropriately paid.

Related Report:

2009 JUL *Medicare Part B Billing for Ultrasound.* OEI-01-08-00100 [Report](#)

Medicare Part A and Part B

Claims Processing:

Review Use of Modifier 59 With Billing Codes and Ensure Correct Payments

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. 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.

Recommendations: CMS should (1) encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59 and (2) ensure that the carriers' claims-processing systems pay claims with modifier 59 only when the modifier is billed with the correct code.

Savings: \$59 million*

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

Management Response Summary: CMS concurred with our recommendations to encourage carriers to conduct prepayment and post-payment reviews of the use of modifier 59 and to ensure that carriers' claims-processing systems pay claims only when modifier 59 is billed with the secondary code. However, CMS reported in its comments

that it was unable to implement system edits to ensure correct coding at the time of the report. In April 2006, CMS published clarifying guidance to chapter 4 of the *Medicare Claims Processing Manual*, which includes the use of modifier 59 (Change Request 4388). In April 2008, CMS issued an MLN Matters article (classified as Special Edition 0810) to provide continuing education to physicians on how to bill modifier 59 appropriately. In its December 2009 comments, CMS indicated that it would explore the development of an edit for modifier 59.

Status: We will continue to monitor CMS's efforts to implement edits to ensure correct coding.

Related Report:

2005 NOV *Use of Modifier 59 To Bypass Medicare's National Correct Coding Initiative Edits.* OEI-03-02-00771 [Report](#)

Medicare Part A and Part B

Dialysis Facilities:

Reduce Medicare End Stage Renal Disease Payment Rates

Background: The Medicare program includes coverage for eligible persons suffering from kidney failure under the end stage renal disease (ESRD) program. The ESRD program currently covers outpatient dialysis items and services for over 400,000 beneficiaries with ESRD. The Omnibus Budget Reconciliation Act of 1981 (OBRA 1981) established a PPS for outpatient dialysis treatments under Medicare's ESRD program. To reimburse ESRD dialysis facilities for these treatments, CMS pays a composite rate per treatment based on audited median costs. The composite rate covers the costs of items and services related to the dialysis treatment such as labor costs, related supplies, routine tests, and certain drugs. Other items and services, such as injectable drugs, and nonroutine laboratory tests are not included in the composite rate and are billed separately to Medicare. In 2003, Congress included provisions to reform drug reimbursement in the MMA. The MMA required that Medicare base payments for certain ESRD drugs on their acquisition costs as determined by OIG.

Finding(s): The OIG, through a body of work examining the appropriateness of payments for ESRD services, concluded that payments for ESRD services are excessive and need to be adjusted. In a 1990 audit of 1985 ESRD payments under the composite rate, we determined that a median cost per treatment, including home dialysis costs, was less than the average payment rate. 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. We recommended that the Medicare reimbursement rates reflect the cost of dialysis treatment in efficiently operated facilities.

In the early to late 1990's, we issued numerous reports concerning the excessive Medicare payments for separately billable items such as ESRD drugs. In a 1992 audit, we suggested that CMS consider folding all separately billable drugs into the composite rate to achieve savings on administrative costs and reduce payment errors. In a 1993 audit of the reimbursement of the drug Epogen under the Medicare ESRD program, we indicated that dialysis providers were being overpaid for Epogen and we suggested a reduction in the reimbursement rate. In 1997, OIG conducted a followup review of Medicare reimbursement for Epogen and found that the reimbursement rate, which at that time was \$10 per 1,000 units administered, exceeded the cost of purchasing Epogen by approximately \$1 per 1,000 units. In June 2000, OIG issued another report on ESRD

drugs which found that the Department of Veterans Affairs paid between 37 percent and 56 percent less than Medicare for five high-expenditure ESRD drugs.

The OIG conducted two studies, as mandated by MMA, related to Medicare reimbursement for ESRD drugs. In the first study, the OIG reported in May 2004 that the four largest freestanding corporate dialysis providers and a random sample of freestanding nonchain dialysis facilities were able to acquire 10 high-expenditure drugs at costs averaging 14 to 22 percent below the Medicare reimbursement amounts. For the second study, with a report issued in March 2006, we evaluated Medicare payments for the drug Aranesp because it accounted for 99.9 percent of Medicare reimbursement for new ESRD drugs. We found that, on average, responding freestanding dialysis facilities were able to acquire Aranesp for between 14 and 27 percent below the Medicare reimbursement amounts in 2005. We concluded that responding facilities, on average, could acquire the majority of ESRD drugs at prices below Medicare reimbursement amounts and that aggregate acquisition costs were below aggregate Medicare reimbursement amounts.

Through audits and investigations, the OIG has also identified instances of improper billing and utilization of services in ESRD facilities, including inappropriate billing for services outside the composite rate and the provision of medically unnecessary services. In a 2004 audit, we found that 44 of the 143 claims reviewed did not meet Medicare payment requirements for Epogen. In an audit report issued in April 2009, we reported that dialysis facilities incorrectly billed for laboratory tests that were not included in the composite rate, and claims did not comply with Medicare requirements.

Recommendation: CMS should fold all ESRD services into the composite rate and reduce the ESRD payment rates for outpatient dialysis services to reflect current efficiencies and economies in the marketplace. We believe that this would achieve savings and reduce payment errors.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: The Tax Relief and Health Care Act of 2006 (TRHCA), Division B, Title 1, § 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. Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) replaces the current basic case-mix adjusted composite payment system with a bundled ESRD prospective payment system, or the ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011.

Status: Although legislative mandates have increased the composite payment rates for outpatient dialysis treatments, we continue to recommend that these rates should reflect

the costs in efficiently operated facilities and that the reimbursement amounts for ESRD drugs should reflect the cost to acquire the drug. OIG remains committed to ensuring that Medicare ESRD beneficiaries receive quality services and that this care is being reimbursed at appropriate levels. Therefore, we will continue to conduct audits, evaluations, and investigations, as warranted, to oversee payment and quality of care at ESRD facilities. We plan to reexamine whether the payment rates for outpatient dialysis services reflect current efficiencies and economies in the marketplace.

Related Reports:

- 2009 APR *Review of Separately Billed Laboratory Tests Paid by National Government Services, Inc., for Medicare Beneficiaries With End-Stage Renal Disease.* OAS-01-07-00522 [Report](#)
- 2006 MAR *Medicare Reimbursement for New End Stage Renal Disease Drugs.* OEI-03-06-00200 [Report](#)
- 2004 MAY *Medicare Reimbursement for Existing End Stage Renal Disease Drugs.* OEI-03-04-00120 [Report](#)
- 2004 APR *Review of Medicare Payments to DaVita Inc. for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania.* OAS-03-03-0003 [Report](#)
- 2000 JUN *Medicare Reimbursement of End Stage Renal Disease Drugs.* OEI-03-00-00020 [Report](#)
- 1997 NOV *Review of EPOGEN Reimbursement.* OAS-01-97-00509 [Report](#)
- 1993 FEB *Review of EPOGEN Reimbursement.* OAS-01-92-00506 [Report](#)
- 1992 OCT *Cost of Dialysis-Related Drugs.* OAS-01-91-00526 [Report](#)
- 1990 JUL *Management Advisory Report: Reductions Continue To Be Needed in Medicare's End Stage Renal Disease Dialysis Rates.* OAS-14-90-00215 [Report](#)

See Also:

- 2007 JUN *OIG Testimony before House Committee on Ways and Means: "OIG Work Related to Payment and Quality at Dialysis Facilities."* [Testimony](#)

Improve the Availability of Quality-of-Care Data on Dialysis Treatments

Background: Patients with ESRD rely on dialysis treatment to compensate for kidney failure. In 2000, OIG and the GAO issued reports documenting problems with CMS's oversight of ESRD dialysis facilities. Since then, 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. Our work assessed the extent to which data were available to help networks identify facilities with quality improvement needs.

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

Recommendations: CMS should (1) develop facility-specific quality improvement information and (2) increase its efforts to regularly collect data on all of the CPMs that were identified by CMS to address quality-of-care issues in the ESRD program.

Management Response Summary: CMS did not indicate whether it concurred with our recommendations. The agency said that it had made progress in collecting data to improve the quality of care in the ESRD program and indicated that opportunities for improvement remain. CMS said that steps had been taken to improve quality of care in the ESRD program, including the development of CPMs, definition of the core data set, and proposed regulations that would require facilities to electronically submit CPMs on ESRD patients. CMS also said that it would develop a new Web-based data collection system called Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which would consolidate data sources into one system. On April 15, 2008, CMS published final rule CMS-3818-F, *Conditions for Coverage for End Stage Renal Disease Facilities*, which established new conditions that facilities must meet to be certified under the Medicare program. The rule states that beginning on February 2, 2009, ESRD facilities must electronically collect and report to CMS on an ongoing basis the administrative and CPM data annually for eligible ESRD patients via CROWNWeb. In February 2009, CMS began implementing the CROWNWeb System with a number of providers/facilities and plans to expand reporting to more providers/facilities as soon as

practicable. In December 2009, CMS reported that it had implemented Phase II of the CROWNWeb System rollout with an increased number of providers and facilities.

Status: We will continue to monitor CMS's implementation of CROWNWeb.

Report:

2006 NOV *Availability of Quality of Care Data in the Medicare End Stage Renal Disease Program.* OEI-05-05-00300 [Report](#)

See Also:

2007 JUN *OIG Testimony before House Committee on Ways and Means: "OIG Work Related to Payment and Quality at Dialysis Facilities."* [Testimony](#)

Medicare Part A and Part B

Medical Equipment and Supplies:

Ensure Medical Equipment Suppliers' Compliance With Medicare Enrollment Standards

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

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

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

Recommendations: CMS should (1) strengthen the Medicare DMEPOS supplier enrollment process, ensuring that suppliers meet Medicare supplier standards, e.g., (a) conduct more unannounced site visits to suppliers to determine whether suppliers exist at the addresses on record, (b) perform more rigorous background checks of applicants, (c) assess the fraud risk of suppliers and focus monitoring and enforcement on high-risk suppliers, (d) increase prepayment review of

DMEPOS claims, (e) require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years, and (f) establish a minimum number of hours of operation and minimum inventory requirements for product and service types; (2) require DMEPOS suppliers to (a) pay a Medicare enrollment application fee to cover the costs of criminal background checks and site inspections; (b) pay an additional Medicare enrollment fee if, during a site visit conducted during business hours, the supplier's facility is closed or inaccessible; and (3) seek legislative authority to impose temporary moratoriums, as needed, on supplier enrollment in high-fraud areas.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: In its comments to our first report issued in 2007, CMS either agreed with or stated that it would consider the options we recommended for strengthening the Medicare DMEPOS supplier enrollment process. In assessing each newly enrolled or existing supplier, the agency has taken action to implement some of the suggested options, including revising the NSC contractual requirements to increase the number of unscheduled site visits, deactivating suppliers who have not billed the Medicare programs for 12 months, adding additional DMEPOS supplier standards, requiring DMEPOS suppliers to post a surety bond, enhancing review of new DMEPOS enrollment applications in South Florida, prioritizing reenrollment applications over processing new applications in highly vulnerable areas of the country, and conducting targeted background checks on suppliers with high fraud potential.

In reference to the competitive bidding program, CMS fully implemented accreditation for all suppliers of DMEPOS by September 30, 2009. CMS announced on October 6, 2009, a seven-State, stop-gap program to address fraud. The stop-gap program is focused on high-volume, high-risk DMEPOS suppliers, physicians, beneficiaries, and equipment and supplies. On November 1, 2007, CMS began a 2-year demonstration project involving DMEPOS suppliers in specific counties. This demonstration recently concluded, and CMS is evaluating the results of the demonstration to determine if more frequent reenrollment requirements in high-vulnerability areas should be implemented. CMS published a regulation at 73 Fed. Reg. 4503 (January 25, 2008), 42 CFR Part 424, to clarify and enhance supplier standards. In its comments on our second report, issued in February 2008, CMS said that suppliers must pay a fee to the accrediting organization for an initial site visit and that "criminal background checks are conducted as required by State standards." In finalizing that report, we noted, however, that our recommendation is that site inspection and application fees would be paid to the Federal

Government, not the accrediting organization. CMS also stated that it would consider seeking legislative authority to impose temporary moratoriums on supplier enrollment.

Status: We continue to monitor CMS's implementation of program safeguards in the area of DMEPOS, including actions related to temporary moratoriums on supplier enrollments and statutory delay for implementation of competitive bidding.

Related Reports:

2008 FEB *Los Angeles County Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits.* OEI-09-07-00550 [Report](#)

2007 MAR *South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits.* OEI-03-07-00150 [Report](#)

See Also:

2010 MAR *OIG Testimony Before the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies: "Miami Strike Force."* [Testimony](#)

2007 APR *OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Health: "Medicare Integrity and Enrollment Safeguards for Medical Equipment Suppliers."* [Testimony](#)

Reduce the Rental Period for Home Oxygen Equipment

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

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

Recommendations: CMS should (1) work with Congress to further reduce the rental period for oxygen equipment, (2) determine the necessity and frequency of nonroutine maintenance and servicing for concentrators, and (3) determine whether a new payment methodology is appropriate for portable oxygen.

Savings: \$3.2 billion*

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

Management Response Summary: CMS concurred with our recommendations. With regard to the first recommendation, reducing the rental period for most oxygen equipment from 36 to 13 months requires a statutory change. Although bills have been introduced in the past, none has passed. Concerning our second recommendation, on November 2, 2006, CMS issued a final rule that changed how Medicare will pay for oxygen and oxygen equipment. This policy change implemented our recommendations on nonroutine maintenance and servicing and established a new payment methodology for portable oxygen.

Status: We continue to encourage CMS to work with Congress to reduce the rental period.

Related Report:

2006 SEP *Medicare Home Oxygen Equipment: Cost And Servicing.*
OEI-09-04-00420 [Report](#)

Ensure That National Provider Identifiers on Medical Equipment and Supply Claims are Valid and Active (New)

Background: Medicare beneficiaries are eligible to receive medical equipment and supplies deemed medically necessary by a physician under Medicare Part B coverage. In 2007, Medicare allowed almost \$11 billion for medical equipment and supplies. COBRA required CMS to establish unique physician identification numbers (UPIN) for all physicians who provide services to Medicare beneficiaries. A physician was allowed to obtain only one UPIN, but a UPIN may have been associated with more than one practice setting. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required CMS to create national provider identifiers (NPI) to replace UPINs for Medicare claims processing. Medicare instructions require a supplier to provide its own identification number, as well as that of the referring physician. From May 2005 to May 2008, Medicare accepted claims that included UPINs only, NPIs only, or a combination of both.

Finding(s): We found that Medicare allowed more than \$6 million for medical equipment and supply claims with invalid referring physician UPINs in 2007. We also found that Medicare allowed almost \$28 million for claims with inactive referring physician UPINs in 2007, including \$5 million for claims with dates of service after the dates of death of the referring physicians. Medicare also allowed more than \$300,000 for claims with invalid referring physician NPIs in 2007.

Recommendations: CMS should (1) determine why Medicare claims with identifiers associated with deceased referring physicians continue to be paid, (2) implement claims-processing system changes to ensure that NPIs for referring physicians and suppliers listed on medical equipment and supply claims are valid and active, (3) emphasize to suppliers the importance of using accurate NPIs for referring physicians and suppliers when submitting Medicare claims, and (4) determine the earliest date to end the provision that allows suppliers to submit claims without referring physician NPIs while maintaining beneficiary access to services.

Savings: \$34 million*

**Actual amounts in our findings are \$6.1 million for Medicare-allowed amounts for claims with invalid referring physician UPINs and \$27.8 million for Medicare-allowed amounts for claims with inactive referring physician UPINs.*

Management Response Summary: CMS concurred with our recommendations. CMS said that it deactivates Medicare billing privileges of physicians who have not

billed Medicare for 12 consecutive months. CMS also said that it has developed procedures to (1) ensure that the Medicare billing privileges of deceased physicians are promptly terminated and (2) reject claims if the referring physician is not enrolled in Medicare or is not of the medical specialty that can refer. CMS said that it was providing physician and contractor education on the matter. CMS did not address our recommendation that it should determine the earliest date to end the provision that allows suppliers to submit claims without referring physician NPIs while maintaining beneficiary access to services. However, CMS indicated that it will review the provision that allows suppliers to submit claims without referring physician NPIs.

Status: If CMS’s review results in an end date for this provision, that action will close our recommendation with regard to the recommendations specific to this report. However, we continue to do work in this area and have a study underway to determine the extent to which Medicare has paid medical equipment and supply claims that were submitted without referring physician NPIs.

Related Report:

2009 FEB *Medicare Payments in 2007 for Medical Equipment and Supply Claims With Invalid or Inactive Referring Physician Identifiers.*
OEI-04-08-00470 [Report](#)

See Also:

2008 JUL OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations: “Unique Physician Identifiers on Medical Equipment and Supply Claims and Related Issues.” [Testimony](#)

Ensure That Part B Payments are Appropriate for Beneficiaries' Medical Equipment During Non-Part A Nursing Facility Stays (New)

Background: The BIPA requires OIG to monitor Medicare Part B payments during non-Part A nursing home stays. Medicare Part A covers nursing home care for up to 100 days in SNF. If nursing home care is needed after the 100 days or the beneficiary did not qualify for a Part A SNF stay, Medicare Part B may cover certain medical and other health services. However, Part B does not pay for DME unless the nursing home qualifies as the beneficiary's home. Pursuant to the Social Security Act, § 1861(n), a nursing home is excluded from qualifying as a beneficiary's home for DME payments when the nursing home is engaged primarily in providing skilled nursing care. Only a small number of nursing homes may qualify as a beneficiary's home.

Finding(s): We found that \$30 million was inappropriately allowed for DME during non-Part A SNF stays in 2006. Also, we found that Medicare allowed an additional \$11.9 million for DME provided during non-Part A stays in Medicaid nursing facilities (NF) and distinct part nursing homes. CMS and States reported that they do not maintain primary level-of-care designations for nursing homes. Such designations could facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

Recommendations: CMS should (1) use electronic resident assessment data contained in the Minimum Data Set (MDS) to establish a routine process to periodically (e.g., annually) generate a list of non-Part A beneficiary stays in nursing homes that primarily provide skilled care or rehabilitation, (2) implement a process or processes to identify patients entering nursing homes with rented DME, (3) determine which NFs and distinct part nursing homes primarily provide skilled care, thus not qualifying as a beneficiary's home for DME payment purposes, and (4) direct contractors to recoup the inappropriate payments identified in this report.

Savings: \$30 million*

**Suppliers received payments totaling \$30,485,842 for the 309,626 DME claims allowed for Medicare beneficiaries during non-Part A stays in nursing homes certified as SNFs or dually certified as SNF/NFs. Because these nursing homes were primarily providing skilled care or rehabilitation, they could not be considered the beneficiaries' homes, a prerequisite for DME coverage.*

Management Response Summary: CMS concurred with our first recommendation and will seek to provide Medicare Recovery Audit Contractors access to the minimum data set to periodically check whether beneficiaries who received Part B DME services were residents of nursing homes that do not qualify as a beneficiary's home. Although CMS agreed with the underlying objectives, it did not concur with our recommendations to expand the MDS and use the Online Survey Certification and Reporting system as a way to designate NFs or distinct part nursing homes that qualify as a beneficiary's home. CMS suggested alternative approaches using claims processing edits to address these two recommendations. CMS indicated in its December 2009 update on the status of the recommendations that billing system changes are under development and scheduled to be implemented with the July 2010 quarterly release.

Status: We will continue to monitor the implementation of our recommendations.

Related Report:

2009 JUL *Part B Services During Non-Part A Nursing Home Stays: Durable Medical Equipment.* OEI-06-07-00100 [Report](#)

Adjust Acquisition Costs and Services for Power Wheelchairs (New)

Background: Medicare beneficiaries are eligible to receive power wheelchairs under Medicare Part B coverage of DME. Medicare beneficiaries receive power wheelchairs from suppliers that bill the Medicare program for reimbursement. In 2007, about 173,300 Medicare beneficiaries received power wheelchairs, at a total cost of \$686 million. Medicare's fee schedule amounts are based on manufacturer-suggested retail prices. They include reimbursement for wheelchair acquisition cost and services performed in conjunction with providing the wheelchair, such as assembling and delivering it and educating the beneficiary about its use. OIG compared Medicare payments for power wheelchairs with suppliers' acquisition costs and determined the number and types of services that suppliers performed in conjunction with providing power wheelchairs to Medicare beneficiaries.

Finding(s): The findings of this evaluation suggest that CMS's current methodology for developing power wheelchair fee schedule amounts does not reflect actual acquisition costs. We found that during the first half of 2007, Medicare and its beneficiaries paid almost two times the average amount that suppliers paid to acquire complex rehabilitation power wheelchair packages and almost four times the average amount to acquire standard power wheelchairs. Medicare's average allowed amount of \$4,018 for standard power wheelchairs was 383 percent of suppliers' average acquisition cost. The Competitive Bidding Acquisition Program would have reduced the average Medicare payment for standard power wheelchairs to \$3,073, amounting to 293 percent of suppliers' average acquisition cost. To offset the Competitive Bidding Acquisition Program's delay, Medicare's 2009 fee schedule amount was reduced to \$3,641, exceeding the average competitively bid price by \$568. Similarly, Medicare and its beneficiaries paid suppliers an average of \$2,970 beyond the suppliers' acquisition costs to cover general business costs and to perform an average of five services. Medicare and its beneficiaries paid an average of \$5,627 beyond the costs to cover general business costs and to perform an average of seven services.

Recommendation: CMS should determine whether Medicare's fee schedule amounts for standard and complex rehabilitation power wheelchairs should be adjusted by (1) using information from the Competitive Bidding Acquisition Program, (2) seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, or (3) using its inherent reasonableness authority.

Savings: \$84 million*

**We based our estimated savings on the assumption that in 2007 more than 147,000 Medicare beneficiaries received power wheelchairs. Based on the current fee schedule, which was reduced by 9.5 percent, each wheelchair was reimbursed at an average of \$568 greater than the amount by which the current Medicare fee schedule exceeded the average competitively bid price.*

Management Response Summary: CMS concurred with our recommendation and with two of our recommended methods to determine whether Medicare’s fee schedule amounts for standard and complex rehabilitation power wheelchairs should be adjusted. CMS said that it plans to use information from the Competitive Bidding Acquisition Program for its analysis and will consider seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. CMS noted that it is not likely to use its inherent reasonableness authority until the results of the supplier bids for power wheelchairs under the Competitive Bidding Acquisition Program have been assessed.

Status: OIG will continue to monitor CMS’s progress on implementing our recommendations.

Related Report:

2009 AUG *Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services.* OEI-04-07-00400 [Report](#)

See Also:

2007 OCT *A Comparison of Medicare Program and Consumer Internet Prices for Power Wheelchairs.* OEI-04-07-00160 [Report](#)

2004 APR *A Comparison of Prices for Power Wheelchairs in the Medicare Program.* OEI-03-03-00460 [Report](#)

2004 APR *Medicare Payments for Power Wheelchairs.* OEI-03-02-00600 [Report](#)

2004 APR OIG Testimony Before the Senate Committee on Finance: “Abuses of the Medicare Wheelchair Benefit.” [Testimony](#)

Ensure That Claims for Pressure-Reducing Support Surfaces Meet Coverage Criteria (New)

Background: Pressure-reducing support surfaces are used in the care or prevention of pressure ulcers. Pressure ulcers, also known as bed sores or decubitus ulcers, occur commonly among the elderly and individuals with spinal cord injuries. Support surfaces are covered under Medicare Part B as DME. CMS categorizes support surfaces into three groups based on the complexity of their features. Group 2 is the largest, accounting for 80 percent of all support surface payments. OIG assessed the appropriateness of Medicare payments for group 2 pressure-reducing support surfaces and identified the program safeguards that are in place to ensure proper payments.

Finding(s): Based on a review of medical record documentation and supplier documentation, 86 percent of group 2 support surface claims for the first half of 2007 did not meet Medicare coverage criteria. This amounted to an estimated \$33 million in inappropriate payments during that time. We also found that CMS contractors had limited safeguards in place to prevent improper payments for group 2 support surfaces. CMS contractors reported that they relied primarily on two claims processing edits to prevent improper payments for support surfaces. None of the CMS contractors conducted any widespread medical reviews of support surface claims. Also, only half of the CMS contractors responsible for supplier education conducted any educational activities in recent years that focused on group 2 support surfaces.

Recommendations: CMS should (1) ensure that claims for group 2 support surfaces meet Medicare coverage criteria and are paid appropriately and (2) act to resolve the claims in our sample that were inappropriate.

Management Response Summary: CMS concurred with our recommendations and said that it will share OIG's findings on inappropriate claims with its contractors for potential additional prepayment edits and prepayment medical review. It also noted that it will revise instructions to clarify that contractors may initiate widespread service-specific prepayment reviews without first conducting "probe" reviews for problem areas identified by various parties, including OIG. CMS also said that it will issue an MLN Matters article to remind suppliers and health care providers about Medicare coverage criteria for support surfaces. CMS mentioned that it is reviewing the utility and use of the KX modifier, including its application in DME claims. It also stated that it plans to share our recommendation about conducting additional statistical analyses with price data analysts and coding contractors for their consideration in monitoring group 2 pressure-reducing support surface claims. CMS said that once it reviews the inappropriate claims and better understands their nature, it will forward them to the contractors.

Status: We continue to monitor CMS's progress in this area.

Related Report:

2009 AUG *Inappropriate Medicare Payments for Pressure Reducing Support Surfaces.*
OEI-02-07-00420 [Report](#)

Adjust Reimbursement for Negative Pressure Wound Therapy Pumps (New)

Background: Negative pressure wound therapy pumps are portable or stationary devices used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. When Medicare started covering pumps in 2001, it covered only one model, which was produced and supplied by a single manufacturer. Since then, a number of manufacturers have introduced pump models and are charging substantially less for them. CMS requires suppliers to communicate with beneficiaries' clinicians to determine whether the beneficiaries still qualify for Medicare coverage of the pumps. This study compares the prices that suppliers paid for new negative pressure wound therapy pump models to Medicare's purchase prices.

Finding(s): Suppliers paid an average of \$3,604 for new pump models, compared with Medicare's reimbursement rate of \$17,165. Medicare reimbursed suppliers for these pumps based on a purchase price that was four times the average price paid by suppliers. Suppliers acquired one-quarter of the new pump models by leasing, renting, or exchanging them. We found that suppliers reported not always communicating with almost one-quarter of beneficiaries' clinicians, as required.

Recommendations: CMS should reduce Medicare's reimbursement amount for the pump and consider the following methods to reduce the reimbursement amount: (1) use its inherent reasonableness authority to reduce the reimbursement amount for the pump, and include the pump in the second round of the Competitive Bidding Acquisition Program; (2) continue to monitor the growth of the new pump market; (3) educate suppliers of new pump models on the importance of communication with beneficiaries' treating clinicians; and (4) follow up on the claims that we identified that may be inappropriate.

Management Response Summary: CMS concurred with three of our four recommendations and partially concurred with one. CMS said that it will consider the recommendation about including pumps when designing the second round of the Competitive Bidding Acquisition Program. It noted that it has worked on a number of regulatory and administrative initiatives related to the prescription, coding, and coverage of pumps in response to the significant growth in expenditures for these items. CMS concurred that it has the authority to adjust payment rates using Medicare's inherent reasonableness authority. It said that it will consider whether it would be able to gather valid and reliable data to make a determination that the payment amount for pumps is grossly deficient or excessive and to establish, if needed, a new amount that is realistic and equitable. CMS said that it will monitor and track trends in utilization of

pumps and track the market share among pump suppliers. CMS also concurred with our recommendation to educate pump suppliers on the importance of communication with clinicians who treat beneficiaries. CMS concurred with our recommendation to follow up on pump claims that may be inappropriate and said that it is working with its contractors to strengthen its oversight in this area.

Status: We encourage CMS to include negative pressure wound therapy items in its second round of competitive bidding.

Related Report:

2009 MAR *Comparison of Prices for Negative Pressure Wound Therapy Pumps.*
OEI-02-07-00660 [Report](#)

Strengthen the Appeal Process for Medicare Equipment Suppliers in South Florida (New)

Background: CMS may deny or revoke a DME supplier's billing privileges if the supplier fails to comply with Medicare standards. In March 2007, OIG issued a report about South Florida suppliers and referred 491 suppliers that it had identified as likely being noncompliant with Medicare standards to CMS. CMS revoked these suppliers' billing privileges and some appealed. OIG conducted a review of the evidence that hearing officers reviewed as part of the suppliers' appeals and the results of the appeals.

Finding(s): We found that nearly half of the 491 revoked South Florida suppliers appealed and received hearings. Hearing officers reinstated billing privileges for 91 percent of the suppliers. We found that because there are no criteria regarding the types of evidence necessary to reinstate the billing privileges of suppliers, hearing officers reinstated the suppliers' billing privileges based on a variety of evidence. Finally, we found that two-thirds of suppliers whose billing privileges were reinstated subsequently had their privileges revoked or inactivated and that some individuals connected to reinstated suppliers had been indicted.

Recommendation: CMS should strengthen the appeal process by developing criteria on the types of evidence required for hearing officers to reinstate suppliers' billing privileges.

Management Response Summary: CMS concurred with our recommendation. CMS agreed that it should consider establishing guidelines for the evaluation of evidence that a hearing officer would review. CMS believes that it would be useful for OIG to provide specific suggestions on criteria for hearing officers. However, CMS said that any guidance should not impinge on a hearing officer's ability to make an independent determination or with a supplier's ability to submit any evidence that it believes would support the reversal of a revocation or denial decision.

Status: We agree that CMS should develop criteria that maintain the independence of hearing officers and suppliers' ability to submit evidence. We suggest that CMS develop a list of evidence that it believes would support the need for overturning various types of revocation and that such evidence be germane to the reason for revocation. We encourage CMS to develop criteria for the types of evidence required for hearing officers to reinstate suppliers' billing privileges.

Related Report:

2008 OCT *South Florida Durable Medical Equipment Suppliers: Results of Appeals.*
OEI-03-07-00540 [Report](#)

Eliminate Medicare's Vulnerability to Fraudulent or Excessive Inhalation Drug Claims in South Florida (New)

Background: Medicare Part B covers inhalation drugs when they are used in conjunction with DME. A multiagency, multijurisdictional task force formed in 2007 to detect, prosecute, and prevent Medicare fraud by DME suppliers in South Florida identified inhalation drugs as one area vulnerable to fraud, particularly fraud committed by suppliers paying physicians to write fraudulent prescriptions and paying beneficiaries to accept unnecessary medication. We conducted a review that compared Medicare utilization and spending for inhalation drugs among beneficiaries and suppliers in South Florida to that among beneficiaries and suppliers in the rest of the country, as well as to LCD guidelines set by the Medicare program.

Finding(s): We found that even though just 2 percent of Medicare beneficiaries live in South Florida, the area accounted for 17 percent of Medicare's total spending for inhalation drugs in 2007. In addition, on 62 percent of South Florida inhalation drug claims, the beneficiaries did not have Medicare-billed office visits or other services in the preceding 3 years with the physicians who reportedly prescribed the drugs. Medicare spent an average of five times more per beneficiary on inhalation drugs in South Florida than in the rest of the country, with the greatest spending differences attributable to the more expensive brand-name drugs levalbuterol and budesonide. In addition, three-fourths of South Florida beneficiaries who received budesonide had Medicare-reimbursed budesonide claims that exceeded the utilization guidelines, compared to 14 percent in the rest of the country.

Recommendations: CMS should (1) ensure that its contractors are enforcing the coverage guidelines for inhalation drugs, (2) eliminate Medicare's vulnerability to potentially fraudulent or excessive inhalation drug claims in South Florida, and (3) review cases in which the DME supplier appears to be fraudulently billing Medicare for inhalation drugs and take appropriate action based on the review's results.

Management Response Summary: CMS concurred with our recommendations. CMS said that through its Program Integrity Miami field office and the DME Stop Gap Plan, it has identified and begun to address many of the issues cited in our report. CMS noted that a "medically unlikely" edit for budesonide was implemented in September 2008. Additionally, CMS described efforts by its Miami and Los Angeles field offices to identify suppliers whose beneficiaries had no clinical relationship with the physicians listed on DME claims and revoke the Medicare billing numbers for suppliers not meeting supplier standards. CMS recently indicated that it will reinforce with its contractors the necessity to enforce the LCD for inhalation drugs.

Status: To close our recommendation that CMS ensure that all Program Safeguard Contractors (PSC), particularly the PSC covering Florida, are enforcing the guidelines for maximum milligrams per month for all inhalation drugs, especially budesonide, stronger action, such as ensuring that claim edits are put in place, may be necessary. We will continue to monitor CMS's progress in the area of DME Medicare fraud control.

Related Report:

2009 APR *Aberrant Claim Patterns for Inhalation Drugs in South Florida.*
OEI-03-08-00290 [Report](#)

See Also:

2010 MAR OIG Testimony Before the House Committee on Appropriations,
Subcommittee on Labor, Health and Human Services, Education, and
Related Agencies: "Miami Strike Force." [Testimony](#)

Medicare Part A and Part B

Part B Prescription Drugs:

Expedite the Process To Ensure That Medicare Payments for Drugs With Newly Available Generic Versions Accurately Reflect Market Prices (New)

Background: In March 2008, a generic version of irinotecan hydrochloride (hereinafter referred to as irinotecan), an injectable drug used to treat patients with colorectal cancer, became available for sale in the United States. Medicare Part B covers irinotecan as a drug administered by a physician. Medicare pays for most Part B covered drugs based on the average sales price (ASP) reported by manufacturers within 30 days after the end of each calendar quarter. There is therefore a two-quarter lag between the time when sales reflected in the ASP occur and the time when they become the basis for Medicare payments. Sections 1847A(d)(1) and (2) of the Social Security Act, as added by the MMA, direct OIG to undertake studies that compare ASPs to widely available market prices and average manufacturer prices (AMP).

Finding(s): We compared the first-quarter 2008 Medicare payment to manufacturer prices for irinotecan and found that the Medicare payment amount for irinotecan exceeded the OIG-calculated average manufacturer sales price by 145 percent in March 2008. Lower-priced generic versions accounted for 86 percent of irinotecan sales in March 2008. We estimated that had Medicare payments for irinotecan been based on the average manufacturer sales price in March 2008, Medicare expenditures for the drug would have been reduced by \$6.5 million in that month alone.

Recommendation: CMS should explore options to expedite the process to ensure that the Medicare payments for drugs with newly available generic versions accurately reflect market prices.

Savings: \$6.5 million*

**We estimated that had Medicare payments for irinotecan been based on the average manufacturer sales price in March 2008, Medicare expenditures for these drugs would have been reduced by \$6.5 million in that month alone.*

Management Response Summary: CMS concurred with our recommendation. CMS expressed its commitment to ensuring accurate payments for drug products under the ASP methodology and will review any specific suggestions OIG may have to further this goal. CMS noted that the third-quarter 2008 Medicare payment for irinotecan was \$74.75, representing a 40-percent decrease from the previous quarter (\$126.24). CMS also noted that this decrease results in a payment differential per unit for the third

quarter that is substantially lower than the differential for March 2008, demonstrating that the ASP methodology reflects market-based prices over time.

Status: OIG considers that the underlying pricing issues identified in this report are not limited to irinotecan. Medicare payment amounts for drugs with new generic versions will continue to be temporarily higher than manufacturer sales prices, sometimes substantially. We continue to recommend that CMS explore options to expedite the process to ensure that the Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices.

Related Report:

2008 AUG *Medicare Payment for Irinotecan.* OEI-03-08-00310 [Report](#)

Adjust Payment Amounts and Ensure That Drug Manufacturers Submit Pricing Data in a Timely Manner (New)

Background: Pursuant to the Social Security Act, § 1847A(d)(3), OIG must compare particular drugs' ASPs with AMPs. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Secretary of HHS has the authority to disregard the ASP for that drug and substitute the payment for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. Since April 2006, OIG has issued several pricing reports comparing ASPs to AMPs. Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits, CMS has not made any changes to reimbursement as a result of OIG's findings.

Finding(s): We identified 71 Medicare Part B drug codes that would have been eligible for price adjustment if a revised payment methodology recently implemented by CMS had been in effect throughout 2007. Additional codes may have been eligible for price adjustments; however, missing or unavailable pricing data prevented OIG from examining certain drug codes. Of the 71 drug codes that met the threshold for price adjustment, one-fourth would have met the 5-percent threshold during multiple quarters of 2007. Because some drug products did not have AMP data, the number of pricing comparisons performed in 2007 was reduced by 25 percent in each of the first and third quarters and by more than 40 percent in the second and fourth quarters. Manufacturers for almost half of drug products without AMPs participated in the Medicaid drug rebate program in 2007 and were generally required to submit AMP data.

Recommendations: CMS should (1) develop a process to adjust payment amounts based on the results of OIG's pricing comparisons, (2) lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold, and (3) ensure that drug manufacturers are submitting the required AMP data in a timely manner.

Savings: TBD*

**Based on a review of ASP and AMP data submitted by manufacturers for the first through fourth quarters of 2007.*

Management Response Summary: CMS concurred with our recommendation to develop a process for adjusting payments but did not indicate that it concurred with our recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold, citing a desire to further analyze the complex pricing issues. CMS said that it

will continue its efforts to ensure that manufacturers are submitting required AMP data in a timely manner.

Status: Consistent with statutory provision, we continue to recommend that Medicare reimbursements for eligible codes be lowered pursuant to section 1847A(d)(3). CMS indicated in its December 2009 comments that it is considering a methodology to make price substitutions in an upcoming Notice of Proposed Rulemaking. OIG will continue to assist CMS in developing a timely and effective price substitution policy and in taking appropriate action against manufacturers that fail to comply with AMP reporting requirements.

Related Report:

2008 DEC *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007.* OEI-03-08-00450 [Report](#)

See Also:

2010 FEB *Comparison of Average Sales Prices to Average Manufacturer Prices: An Overview for Calendar Year 2008.* OEI-03-09-00350 [Report](#)

2010 JAN *Comparison of Second-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009.* OEI-03-09-00640 [Report](#)

2006 JUL OIG Testimony Before the House Committee on Ways and Means, Subcommittee on Health: "Part B Reimbursement for Prescription Drugs and the Average Sales Prices (ASP) Used To Set This Reimbursement." [Testimony](#)

Ensure That Medicare Part B Chemotherapy Administration Claims Are Correctly Paid (New)

Background: Medicare Part B pays for a limited amount of prescription drugs, including chemotherapy agents, and pays physicians separately for their administration. CMS does not specify the particular drugs that qualify for the chemotherapy administration rate, leaving that decision to the carriers with which it contracts to process these Part B physician claims. For the purposes of this study, any chemotherapy administration claim that fell on a service date on which no qualifying drug was billed was classified as an unmatched chemotherapy administration claim.

Finding(s): Although unmatched claims exceeded \$60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether chemotherapy administration payments are appropriate. We also found that lacking a national definition of “qualifying drug,” carriers have implemented inconsistent chemotherapy administration coding policies and review procedures.

Recommendations: CMS should (1) establish a process to determine the specific drugs that qualify for the chemotherapy administration payment rate, (2) instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims, and (3) ensure that drug administration claims are coded and paid correctly.

Savings: TBD*

**Based on a review of 2005 to 2007 Part B claims data.*

Management Response Summary: CMS concurred with our recommendation to instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims. In October 2009, CMS issued transmittal 574 (Change Request 6655), instructing the MACs to review claims data, particularly for chemotherapy services. In addition, the transmittal instructs MACs to take action consistent with their individual prioritized strategy, such as establishing automated prepayment reviews, developing postpayment reviews, and educating physicians and suppliers if the data warrant any action. CMS stated that it shared this report with its program integrity contractors. CMS did not concur with our recommendations to clearly define the criteria for qualifying drugs and ensure that the chemotherapy administration rate is paid only for appropriate drugs by using existing claims infrastructure to capture information about drugs not billed to Part B and instructing carriers to implement related system edits. CMS said that the current procedural terminology guidance “represents the best consensus from the medical community and

CMS.” CMS also said that it believes the current variations in carrier definitions of qualifying drugs may be because of required practice variations in the conditions for which a drug is used and that these variations may decrease as a consequence of contracting reform.

Status: We continue to recommend that CMS establish a process to determine which specific drugs qualify for the chemotherapy administration payment rate, instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims, and ensure that drug administration claims are coded correctly and paid appropriately.

Related Report:

2009 JUN *Medicare Part B Chemotherapy Administration: Payment and Policy.*
OEI-09-08-00190 [Report](#)

Medicare Part C (Medicare Advantage)

Modify Payments to Medicare Advantage Organizations

Background: The BBA established the Medicare+Choice (M+C) program with the primary goal of providing a wider range of health plan choices to Medicare beneficiaries. The BBA 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, which increased payments, redesignated the M+C program as Medicare Advantage (MA). Participating managed care organizations are designated as MA organizations.

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

Improper payments made in Medicare fee-for-service (FFS) expenditures also contributed to the flaws in the 1997 managed care base rates. Our review of Medicare's 1996 and 1997 financial statements identified substantial FFS improper payments. The standardized county rates for 1997 were calculated using 1996 base FFS expenditure data, and the overpayment errors were carried over into the 1997 managed care rates. We estimated the 1996 FFS error rate as 14 percent of 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.*

Management Response Summary: CMS did not concur with our recommendation to modify payments to MA organizations, noting that the BBA and the BBRA had increased these payments.

Status: Because the 1997 base rate was flawed, we have concerns that Federal payments to MA organizations continue to be excessive. We are updating our examination of MA organization payments and continue to recommend that CMS modify monthly capitation rates to a level fully supported by empirical data.

Related Report:

2000 SEP *Adequacy of Medicare's Managed Care Payments After the Balanced Budget Act of 1997.* OAS-14-00-00212 [Report](#)

Place a Ceiling on Administrative Costs Included in Medicare Advantage Organizations' Bid Proposals

Background: The BBA established the M+C program with the primary goal of providing a wider range of health plan choices to Medicare beneficiaries. Subsequently, the MMA, which increased payments, redesignated the M+C program as MA. Participating managed care organizations are designated as MA organizations.

MA organizations are required to submit a bid proposal (formerly called adjusted community rate (ACR) 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 that reasonable cost principles be followed, nor does it set a ceiling percentage on the administrative cost rate proposed as part of the bid.

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

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

Savings: TBD*

**Savings not estimated.*

Management Response Summary: In its comments on our January 2000 draft report, CMS did not concur with our recommendation, stating that it expected some MA organizations 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. In December 2009, CMS agreed

that a more thorough analysis of bid proposals should be performed, but it reiterated that it did not support setting a ceiling on administrative costs.

Status: We continue to monitor implementation of our recommendation, and to do so we are initiating new work to update our examination of administrative costs under provisions of the MMA.

Related Reports:

2001 NOV *Summary Results of Review of the Administrative Cost Component of the Adjusted Community Rate Proposal at Ten Medicare+Choice Organizations for the 2000 Contract Year.* OAS-03-01-00017 [Report](#)

2000 JAN *Review of the Administrative Cost Component of the Adjusted Community Rate Proposal at Nine Medicare Managed Care Organizations for the 1997 Contract Year.* OAS-03-98-00046 [Report](#)

2000 JAN *Administrative Costs Reflected on the Adjusted Community Rate Proposals Are Inconsistent Among Managed Care Organizations.* OAS-14-98-00210 [Report](#)

Medicare Part D (Prescription Drug Program)

Ensure Accuracy of Prescription Drug Plan Sponsors' Bids and Prospective Payments

Background: The Medicare prescription drug program provides an optional outpatient drug benefit to Medicare beneficiaries. CMS contracts with private insurance companies, known as Part D sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program. During 2006, the first year of the benefit, Part D expenditures totaled more than \$47 billion.

CMS makes monthly prospective payments to sponsors for providing prescription drug coverage to Medicare beneficiaries. These payments are based on estimates that sponsors provide in their approved bids before the beginning of the plan year. CMS makes prospective payments to sponsors in the form of three separate subsidies to cover the Federal Government's share of the cost of direct, catastrophic, and low-income prescription drug benefits. The amounts of the three subsidies are based on sponsors' approved bids.

After the close of the plan year, CMS must reconcile these prospective payments with sponsors' actual costs to determine whether sponsors owe money to Medicare, Medicare owes money to sponsors, or payment to CMS or to a sponsor is required to share the risk of unexpected losses (or the benefit of unexpected profits).

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

A subsequent report issued in September 2009 found that sponsors owed a net \$18 million to Medicare for reconciliation of the 2007 benefit year.

We found that sponsors continue to make large unexpected profits in addition to expected profits that they included in their bids. We also found that CMS collected almost all of the funds that sponsors owed from the 2006 benefit year to Medicare in November and December 2007. We reported in 2007 that CMS had not collected \$14 million from five sponsors for 2006. However, CMS noted in its comments to our 2009 report that it has since collected amounts owed.

Recommendations: Our 2009 recommendations were similar to our 2007 report recommendations, including that CMS should (1) ensure that sponsors' bids more accurately reflect their costs of providing the benefit to Medicare beneficiaries, (2) hold sponsors more accountable for inaccuracies in the bids, (3) determine whether changes to the risk corridors (triggers that protect plans from unexpected losses and allow the Government to share in unexpected gains) are appropriate, (4) determine whether alternative methodologies would better align payments with sponsors' costs for the low-income cost-sharing and reinsurance subsidies, and (5) follow up with the sponsors that owe funds for 2006.

Management Response Summary: In response to our first recommendation, CMS concurred and stated that it has already incorporated plan-level experience in its current bid-desk review. In response to our second recommendation, CMS stated that it has the authority to ensure Part D sponsors' compliance with the operational requirements of the Part D program.

In response to our third recommendation, CMS stated that it has reviewed the statutory risk corridors and risk-sharing percentages and does not believe that changes would be appropriate. Further, CMS noted that it estimates that because plans' bids dropped significantly for the 2008 benefit year, the Government, on average, will owe plans for the 2008 reconciliation. In response to our fourth recommendation, CMS agreed and stated that it was evaluating changing the method for paying the low-income cost-sharing subsidy. In response to our fifth recommendation, CMS noted that it has since collected amounts owed from all sponsors that are solvent.

Status: We will continue to monitor the actions CMS takes to further address our recommendations, including that CMS use its current authority to hold sponsors more accountable for inaccuracies in their bids. However, we note that CMS's current authority may not allow it to impose sanctions in all situations that lead to inaccuracies in the bids. We asked that in its final management decision, CMS more clearly indicate whether it concurs with our second and third recommendations and what steps, if any, it will take to implement them.

Related Report:

2009 SEP *Medicare Part D Reconciliation Payments for 2006 and 2007.*
OEI-02-08-00460 [Report](#)

Modify Audits of Bids To Ensure Plan Sponsors' Accountability (New)

Background: The Medicare prescription drug program, known as Medicare Part D, provides an optional drug benefit to Medicare beneficiaries. CMS contracts with private insurance companies known as plan sponsors, to provide outpatient prescription drug coverage for beneficiaries who choose to enroll in the program. For plan sponsors to offer prescription drug plans, CMS must approve the plan sponsors' bid amounts. The bid amounts are the plan sponsors' per-member, per-month estimated costs of providing drug coverage. To calculate bid amounts, plan sponsors apply actuarial assumptions to base period data, which are actual data from a previous year of providing drug coverage. Bid amounts are used to determine payments to plan sponsors. CMS uses bid audits as part of its oversight of Medicare Part D bidding. There are two types of bid audit findings: material findings and observations. Material findings are significant issues that if corrected, would affect payments or beneficiary benefits. Observations are the nonmaterial findings. This study assesses the results of bid audits conducted by CMS and the extent of CMS's use of bid audits and financial audits to oversee Part D bidding.

Finding(s): We found that one-quarter of the bid audits completed for plan years 2006 and 2007 identified at least one material finding. The largest number of bid audits with material findings identified nonpharmacy costs and methodology errors. We found that CMS has not adjusted plan sponsors' bid amounts based on bid audit material findings. Instead, CMS uses bid audits to influence the submission, review, and audit of future bid amounts. We also found that as of April 2008, only 4 percent of the required financial audits of plan year 2006 had begun.

Recommendations: We recommend that CMS (1) modify the bid audit process to hold plan sponsors more accountable for material findings identified in bid audits and (2) conduct the required number of financial audits in a timely manner.

Management Response Summary: CMS indicated that to hold bid sponsors accountable for audit findings by confirming that similar issues are not repeated in future bid submissions, starting with contract year 2011, the Office of the Actuary (OACT) within CMS will evaluate plan sponsors' and certifying actuaries' compliance with bid instructions, CMS guidance, and the actuarial standards of practice. OACT will share the results of its evaluation and any material findings identified in the 2010 bid audits with the Program Oversight and Evaluation Group. OACT has established a process to review findings of the financial audits and provide guidance to the auditors in the field. As of December 2009, CMS had initiated audits of 169 organizations for the

2006 benefit year and 170 organizations for the 2007 benefit year. By mid-August 2009, 62 percent of the audits for the 2006 benefit year and 14 percent of the audits for the 2007 benefit year were complete.

Status: We will continue to monitor CMS's implementation of our recommendations.

Related Report:

2008 NOV *Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids.*
OEI-05-07-00560 [Report](#)

Medicare Part D > Part A Exclusion

Ensure That Medicare Part D Excludes Payments for Drugs for Beneficiaries in Part A Skilled Nursing Facility Stays (New)

Background: Medicare Part D provides outpatient prescription drug coverage for Medicare beneficiaries who enroll. Part D covers most prescription drugs; however, it excludes drugs that are covered under Medicare Part A or Part B. Part D excludes drugs for beneficiaries in Part A SNF stays if the drugs were for use in the facility or to facilitate the beneficiaries' discharge.

Finding(s): Our review found that 60 percent of the drugs Part D paid for while beneficiaries were in Part A SNF stays in 2006 were dispensed by LTC pharmacies. These pharmacies dispense drugs for use in LTC settings, including SNFs. Because these drugs probably were dispensed for use in the facility during Part A SNF stays, Part D payments for them, which amounted to \$41.3 million, likely were inappropriate. The remaining 40 percent of drugs paid for by Part D for beneficiaries in Part A SNF stays were dispensed by retail and other types of pharmacies. If these drugs were for use in the facility or were to facilitate the beneficiaries' discharge, then Part D payments were also inappropriate. Nearly every SNF and half of the pharmacies had beneficiaries who had drugs paid for by Part D during their Part A SNF stays. At the same time, a small number of SNFs and pharmacies were responsible for a large percentage of these Part D payments. Notably, 160 SNFs accounted for 12 percent (\$8.6 million) of the payments, and 30 pharmacies accounted for 18 percent (\$13 million) of all Part D payments for beneficiaries in Part A SNF stays.

Recommendations: CMS should (1) ensure that Part D payments for drugs for beneficiaries in Part A SNF stays are appropriate; (2) provide additional guidance about when Part A or Part D can pay for drugs for beneficiaries preparing for discharge; (3) educate SNFs, pharmacies, and Part D sponsors about the rule that drugs covered under Part A or Part B for beneficiaries in SNF stays are not eligible for coverage under Part D; (4) implement retrospective reviews to prevent inappropriate Part D payments for drugs for this population; and (5) follow up with the SNFs and pharmacies that were responsible for a large percentage of Part D payments for beneficiaries in Part A SNF stays.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: CMS concurred with our recommendations. In response to CMS's comments on our draft report, we clarified language in the report and added a recommendation that CMS provide more guidance that clarifies the

circumstances under which Part A and Part D can pay for drugs for beneficiaries preparing for discharge.

In response to our recommendation to educate SNFs, pharmacies, and Part D sponsors, CMS noted that it had recently issued a memorandum to Part D sponsors reminding them of the exclusion of Part D payments for drugs covered under Medicare Part A stays. In response to our recommendation to implement retrospective reviews, CMS said that it expects to better understand the most appropriate controls for prevention and detection of inappropriate Part D payments after it looks at the information that OIG provides about the SNFs and pharmacies that were responsible for the largest percentage of payments.

In response to our recommendation to follow up with the SNFs and pharmacies that were responsible for a large percentage of the payments, CMS said that it will investigate the allegations of duplicate payments (i.e., our finding that nearly every SNF and half of the pharmacies had beneficiaries who had drugs paid for by Part D during their Part A SNF stays) upon receipt of OIG's data. In its December 2009 comments, CMS indicated that it will include additional guidance in its next update to the *Medicare Prescription Drug Manual* to clarify when Parts A and D pay for drugs for beneficiaries preparing for discharge.

Status: We encourage CMS to follow up with the Part D plans that allowed improper Part D payments during Part A SNF stays.

Related Report:

2009 JUN *Medicare Part D Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006.* OEI-02-07-00230 [Report](#)

Ensure the Accuracy of Plans' Drug Prices on the Medicare Prescription Drug Plan Finder (New)

Background: The Medicare prescription drug program provides an optional prescription drug benefit for Medicare beneficiaries. CMS contracts with private insurance companies, known as Part D sponsors, to provide outpatient prescription drug coverage for beneficiaries who choose to enroll in the program. Medicare created the Plan Finder, an online tool to help beneficiaries compare and select Part D plans. The plans' drug prices are a significant factor in selecting a plan. Drug prices listed on the Plan Finder that do not reflect actual drug costs may cause beneficiaries to enroll in a plan based on incorrect information, incur unexpected costs, or decline to enroll in a Part D plan. The Plan Finder indicates on the plan drug details screen that "actual drug costs at the pharmacy may vary slightly." To determine whether Plan Finder drug prices accurately reflect actual drug costs, we compared plans' retail prices listed on the Plan Finder for 10 drugs commonly used by Medicare beneficiaries to actual drug costs on corresponding prescription drug event (PDE) claims for the same period (September 24 to October 7, 2007).

Finding(s): Drug prices posted on the Plan Finder exceeded actual drug costs for 92 percent of the claims. The median amount by which the Plan Finder exceeded the actual price was 28 percent. The Plan Finder price was less than the actual price for 7 percent of claims and equaled the actual price for only 1 percent of claims. Percentage differences between Plan Finder prices and actual costs were generally greater for the generic drugs we reviewed, while dollar differences were greater for the brand name drugs reviewed.

Recommendations: CMS should (1) ensure that plans' drug prices displayed on the Plan Finder accurately reflect actual drug costs on Part D claims and (2) as an immediate measure, modify the disclaimer on the Plan Finder search results screen to indicate that drug cost estimates may differ more than "slightly" from actual drug costs.

Management Response Summary: CMS concurred with our first recommendation that the plans' drug prices on the Plan Finder accurately reflect actual drug costs on Part D claims. However, CMS did not concur with our recommendation to modify the disclaimer on the Plan Finder to indicate that drug cost estimates may differ more than slightly from actual drug costs. CMS asserts that the current disclaimer on the Plan Finder indicating that drug cost estimates may differ slightly from actual drug costs is sound and that OIG's recommended modification to the disclaimer is unwarranted. In August 2009, CMS said that it has repeatedly expressed concerns that our study's methodology has serious limitations regarding the relationship between prices

displayed on the Plan Finder and the prices charged at the point of sale because OIG conducted a general search rather than a pharmacy-specific search in the Plan Finder. Consequently, CMS considers that findings of frequent price differences between Plan Finder and PDE data are highly misleading. CMS continues to recommend that beneficiaries perform a general (nonpharmacy-specific) search to find the least expensive plan for their needs. CMS continues to stress that OIG should then compare the PDE data to the Plan Finder prices for the same pharmacy to perform a valid evaluation of price accuracy.

Status: We will continue to encourage CMS to implement our recommendations, and we assert that it should routinely ensure that the Medicare Prescription Drug Plan Finder prices closely reflect PDE costs. We also encourage it to raise beneficiaries' awareness of potential significant discrepancies between drug prices displayed on the Plan Finder and actual drug costs.

Related Report:

2009 JUL *Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder.* OEI-03-07-00600 [Report](#)

Ensure That Marketing Materials for Medicare Prescription Drug Plans Comply With Program Guidelines (New)

Background: CMS's Medicare Marketing Guidelines specify what information the marketing materials must include when describing prescription drug plan (PDP) coverage. To help ensure accuracy and expedite the review of certain marketing materials, CMS created model documents, which include uniform text that contains pertinent information. Before PDP sponsors distribute marketing materials, they must submit them to CMS under one of its review processes: standard review or "file & use." The guidelines also outline CMS's oversight activities in monitoring marketing materials, including requiring identification numbers on materials. We assessed CMS's oversight of PDP marketing materials based on its oversight strategy.

Finding(s): We found that CMS's oversight for PDP marketing materials is limited. For example, CMS did not complete a retrospective review of file & use marketing materials for 2006 until April 2008. Although CMS completed standard reviews of marketing materials in a timely manner, the reviews lacked consistency across regions. Identification numbers from 45 percent of the materials we reviewed failed to match the numbers in CMS's system. CMS also lacked a systematic way to track materials. We also found that CMS's model documents were not consistent with its guidelines. And we found that overall, PDP marketing materials did not meet CMS guidelines. Eighty-five percent of marketing materials failed to meet at least one element of the guidelines.

Recommendations: CMS should (1) revise model documents to ensure consistency between the model documents and the guidelines, (2) develop protocols for the review of marketing materials, (3) conduct and complete more frequent retrospective reviews of file & use materials, (4) enforce the use of the tracking system, and (5) improve it to include identifiers for marketing materials written in languages other than English and those written in alternative formats.

Management Response Summary: CMS concurred with our recommendations, noting that it had implemented steps to improve its oversight of marketing materials. These steps include developing standardized review protocols, piloting a national retrospective review process, updating model documents to include all of the requirements from the guidelines, focusing reviews on marketing materials that are most critical to beneficiary understanding, developing checklists for creating marketing materials, developing electronic attestations of material accuracy, and enhancing the electronic tracking system.

Status: We continue to encourage CMS to develop protocols for the review of marketing materials and improve and enforce the use of the tracking system.

Related Report:

2008 SEP *Marketing Materials for Medicare Prescription Drug Plans.*
OEI-01-06-00050 [Report](#)

Support Outreach and Education for Beneficiaries Before They Enter the Coverage Gap (New)

Background: Medicare Part D provides an optional outpatient drug benefit to Medicare beneficiaries. During the coverage year, the financial responsibilities of beneficiaries, plan sponsors, and CMS vary during four distinct coverage phases: annual deductible, initial coverage, coverage gap, and catastrophic coverage. Beneficiaries may receive financial assistance for drug costs during the coverage gap from several sources (such as from low-income subsidies or third-party payers), but some do not. Some research suggests that beneficiaries who entered the Medicare Part D coverage gap may have changed their prescription drug use behavior because they were responsible for 100 percent of their drug costs during the coverage gap. OIG studied the prescription drug use of beneficiaries who entered the coverage gap without financial assistance in 2006.

Finding(s): Seven percent of Part D beneficiaries entered the coverage gap and did not receive financial assistance with prescription drug costs in 2006. During the coverage gap, drug-purchasing behavior changed for 98 percent of the beneficiaries, with 69 percent reducing the average number of drugs they purchased during the coverage gap. The greater the average number of drugs per month that they purchased before the coverage gap, the more they reduced the average number of drugs purchased during the coverage gap. Beneficiaries who purchased an average of at least nine drugs per month had the largest decrease at 18 percent. When surveyed, beneficiaries identified specific changes in the way they purchased or used drugs during the coverage gap, including 38 percent who reported seeking at least one less-costly alternative to purchasing drugs and one-third who compromised their drug regimens.

Recommendations: CMS should (1) support outreach and education targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap (such as by encouraging plan sponsors to augment outreach and beneficiary education efforts, supplementing those efforts by working with beneficiaries to explore cost-saving strategies, and targeting these beneficiaries for counseling about choosing the most cost-effective plan in the following year) and (2) target low-income subsidy outreach to beneficiaries who entered the coverage gap in previous years without financial assistance.

Management Response Summary: CMS concurred with one of our two recommendations. CMS said that it would not be feasible to provide additional personalized outreach to individual beneficiaries who used a large number of drugs each month based on the prior year's PDE data. We continue to recommend that

targeting beneficiaries who had more prescription drug purchases before the coverage gap for outreach and education would assist those beneficiaries in identifying cost-saving strategies. CMS concurred with our second recommendation and said that it would continue to emphasize the value of the low-income subsidy to attract beneficiaries with significant drug utilization who might benefit from the subsidy. In its December 2009 update, CMS indicated that it had taken several steps to refine outreach methods. However, the actions CMS said it would take may not fully address our concerns.

Status: We continue to recommend focusing on a specific category of beneficiaries for outreach and using prescription drug utilization data to identify potential beneficiaries for the subsidy.

Related Report:

2009 MAR *Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006.* OEI-05-07-00610 [Report](#)

Track Beneficiaries' True Out-of-Pocket Costs

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

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

Recommendations: CMS and its contractors should (1) ensure that Part D plans collect, process, and submit all of the data that are required to track enrollees' TrOOP costs in a timely manner; (2) consider options for increasing the number of data-sharing agreements and for seeking to expand its authority to collect data under those agreements; and (3) begin or complete implementation of oversight activities regarding tracking TrOOP costs.

Management Response Summary: CMS agreed that the report identified potential issues linked to the accurate tracking of TrOOP costs and that more work is needed to ensure that Part D plans are calculating TrOOP costs correctly. The agency did not concur with our three recommendations but noted that it had taken or will take steps to respond to each of our recommendations. In its March 2009 status update to OIG, CMS said that it had implemented an automated TrOOP balance transfer process among Part D plans and between Point-of-Sale Facilitated Enrollment (POS FE) Contractors and Part D plans, which went into effect on January 1, 2009. CMS said that it would monitor performance via standard and exception reporting.

With the enactment of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), § 111, all group health plans are required to report coverage information related to hospital and medical benefits that are primary to Medicare. CMS expects to receive a significant number of reports of prescription drug data via the Section 111 process. CMS also stated in its March 2009 status update that it was conducting audits of one-third of the MA and Medicare PDPs. The audit protocol includes a review to verify that PDPs are accurately calculating TrOOP costs. In CMS's December 2009 comments, it indicated that as of November 2009, it had started its financial audits for 2006 and 2007. However, until one-third of financial audits are completed and show that TrOOP is calculated correctly, our recommendations are not fully implemented.

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

Related Report:

2007 DEC *Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit.* OEI-03-06-00360 [Report](#)

Ensure Adequacy of Sponsors' Compliance Plans

Background: The MMA established Medicare Part D to provide outpatient prescription drug benefits under the Medicare program beginning January 1, 2006. Part D prescription drug coverage is provided by private entities known as “plan sponsors.” Federal regulations require that PDP sponsors have compliance plans in place to protect the integrity of Medicare funds by preventing fraud, waste, and abuse and that these compliance plans address eight elements. In June 2005, CMS issued a summary document, *Review of Sponsor Fraud, Waste, and Abuse Responsibilities*, that included 17 more requirements, each associated with one of the eight elements. CMS’s *Prescription Drug Benefit Manual*, Chapter 9, issued in April 2006, outlined requirements that sponsor compliance plans must address to ensure that the eight elements established by the regulation are met.

OIG released a report on PDP sponsors’ compliance plans in December 2006 and found that most sponsors’ compliance plans did not address all of CMS’s requirements or recommendations. In a followup report to our 2006 study, OIG issued a report in October 2008 about CMS’s oversight of plan sponsors’ compliance plans. In August 2008, GAO released a report on prescription drug plan sponsors’ implementation of the fraud, waste, and abuse provisions of sponsors’ compliance plans and CMS’s oversight of sponsors’ efforts. GAO found that some plan sponsors have not completely implemented fraud and abuse programs and that CMS oversight has been limited. OIG issued a report in October 2008 about compliance plan oversight activities, including audits of PDP sponsors, PDP sponsors’ compliance plan self-assessment, and CMS followup regarding the OIG December 2006 report on PDP sponsors’ compliance plans.

Finding(s): We reviewed CMS oversight of PDP sponsors’ compliance plans in followup to a 2006 OIG report and found that CMS conducted only one audit of a PDP sponsor’s compliance plan in 2007. This was a focused audit; none of CMS’s 17 routine audits included a compliance plan review. Although CMS had planned to begin routine compliance plan audits in January 2007, it had not conducted any routine audits of PDP sponsors’ compliance plans as of early August 2008. CMS instructed PDP sponsors to complete compliance plan self-assessments, but OIG found that CMS did not verify sponsors’ responses. The self-assessments were based on requirements and recommendations in CMS’s *Prescription Drug Benefit Manual*, Chapter 9. However, some self-assessments did not include all of the compliance plan requirements that are in Chapter 9. CMS followed up with 23 PDP sponsors that attested that they had not implemented one or more of the compliance plan requirements in the self-assessments. However, CMS did not request supporting documentation to confirm that these PDP sponsors corrected their compliance plans.

Recommendations: CMS should (1) conduct audits to verify that PDP sponsors' compliance plans meet requirements (covering all of the compliance plan requirements that are contained in regulations and in Chapter 9 of CMS's *Prescription Drug Benefit Manual* and, (2) assess implementation of its compliance plan recommendations.

Management Response Summary: CMS concurred with our recommendation in the 2006 report and had planned to begin routine compliance plan audits in January 2007. CMS had not conducted any routine audits of PDP sponsors' compliance plans as of early August 2008. CMS instructed PDP sponsors to complete compliance plan self-assessments; however, some of the self-assessments did not include all of the requirements from Chapter 9 of the *Prescription Drug Benefit Manual*, and CMS did not verify their responses.

In response to our 2008 draft report, CMS agreed that it is important to conduct reviews of compliance plans. However, because of critical funding shortfalls, CMS had to reprioritize its program integrity oversight activities and was not able to conduct compliance plan audits before our report was issued. CMS said that it would begin a limited number of desk audits of Part D sponsors' compliance plans in September 2008. As more resources become available, CMS said, it would include more audits, onsite reviews, and other more comprehensive fraud-prevention activities. In response to another OIG review, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, issued in October 2009, CMS acknowledged that there was a delay in starting the compliance plan audits. However, it has recently conducted a compliance plan audit of its largest MA and Part D contractor.

In December 2009, CMS reported that Medicare Prescription Drug Integrity Contractors (MEDIC) had conducted compliance plan audits of 16 stand-alone PDP sponsors in FY 2009. In an effort to strengthen its compliance oversight activities, CMS has restructured the MEDIC program for the coming contract year. One MEDIC will focus solely on compliance activities for the entire country and will be responsible for conducting compliance plan audits in addition to other compliance-related activities. CMS also informed us that the MEDICs had approval to conduct compliance plan audits in FY 2010 for PDP and MA organizations to include assessing an entity's compliance with CMS requirements in 42 CFR §§ 422.504(b)(4)(vi) and 422.503(b)(4)(vi), which contain measures to detect, correct, and prevent fraud, waste, and abuse.

Status: We will continue to monitor CMS's implementation of compliance plan audits and actions taken based on those audits.

Related Reports:

2008 OCT *Oversight of Prescription Drug Plan Sponsors' Compliance Plans.*
OEI-03-08-00230 [Report](#)

2006 DEC *Prescription Drug Plan Sponsors' Compliance Plans.*
OEI-03-06-00100 [Report](#)

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

Background: CMS is responsible for safeguarding the Medicare Part D program against fraud and abuse. CMS is statutorily required to perform financial audits of PDPs that are contracted to provide outpatient prescription drug benefits to Medicare beneficiaries. Beyond this, CMS has discretion in structuring program safeguards.

We identified six major safeguards conducted by CMS during FY 2006: implementation of a complaint process, data-monitoring, financial audits, monitoring PDP sponsors' compliance with contract requirements, oversight of PDP sponsors' efforts to reduce fraud and abuse, and providing education and guidance to stakeholders on fraud and abuse identification. During FY 2006, CMS had contracted with one MEDIC to perform some of these functions. We reviewed a variety of documents and conducted interviews with CMS and MEDIC staff members to determine the status of safeguards at the time of our review.

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

Recommendations: CMS should (1) develop a comprehensive safeguard strategy for Medicare Part D PDPs, (2) ensure that fraud complaints receive proper attention, and (3) address legal concerns that may impede program integrity efforts.

Management Response Summary: CMS did not indicate whether it concurred with our recommendations in the draft report. In its comments, CMS responded that many of its ongoing activities already satisfy our recommendations. It further stated that the report does not fully explain the immense workload required for CMS to develop and administer the benefit in its first year and indicated that processes and procedures have improved over time. CMS additionally reported several advances in this safeguard strategy that occurred after the end of our data collection period (FY 2006). We revised the draft report, as appropriate, based on these comments.

In its March 2009 status update to OIG, CMS reported that it had developed a corrective action plan to address OIG's recommendations and had completed the following activities to close the recommendations: (1) implemented a regional TriMEDIC structure

in which the three MEDICs work together to analyze data and identify national fraud schemes, (2) assigned a Government Task Leader to each regional MEDIC to oversee and monitor all MEDIC activities, and (3) rewrote the MEDIC Umbrella SOW to further refine CMS's coordination and oversight of the MEDICs.

In September 2008, CMS began its transition to consolidate the work of Medicare's PSCs and the MEDICs with new Zone program integrity contractors (ZPIC). Eventually, the new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Parts A and B (e.g., hospital, skilled nursing, home health, DME, and other provider and supplier claims); Part C (MA health plans); and Part D PDPs and coordinating Medicare-Medicaid data matches (Medi-Medi). The first two ZPIC contracts were awarded to Health Integrity (Zone 4) and SafeGuard (Zone 7), and CMS is in the final stages of awarding more contracts.

CMS indicated in December 2009, that it expected all the MEDICs to be fully operational in January 2010.

Status: We continue to monitor CMS's implementation of its safeguard strategy and have requested that it provide status on its progress.

Related Report:

2007 OCT *CMS's Implementation of Safeguards During Fiscal Year 2006 To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans.*
OEI-06-06-00280 [Report](#)

See Also:

2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security: "Oversight Challenges in the Medicare Prescription Drug Program."
[Testimony](#)

Ensure That Plan Sponsors Have Comprehensive and Effective Programs To Detect and Deter Fraud and Abuse (New)

Background: The MMA established Medicare Part D to provide outpatient prescription drug benefits under the Medicare program beginning January 1, 2006. Part D prescription drug coverage is provided by private entities known as “plan sponsors.” Part D expenditures for 2007 were about \$49.5 billion. As of August 2008, 26 million beneficiaries were enrolled in Part D, and two-thirds of this total were in stand-alone drug plans. Plan sponsors are private companies that contract with CMS to provide Part D drug coverage to Medicare beneficiaries. Sponsors are required to have a comprehensive program to detect and deter fraud and abuse. When potential fraud or abuse is found, sponsors must conduct an inquiry and initiate corrective action and are advised to refer incidents to a MEDIC for investigation. The only fraud and abuse information that CMS requires sponsors to report is the quarterly number of fraud and abuse complaints they receive from beneficiaries. We analyzed data for the first 6 months of 2007 from 86 of 91 stand-alone drug plan sponsors.

Finding(s): We found that 24 of 86 Part D stand-alone plan sponsors did not find any potential fraud and abuse incidents and that most such incidents were associated with only a small number of plan sponsors. We also found that inappropriate billing was the most prevalent type of potential fraud and abuse and that pharmacies were associated with most of the incidents. We found that of the 62 plan sponsors that identified potential fraud and abuse, not all conducted inquiries, initiated corrective actions, or made referrals for investigation.

Recommendations: CMS should (1) review Part D plan sponsors to determine why certain sponsors have especially high or low volumes of potential fraud and abuse incidents, (2) determine whether the Part D plan sponsors that found potential fraud and abuse initiated inquiries and corrective actions and made referrals for investigations as recommended by CMS, (3) require Part D plan sponsors to maintain and report information about the results of sponsors’ fraud and abuse programs, and (4) use this information to help determine the effectiveness of the programs.

Management Response Summary: CMS concurred with our first and second recommendations. It did not indicate whether it concurred with our third recommendation, and it did not address our fourth recommendation. With respect to the first recommendation, CMS said that it would examine the data on potential fraud and abuse more closely by referring OIG findings to MEDICs and that it intended to revise the reporting requirements and provide sponsors with more specific guidance on

how to track and label incidents. With respect to the second recommendation, CMS agreed to refer the data in the report to MEDICs for investigation.

Status: We encourage CMS to have MEDICs (1) determine why certain sponsors have especially high or low volumes of potential fraud and abuse incidents, (2) determine whether the Part D plan sponsors that identified potential fraud and abuse initiated inquiries and corrective actions and made referrals for further investigations as recommended by CMS, and (3) use the information related to the results of sponsors' fraud and abuse programs to help determine the effectiveness of those programs.

Related Report:

2008 OCT *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse.*
OEI-03-07-00380 [Report](#)

See Also:

2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security: "Oversight Challenges in the Medicare Prescription Drug Program."
[Testimony](#)

Medicare Administration

Improve Medicare Systems Controls

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

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

Finding(s): Information systems controls were considered a material weakness in the FY 2009 financial statement audit because: (1) some MACs did not implement all of the system settings, and the Enterprise Data Centers did not implement all of the mainframe security settings as required by CMS to secure their information systems; (2) the application security design for a Medicare contractor's shared systems did not support the appropriate segregation of duties between security administrators and computer support activities or business functions; (3) conflicts with the segregation of duties for the change management software were noted for several Medicare applications because an individual could develop and approve system changes; (4) CMS's Office of Financial Management (OFM) did not segregate duties between its business function and its information security administration function relating to the Financial Accounting Control System (FACS) general ledger-related application; and (5) nine central office Medicare or financial applications had an inadequate change control process to manage configuration changes.

Recommendations: CMS should (1) strengthen its IT systems by ensuring that system and security settings have been implemented and monitored for compliance; (2) ensure that appropriate segregation of duties is established in all systems that support Medicare and financial processing to prevent excessive or inappropriate access; (3) address the FACS deficiency by moving the FACS application security administration process and configuration management process from personnel within OFM to its Office of Information Systems; and

ensure that all changes to Medicare and financial applications follow the National Institutes of Standards and Technology guidance regarding reviewing and approving all changes.

Management Response Summary: According to CMS's Financial Report for FY 2009, CMS has continued making progress to remediate specific information security weaknesses. The agency believes that the findings related to information control systems do not rise to the level of a material weakness.

Status: During FY 2009, OIG attended CMS's monthly Risk Management meetings that discussed and tracked the progress of CMS's corrective action plans. As part of our FY 2010 financial statement audit, we will review CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations.

Related Report:

2009 NOV *CMS Financial Report, Fiscal Year 2009. Audit Opinion Section.*
Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2009.*
OAS-17-09-02009 (pp. 86, 96, 102) [Report](#)

Financial Management: Improve CMS's Financial Reporting Systems and Processes

Background: Financial management in the Federal Government requires accountability by financial and program managers, control over the Federal Government's financial resources, and protection of Federal assets. To meet these needs, financial management systems must be in place to process and record financial events effectively and efficiently and to provide complete, timely, and reliable financial information. The Office of Management and Budget's (OMB) Circular A-127, *Financial Management Systems*, prescribes the policies and standards that each agency should follow in developing, operating, evaluating, and reporting on financial management systems. CMS relies on a decentralized organizational structure and complex financial management systems—not only within its central office and regional offices' processes, but also within many of the Medicare contractor organizations—to accumulate data for its financial reporting.

Finding(s): The FY 2009 financial statement audit noted that: (1) CMS's central office performed limited analytical procedures on financial information, increasing the likelihood that any necessary adjustments to its financial statements would not be made in a timely manner; (2) CMS did not perform a claims-level detailed look-back analysis of the \$24.9 billion accrual for Medicaid Entitlement Benefits Due and Payable (EBDP) to determine the reasonableness of the various State calculations of unpaid claims; and (3) CMS needed to do more to ensure that its monitoring activities regarding CERT and Payment Error Rate Measurement (PERM) programs were well understood, susceptible to replication, and highly credible. Although CMS continued its efforts to implement the Healthcare Integrated General Ledger Accounting System (HIGLAS), the lack of a single integrated accounting system impairs CMS's ability to efficiently and effectively support and analyze financial reports. Further, Medicare contractors that have not implemented HIGLAS continue to rely on manual processes that are subject to increased risk that inconsistent, incomplete, or inaccurate information will be submitted to CMS.

Recommendations: CMS should: (1) perform more analysis of accounting information and circulate it for review as part of the monthly, quarterly, and annual financial report closing process; (2) establish a process to perform a claims-level detailed look-back analysis on the Medicaid EBDP to determine the reasonableness of the methodology used to estimate the accrual; (3) continue to improve the integrity and efficiency of CERT and PERM tools; and (4) continue to implement an integrated financial management system to promote consistency and reliability in accounting and financial reporting.

Management Response Summary: CMS concurred with these recommendations made in the FY 2009 financial statement audit report. In FY 2009, the agency continued to improve its financial management performance in many areas.

Status: We acknowledge that CMS is developing corrective actions for the FY 2009 audit findings, and as part of our FY 2010 financial statement audit, we will review CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations.

Related Report:

2009 NOV *CMS Financial Report, Fiscal Year 2009. Audit Opinion Section.*
Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2009.*
OAS-17-09-02009 (pp. 86, 96, 102) [Report](#)

See Also:

2009 NOV *Department of Health and Human Services Fiscal Year 2009 Agency Financial Report. Section II.* Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2009.* OAS-17-09-00001 (pp. II-7, II-14) [Report](#)

Improve the Performance Evaluation Process for Program Safeguard Contractors

Background: HIPAA, § 202, authorized CMS to contract out 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 PSCs. Once under contract, PSCs are awarded task orders to carry out specific duties.

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

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

Management Response Summary: CMS partially concurred with our recommendations. The agency disagreed with our recommendations about the areas that should be addressed in PSC performance evaluation reports. In April 2009, CMS said that it has been collecting and tracking quantitative data about PSCs in its CMS Analysis, Reporting, and Tracking System (CMS-ARTS) database. It did not indicate that the data have been included in performance evaluation reports, nor did it provide documentation showing that the data are now used in performance evaluation reports. Although the umbrella SOW was revised, it no longer contains a timetable for issuing draft and final reports. CMS also indicated that it complies with the time constraints associated with contract renewal dates so that only PSC contracts with acceptable performance are renewed. However, it has not explained how it ensures that performance evaluation reports are issued by the time the task order renewal notices are due, and it has not provided documentation showing how or whether this has been accomplished.

CMS also reported in its March 2009 status update that it developed a milestone date chart reflecting the significant evaluation dates. However, because of resource constraints, the chart is updated manually, and CMS has not been able to enhance CMS-ARTS to capture this information. The purpose of central tracking is to identify where delays occur so that improvements can be made in the agency's performance evaluation process. Thus, we continue to recommend that the milestones be tracked in a central system that can be accessed by management. In its December 2009 update, CMS indicated that it had contracted to develop a template for monthly reporting, including fraud and abuse activities. CMS also began its transition to consolidate the work of Medicare's PSCs and the MEDICs with new ZPICs. Eventually, the new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Part A and Part B (e.g., hospital, skilled nursing, home health, DME, and other provider and supplier claims); Part C, MA health plans; and Part D, PDPs and for coordinating Medi-Medi data matches. The first two ZPIC contracts were awarded to Health Integrity (Zone 4) and SafeGuard (Zone 7), and CMS is in the final stages of awarding more contracts.

Status: We will continue to monitor CMS's implementation of its safeguard strategy.

Related Report:

2006 MAR *Medicare's Program Safeguard Contractors: Performance Evaluation Reports.*
OEI-03-04-00050 [Report](#)

See Also:

2007 JUL *Medicare's Program Safeguard Contractors: Activities To Detect and Deter Fraud and Abuse.* OEI-03-06-00010 [Report](#)

Part II: Medicaid Program Recommendations

Federal and State Partnership:

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 was 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.

Recommendations: The Centers for Medicare & Medicaid Services (CMS) should (1) provide States with definitive guidance for calculating the UPL, which should include using facility-specific UPLs that are based on actual cost report data, and (2) require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment.

Savings: \$120 million*

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

Management Response Summary: In its comments on 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, would help ensure that Medicaid funds are used to provide necessary services to Medicaid beneficiaries. However, implementation of this regulation was delayed by passage of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, § 7002, which prohibited implementation of CMS's regulation for 1 year following the date of the law's enactment on May 25, 2007. In addition, the Supplemental Appropriations Act of 2008, § 7001, prevented CMS from implementing the regulation until April 1, 2009, and the American Recovery and Reinvestment Act of 2009 (Recovery Act) provided that it was the sense of Congress that the Secretary of HHS should not promulgate this regulation.

Status: We continue to recommend that CMS limit enhanced payments to cost and require that Medicaid payments returned by public providers be used to offset the Federal share.

Related Reports:

- 2001 SEP *Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers.* OAS-03-00-00216 [Report](#)
- 2001 JUN *Medicaid Enhanced Payments to Hospitals and the Use of Intergovernmental Transfers in North Carolina.* OAS-04-00-00140 [Report](#)
- 2001 MAY *Medicaid Enhanced Payments to Public Hospital Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency.* OAS-04-00-02169 [Report](#)
- 2001 MAR *Illinois' Use of Intergovernmental Transfers to Finance Enhanced Medicaid Payments to Cook County for Hospital Services.* OAS-05-00-00056 [Report](#)
- 2001 MAR *Medicaid Supplemental Payments to Public Hospital District Nursing Facilities and the Use of Intergovernmental Transfers by Washington State.* OAS-10-00-00011 [Report](#)
- 2001 FEB *The Commonwealth of Pennsylvania's Use of Intergovernmental Transfers to Finance Medicaid Supplementation Payments to County Nursing Facilities.* OAS-03-00-00203 [Report](#)
- 2001 FEB *Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the State of Nebraska.* OAS-07-00-02076 [Report](#)
- 2001 JAN *Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency.* OAS-04-00-02165 [Report](#)

See Also:

2005 JUN Office of Inspector General (OIG) Testimony Before the Senate Committee on Finance: "Financing Mechanisms To Shift the Cost of Medicaid to the Federal Government Contrary to Federal and State Sharing Formulas." [Testimony](#)

Improper Payments:

Ensure Compliance With Requirements for Medicaid School-Based Health Services

Background: The Social Security Act, § 1903(c), states that Medicaid payment for school-based health services was allowable for covered Medicaid services that are included in an individualized education plan or individualized family service plan established pursuant to 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.

Recommendations: (1) CMS should recover the overpayments identified during our audits of school-based claims in individual States and (2) States should (a) disseminate CMS guidance and other information to the local education agencies in a timely manner, (b) monitor local education agencies to ensure compliance with Federal and State requirements, and (c) help local education agencies develop written policies and procedures that require service providers to document all pertinent health services and retain those records for review.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: 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. A final regulation was published at 72 Fed. Reg. 73635 (December 28, 2007) to eliminate reimbursement under Medicaid for school administration expenditures and costs related to the transportation of school-age children between home and school. The Supplemental Appropriations Act of 2008, § 7001, prevented CMS from implementing

the regulation until April 1, 2009. Section 5003 of the Recovery Act further extended the moratorium on implementing this regulation until July 1, 2009. In June 2009, CMS rescinded the final rule. In December 2009, CMS stated that it was considering options for providing additional guidance in this area and continued to pursue the recovery of overpayments.

Status: We will continue to monitor CMS's implementation of our recommendations.

Related Reports:

- 2005 AUG *Review of Illinois Medicaid School-Based Administrative Costs for State Fiscal Year 2001.* OAS-05-02-00050 [Report](#)
- 2005 JUN *Review of Medicaid Speech Claims Made by the New York City Department of Education.* OAS-02-02-01029 [Report](#)
- 2005 APR *Medicaid School-Based Administrative Activities in Kansas.* OAS-07-03-00154 [Report](#)
- 2005 JAN *Review of Vermont Medicaid School-Based Services for the Period October 2001 Through September 2002.* OAS-01-03-00004 [Report](#)
- 2005 JAN *Review of Maine's Medicaid Retroactive Claims for School-Based Health Services - January 2001 Through June 2003.* OAS-01-04-00004 [Report](#)
- 2004 SEP *Medicaid School-Based Health Services Administrative Costs - Massachusetts July 1999 Through June 2001.* OAS-01-02-00016 [Report](#)
- 2004 AUG *Review of Medicaid Transportation Claims Made by School Health Providers in New York State.* OAS-02-03-01008 [Report](#)
- 2004 MAY *Audit of Medicaid Fee-for-Service Payments to Local Education Agencies in North Carolina for the Period July 1, 1999 Through June 30, 2000.* OAS-04-01-00005 [Report](#)
- 2004 FEB *Review of Medicaid Speech Claims Made by School Health Providers in New York State.* OAS-02-02-01030 [Report](#)
- 2004 FEB *Audit of the Iowa Department of Human Services' Claim for Medicaid School-Based Administrative Costs.* OAS-07-02-02099 [Report](#)
- 2004 FEB *Medicaid Payments for School-Based Health Services, Rhode Island, for the Period July 1999 Through June 2001.* OAS-01-02-00014 [Report](#)
- 2004 JAN *Audit of Houston Administrative Costs Claimed for Medicaid School-Based Health Services.* OAS-06-02-00037 [Report](#)

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- 2003 DEC *Review of Illinois Medicaid School-Based Services for the Period July 1, 2000 Through June 30, 2001.* OAS-05-02-00049 [Report](#)
- 2003 JUL *Review of Washington State's Medical Assistance Costs Claimed for School-Based Health Services Provided in State Fiscal Year 2000.*
OAS-10-02-00008 [Report](#)
- 2003 JUL *Medicaid Payments for School-Based Health Services - Massachusetts Division of Medical Assistance - July 1999 Through June 2000.* OAS-01-02-00009 [Report](#)
- 2003 MAY *Review of Rate Setting Methodology Medicaid School-Based Child Health Program Costs Claimed by the Connecticut Department of Social Services July 1997 Through June 2001.* OAS-01-02-00006 [Report](#)
- 2003 APR *Review of Payments for Transportation Services Made to Special Service School Districts Under New Jersey's Medicaid Program.*
OAS-02-02-01022 [Report](#)
- 2003 APR *Audit of Medicaid School-Based Services in Oklahoma.*
OAS-06-01-00083 [Report](#)
- 2003 MAR *Review of Medicaid School-Based Services Claimed During State Fiscal Year 2000 by Maryland's Medicaid Program.* OAS-03-01-00224 [Report](#)
- 2003 MAR *Review of Wisconsin Medicaid School-Based Services Program for the Year Ending June 30, 2000.* OAS-05-02-00023 [Report](#)
- 2002 DEC *Followup Review of a Finding Contained in a New York State Office of the State Comptroller Audit Report on Duplicate School Health Claims to Medicaid Made by the New York City Board of Education.*
OAS-02-02-01018 [Report](#)
- 2002 OCT *Audit of Oklahoma Medicaid School-Based Services Provided Free to Other Students and Not Exempt Under the Individuals with Disabilities Education Act.*
OAS-06-01-00077 [Report](#)
- 2002 AUG *Review of Oregon's Medicaid Payments for School-Based Health Services Direct Care in State Fiscal Year 2000.* OAS-10-01-00006 [Report](#)
- 2002 JUN *Review of Medicaid School Based Child Health Service Costs Claimed by Connecticut Department of Social Services October 1999 - September 2000.*
OAS-01-01-00006 [Report](#)
- 2002 MAY *Review of Washington State's Administrative Costs Claimed for Medicaid School-Based Health Services in State Fiscal Year 2000.*
OAS-10-01-00011 [Report](#)

2001 NOV *Medicaid Monthly Payments for School-Based, Health-Related Services in North Carolina.* OAS-04-00-02161 [Report](#)

Identify Duplicate Medicaid and Medicare Home Health Payments

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

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

Recommendations: CMS should (1) ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and (2) clarify its policy on Medicare PPS coverage of routine medical supplies.

Savings: \$1 million*

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

Management Response Summary: CMS said that it “did not disagree” with our first recommendation to ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and indicated that it recognized

the importance of preventing duplicate Medicaid and Medicare billings. The agency also commented that the absence of medical record reviews limited the findings. CMS indicated that it would develop a process to address duplicate claims for nonroutine medical supplies and disseminate the process to State program integrity directors. CMS concurred with our second recommendation to clarify the policy on coverage of routine medical supplies under Medicare's home health PPS and indicated that it planned to clarify coverage during the calendar year (CY) 2010 rulemaking process.

Status: To date, CMS has not taken action on our recommendations. We will continue to monitor CMS's actions on both recommendations.

Related Report:

2008 MAY *Duplicate Medicaid and Medicare Home Health Payments: Medical Supplies and Therapeutic Services.*
OEI-07-06-00640 [Report](#)

See Also:

2009 FEB *Memorandum Report: Medicaid and Medicare Home Health Payments for Skilled Nursing and Home Health Aide Services.*
OEI-07-06-00641 [Report](#)

Enforce Federal Medicaid Payment Policies for Personal Care Services (New)

Background: Personal care services (PCS) provide the elderly, people with disabilities, and individuals with chronic or temporary conditions with the assistance they need to remain in their homes or communities. State Medicaid programs may reimburse the cost of PCS for individuals who are not inpatients or residents of certain institutions but should not separately reimburse for PCS furnished during institutional stays. We reviewed Medicaid PCS and institutional claims and Medicare institutional claims for services provided from October 1 through December 31, 2005, in five States: Minnesota, New Mexico, North Carolina, Texas, and Washington. We compared the dates of service for paid PCS claims with the dates of service for paid Medicaid and Medicare institutional stays to identify Medicaid payments for PCS provided during institutional stays.

Finding(s): OIG found that in the first quarter of (fiscal year) FY 2006, the five States reviewed paid nearly \$500,000 in error for PCS provided during periods of institutionalization. Forty-three percent of the claims paid in error were identified by using data that were available in the States' Medicaid payment systems. Billing practices in three States created vulnerabilities that could mean that nearly \$11 million in that quarter may have been paid in error. Because these three State Medicaid programs allowed PCS providers to bill for services using date ranges that included days on which no PCS were provided, we could not determine, using existing claims data, whether 93 percent of these States' overlapping PCS claims representing approximately \$10.9 million were paid in error. Although the five States reported having Medicaid controls to prevent payments for PCS provided during institutional stays, the controls did not fully prevent erroneous payments.

Recommendations: CMS should (1) enforce Federal Medicaid payment policies that prohibit Medicaid reimbursement for PCS provided over a range of dates if the range includes dates on which the beneficiary was institutionalized and (2) work with States to reduce erroneous Medicaid payments for PCS provided during institutional stays.

Management Response Summary: CMS concurred with our recommendation that Medicaid payments for PCS provided during institutional stays should be reduced. However, CMS did not concur with our recommendation to prohibit Federal Medicaid reimbursement for PCS claims billed with date ranges that include days on which no PCS were provided. CMS said that Federal reimbursement policies are sufficient to prohibit such payments when States have effective controls in place. We revised the recommendation in the final report to say that CMS should enforce its policies. In its

December 2009 update, CMS indicated that it is working with its regional offices and States on a solution for disseminating information to ensure that Medicaid does not pay for Medicare-paid services. CMS also indicated that it was drafting a program integrity alert.

Status: We continue to encourage CMS to enforce policies to reduce erroneous Medicaid payments for PCS during institutional stays.

Related Report:

2008 AUG *Payments Made in Error for Personal Care Services During Institutional Stays.*
OEI-07-06-00620 [Report](#)

Prescription Drugs:

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

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

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

Recommendation: CMS should encourage the States to align pharmacy reimbursement more closely with the actual acquisition cost of brand-name drugs paid by pharmacies in their States, e.g., by implementing a four-tier approach to reimbursement: (1) single-source innovator drugs, (2) multiple-source innovator drugs without Federal upper limits (FUL), (3) multiple-source noninnovator drugs without FULs, and (4) multiple-source noninnovator drugs with FULs.

Savings: \$1.08 billion*

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

Management Response Summary: In its comments on our 2001 draft report, CMS concurred with our recommendation, stating that it was working with States to review their estimates of acquisition costs in light of our findings. In addition, the President's FY 2006 budget proposed a legislative change that would limit the Federal reimbursement to States for Medicaid pharmacy payments to the amount that a State would have paid, in the aggregate, for covered outpatient drugs based on the manufacturers' average sales prices (ASP). The proposed legislative change was not enacted or included in the President's FY 2007, 2008, 2009, or 2010 budgets.

Status: We plan to continue to monitor the pricing of Medicaid drug reimbursements for brand-name drugs.

Related Reports:

2002 SEP *Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products.* OAS-06-02-00041 [Report](#)

2001 AUG *Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products.* OAS-06-00-00023 [Report](#)

Encourage States To Align Medicaid Generic Drug Pharmacy Reimbursements With Pharmacies' Acquisition Costs

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

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

Finding(s): In 1999, State pharmacy reimbursement formulas, on average, estimated pharmacy acquisition costs to be AWP minus 10.31 percent. We found that this 10.31 percent discount is not sufficient to ensure that drug reimbursement accurately reflects pharmacy acquisition costs. We estimated that pharmacies' actual acquisition costs for generic drugs averaged 65.93 percent below the AWP in 1999. We estimated that changing the reimbursement policy to more accurately reflect pharmacies' actual acquisition costs could have saved the Medicaid program as much as \$470 million for the 200 generic drugs with the highest Medicaid reimbursement for CY 1999. OIG's subsequent study also found that overall FUL amounts for generic drug products were five times higher than the average AMP amounts for the same products in the third quarter of 2004. During the same period, the FUL amount was, on average, 22 times higher than the lowest reported AMP.

Recommendations: CMS should (1) encourage the States to align Medicaid generic drug pharmacy reimbursements more closely with the actual acquisition costs paid by pharmacies in their States (e.g., by implementing a four-tier approach to reimbursement: single-source innovator drugs, multiple-source innovator drugs without FULs, multiple-source noninnovator drugs without FULs, and multiple-source noninnovator drugs with FULs) and (2) work with Congress to set FUL amounts that more closely approximate acquisition costs.

Savings: TBD*

**Savings not estimated.*

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

The Deficit Reduction Act of 2005 (DRA) changed the FUL calculation for generic drugs. For generic drugs with FULs, the Federal Government capped Medicaid drug reimbursement at 250 percent of the lowest AMP for a therapeutically equivalent version of a drug. CMS promulgated a final rule pursuant to this change in July 2007 (72 Fed. Reg. 39142). The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of the rule. While this prohibition is in effect, CMS continues to calculate FUL amounts based on the previous formula (i.e., 150 percent of the lowest published price). In April 2008, CMS told us that it would follow up to ensure that States take OIG's findings into account.

Status: We plan to continue to monitor the pricing of Medicaid drug reimbursements for generic drugs until the injunction is lifted and the rule becomes effective.

Related Reports:

- 2005 JUN *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices.* OEI-03-05-00110 [Report](#)
- 2002 SEP *Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products.* OAS-06-02-00041 [Report](#)
- 2002 MAR *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products.* OAS-06-01-00053 [Report](#)

Medicaid > Prescription Drugs > Pharmacy Reimbursement—Federal Upper Limits
Review Impact of New Federal Upper Limit Calculations

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

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

Recommendations: CMS should take steps to (1) identify cases in which a new FUL amount may not be representative of a drug's acquisition cost to pharmacies and, (2) 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.

Management Response Summary: CMS did not concur with our findings on 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 asked that we revise our analysis. According to CMS, as of the first quarter of FY 2008, it changed the way it identifies which drugs are subject to FUL and the way it calculates prices.

The DRA required CMS to change its FUL calculation to base these limits on AMP, a sales-based price, by January 2008. However, in December 2007, a Federal district court issued a preliminary injunction that prevented CMS from implementing the new FULs. Therefore, FULs are calculated using the prior formula based on the lowest published prices (i.e., AWP or wholesale acquisition costs), which OIG has found to result in inflated payments.

Status: We will continue to work with CMS to ensure that the FUL amounts are fair and appropriate to the Medicaid program and to providers.

Related Report:

2007 JUN *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program.* OEI-03-06-00400 [Report](#)

See Also:

2005 JUN OIG Testimony Before the Senate Committee on Finance. Medicaid Pays Too Much for Prescription Drugs. [Testimony](#)

Establish a Connection Between the Calculations of Medicaid Drug Rebates and Drug Reimbursements

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

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

Recommendations: CMS should (1) seek legislation that would require Medicaid drug rebates and reimbursements to be developed using the same basis or (2) study viable alternatives to the current program.

Savings: TBD*

**We estimated that if rebates had been based on AWP (instead of on the statutorily required AMP) for CY 1994 through CY 1996, Medicaid would have achieved more than \$1 billion in added rebates for only the top 100 Medicaid-reimbursed brand-name drugs. We did not calculate the savings that would be achieved in an AMP-to-AMP scenario.*

Management Response Summary: CMS did not concur with our recommendation, stating that it did not believe that a legislative proposal was feasible at the time of our report. However, in accordance with the DRA, in July 2006 CMS began providing States with AMP data on a monthly basis. Under the DRA, States may choose (but are not required) to use AMP data to revise their reimbursement formulas. In July 2007, pursuant to the DRA, CMS promulgated a final rule about making AMP data available to States. The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of the rule.

Status: We are concerned that until all States use AMPs in their reimbursement formulas, there will be no connection between reimbursement and rebates. We plan to continue monitoring this issue.

Related Report:

1998 May *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs.*
OAS-06-97-00052 [Report](#)

See Also:

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: "Medicaid is Paying Too Much for Prescription Drugs." [Testimony](#)

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

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

Finding(s): Requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG has focused primarily on how manufacturers calculate AMP, and it has found that manufacturers interpret AMP requirements differently. 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. 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. Industry groups raised other 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 and rebate errors.

Recommendations: CMS should (1) clarify requirements with regard to the definition of "retail class of trade" and the treatment of pharmacy benefit manager rebates and Medicaid sales; (2) 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; (3) issue guidance in the near future that specifically addresses implementation of AMP-related reimbursement provisions of the DRA, and (4) encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Management Response Summary: CMS concurred with our recommendations. In July 2007, CMS issued a final rule that modified the definition of the AMP and appears to increase the transparency of the AMP calculation. The rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing provisions of this rule.

Status: OIG audits continue to identify variations among calculation methods, and we continue to recommend that CMS provide oversight to ensure that methods used to calculate AMPs are consistent among manufacturers. We will continue monitoring this issue.

Related Reports:

2006 MAY *Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005.* OAS-06-06-00063 [Report](#)

1992 NOV *Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program.* OAS-06-91-00092 [Report](#)

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

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

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

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

Savings: \$123 million*

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

Management Response Summary: CMS did not concur with our recommendation. In its comments on our 2002 *Red Book*, CMS said that it believed that savings would be achieved through a President's budget proposal for a legislative change that would have based the Medicaid drug rebate on the difference between AWP and the best price of the drug. However, this proposal was not enacted. In November 2008, CMS noted that the Administration's position, as reflected in the FY 2008 President's budget, was to eliminate the best price; however, this proposal was not enacted.

Status: 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.

Related Report:

1995 OCT *Special Report for the Ranking Member of the Senate Special Committee on Aging: Potential Impact on the Use of an Indexed Best Price Calculation in the Medicaid Drug Rebate Program.* OAS-06-94-00039 [Report](#)

Extend Additional Rebate Payment Provisions to Generic Drugs

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

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

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

Savings: \$966 million*

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

Management Response Summary: CMS said that it could not commit to pursuing the legislative change because, at the time of our report, it did not have sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the DRA. However, CMS indicated that it would consider our recommendation as it considers future legislative proposals. In December 2009, CMS told us that it continues to consider all improvements to the Medicaid drug rebate program, including seeking legislative change when CMS believes it is appropriate.

Status: We will continue to monitor CMS's progress in seeking legislation and other improvements toward implementing the recommendation.

Related Report:

2007 OCT *Review of Generic Drug Price Increases.* OAS-06-07-00042 [Report](#)

Identify Drugs That Are Ineligible for Federal Payments Under Medicaid (New)

Background: For Federal payments to be available for covered outpatient drugs provided under Medicaid, the Social Security Act, §§ 1927(a)(1) and (b)(1), require drug manufacturers to (1) enter into rebate agreements with the Secretary of HHS and (2) pay quarterly rebates to State Medicaid agencies. Covered outpatient drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness, with certain exceptions, to qualify for Federal payments. As set forth in section 1927(b)(3), manufacturers must provide CMS with the AMP,² by national drug code (NDC), for each of their covered outpatient drugs. The rebate amount for a drug is based in part on whether it is categorized as an innovator or noninnovator product. Innovator products are generally subject to higher reimbursement. Manufacturers provide CMS with the drug categorization in conjunction with AMP data. We compared drug categorizations in CMS's fourth quarter 2007 AMP file to drug categorizations in two national compendia.

Finding(s): We found that most AMP file drug categorizations matched the categorizations in two national compendia. For 90 percent of NDCs in our comparison, the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. However, drug categorizations did not match for 10 percent of NDCs. Overall, these nonmatching NDCs were associated with 3 percent of total fourth-quarter 2007 Medicaid expenditures for the NDCs under review. A manual review of 75 high-expenditure nonmatching NDCs revealed that 32 NDCs were for drugs that had not been approved by FDA. Medicaid paid \$20 million for these drugs in the fourth quarter of 2007.

In addition, a substantial number of NDCs were excluded from the drug categorization comparison, primarily because of missing data. We were unable to compare drug categorizations for 42 percent of NDCs with fourth-quarter 2007 Medicaid utilization for several reasons: (1) the NDCs were not listed in the AMP file, (2) the NDCs were not listed in one or both of the two national drug compendia, or (3) the NDCs had drug categorizations that differed in the two national compendia.

Recommendation(s): CMS should (1) work closely with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA; (2) work with manufacturers to determine the correct categorizations of the drugs that we identified as being potentially

² In December 2007, the U.S. District Court for the District of Columbia preliminarily enjoined the implementation of AMP-based FULs.

miscategorized in the AMP file, (3) assist States in collecting any unpaid rebates that they are owed; and (4) continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG on administrative remedies for noncompliance.

Savings: \$20 million*

**Based on OIG analysis of 2007 fourth-quarter Medicaid expenditures.*

Management Response Summary: In its response to the first recommendation, CMS said that it has worked and will continue to work closely with FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug for the purposes of the Medicaid drug rebate program. CMS explained that FDA provides it with information on unapproved drugs that may be ineligible for coverage and that CMS reviews the information to determine whether action should be taken to remove these drugs from the list of covered drugs.

In its response to the second recommendation, CMS said that it is contacting the manufacturers for which OIG identified a potential problem with drug categorizations. CMS said that it will work with manufacturers to correct categorizations and ensure that payments to States are appropriate. CMS also noted that it has been working with manufacturers to correctly categorize drugs that manufacturers have identified as being misreported.

In its response to the third recommendation, CMS said that it will continue to contact manufacturers that fail to submit timely AMP data after each quarter to remind them of their responsibilities and request that their data be submitted immediately. As of January 2010, CMS had taken steps to address the first and third recommendations.

Status: We continue to encourage CMS to work with manufacturers to determine the correct drug categorizations and continue to monitor CMS's progress through current work.

Related Report:

2009 JUL *Accuracy of Drug Categorizations for Medicaid Rebates.*
OEI-03-08-00300 [Report](#)

Medicaid Administration:

Enforce Federal Requirements for Submission of Medicaid Managed Care Encounter Data (New)

Background: Encounter data are the primary records of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. As of 2006, 65 percent of the 45.6 million Medicaid beneficiaries were receiving all or part of their health care services through Medicaid managed care. The Balanced Budget Act of 1997 (BBA) requires that Medicaid claims submitted to CMS “on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary of HHS and consistent with the Medicaid Statistical Information System (MSIS).” As the only national database of Medicaid claims and beneficiary eligibility information, the MSIS is used by CMS to manage, analyze, and disseminate information on Medicaid beneficiaries, services, and payments. The MSIS is also widely used for research and policy analysis by public and private organizations and may also be used for detecting fraud, waste, and abuse. The MSIS must include encounter data to be representative of Medicaid beneficiaries and services.

Finding(s): We found that the 40 States with capitated Medicaid managed care collect encounter data from managed care organizations (MCO); however, the usefulness of the MSIS is limited because CMS does not enforce encounter data requirements.

Recommendations: CMS should (1) clarify Federal requirements that States include encounter data in MSIS submissions, (2) enforce Federal requirements that States include encounter data in MSIS submissions, and (3) seek legislative authority to impose sanctions against States that fail to meet the MSIS reporting requirements for encounter data.

Management Response Summary: CMS concurred with two of our recommendations. With regard to our third recommendation, CMS said that it first wanted to pursue efforts that address our first two recommendations before considering seeking sanction authority. CMS also said that it will (1) issue a State Medicaid Director letter to States that use managed care to clarify Medicaid managed care encounter data reporting requirements, (2) inform States that CMS staff members will be available to provide technical assistance, (3) use State Technical Advisory Groups to collaborate with States on best practices, and (4) establish an Encounter Data Workgroup. CMS said it intends to increase efforts to consistently enforce the Federal encounter data reporting requirements and will review authorities to determine areas in which it can strengthen authorities to improve reporting of encounter data. We agree that CMS should address our first two recommendations as an initial step. In its December 2009 update, CMS

indicated that it established an Encounter Data Workgroup. The purpose of the workgroup is to address and make recommendations pertaining to specific issues experienced by States with encounter claims submissions.

Status: We will monitor CMS's efforts in the implementation of its planned actions as explained above in the "Management Response Summary."

Related Report:

2009 MAY *Medicaid Managed Care Encounter Data: Collection and Use.*
OEI-07-06-00540 [Report](#)

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. Credit balances generally occur when the reimbursement that a provider receives for services provided to a Medicaid beneficiary exceeds the charges billed, such as when a provider receives a duplicate payment for the same service from the Medicaid program or a third-party payer.

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

Recommendations: CMS should (1) establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A and (2) require its regional offices to actively monitor the reporting mechanism that is established.

Savings: TBD*

**Savings not estimated.*

Management Response Summary: When commenting on our 1995 report, CMS concurred with our recommendation to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. However, CMS decided not to do so, citing the uncertain and minimal savings potential; the Administration's commitment to enhancing States' flexibility; and, specifically, avoiding the imposition of an unfunded mandate.

In 2008, CMS described actions it had taken to update its financial management review guides addressing Medicaid provider overpayments and to develop an annual work plan for reviewing high-risk financial management areas. However, CMS has not implemented a credit balance reporting mechanism.

Status: We continue to recommend that CMS establish a national Medicaid credit balance reporting mechanism and require its regional offices to monitor reporting.

Related Reports:

1995 MAY *Quarterly Credit Balance Reporting Requirements for Medicaid.*
OAS-05-93-00107 [Report](#)

1993 MAR *Nationwide Audit of Medicaid Credit Balances.* OAS-04-92-01023 [Report](#)

Advise States of Their Authority To Collect From Noncustodial Parents With the Ability To Contribute Toward Their Children’s Medicaid or Children’s Health Insurance Program Costs

Background: Regulations require State agencies operating child support enforcement programs pursuant to Title IV-D of the Social Security Act 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 Social Security Act, which authorizes the Children’s Health Insurance program (CHIP), is silent with regard to collecting CHIP 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. Medicaid regulations do not address how State Medicaid agencies should coordinate with State Title IV-D agencies or how the States should establish and administer Medicaid fee-for-service (FFS) recoveries.

States also have an opportunity to enroll uninsured Title IV-D children in CHIP and provide a means for noncustodial parents to fulfill their medical support obligations. Unlike Federal Medicaid laws, CHIP 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 CHIP costs from noncustodial parents, others have questioned their authority to do so or expressed concern about the costs that would be incurred.

Recommendations: CMS should (1) clarify third-party liability regulations to help State Medicaid agencies coordinate with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders; (2) seek legislation that would allow States to accumulate medical support payments to offset Medicaid FFS costs for a reasonable period; (3) determine whether more Federal funds are needed to help States interface their Title IV-D and CHIP databases; (4) implement a process to collect CHIP costs from noncustodial parents; and (5) as appropriate, provide funds for this purpose.

Savings: \$99 million – Medicaid*
\$14 million –CHIP**

**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 CHIP benefits had noncustodial parents who could potentially contribute \$14 million toward the CHIP premiums based on the most recent data available from each State in 2001 or 2002.*

Management Response Summary: 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 Federal laws and regulations prohibit States from accumulating additional medical support payments. CMS did not concur with our recommendations that issuing formal guidance on CHIP costs was necessary but agreed to alert States to their option to pursue the Federal and State shares of these costs. Subsequent to our reports, CMS told us during a series of Medical Support Collaboration meetings sponsored by the Administration for Families and Children (ACF) in 2005 that it had provided guidance to States on the collection of Medicaid costs from available employer-sponsored health care coverage of noncustodial parents and on their authority under Federal law to collect CHIP costs from noncustodial parents. CMS also noted that States had the authority to fund the administrative costs of building an infrastructure with the State Title IV-D agency under their 10-percent administrative CHIP cap and recognized that there is no mechanism in CHIP to provide States with more funding if they spend funds up to the 10-percent cap.

Status: 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.

Related Reports:

2005 JUN *Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children That Were Paid Under the Medicaid Program.* OAS-01-03-02501 [Report](#)

2005 MAY *Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children Under the State Children's Health Insurance Program.* OAS-01-03-02502 [Report](#)

**Part III: Public Health and
Human Services Programs
and Departmentwide Issues**

Public Health Recommendations

Improve States' and Localities' Medical Surge Preparedness for Pandemics (New)

Background: A pandemic would affect much of the country at the same time, so medical resources—such as hospital beds, medical equipment, and personnel—likely would be scarce. The ability to rapidly respond to an increased demand for medical resources is often referred to as a “medical surge.” The recent public health emergency caused by an outbreak of human cases of H1N1 influenza has highlighted the need for States and localities to be prepared for a medical surge.

We assessed the extent to which selected States and localities have prepared for a medical surge in response to an influenza pandemic and have conducted and documented exercises that test their medical surge preparedness. This study is based on a purposive sample of 5 States and 10 localities and presents a snapshot of these States' and localities' preparedness for an influenza pandemic as of late summer 2008. The study is based on a review of documentation from the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the selected States and localities, as well as structured in-person interviews with key officials in each of the selected States and localities.

Finding(s): We found that all of the 10 localities that we reviewed had established partnerships to prepare for a medical surge; however, the degree to which coordination occurred varied. We also found that fewer than half of the localities had started to recruit medical volunteers, and none of the five States that we reviewed had implemented an electronic system to manage the volunteers. Similarly, the 10 localities had acquired limited medical equipment for a pandemic, but only 3 of the 5 States had electronic systems to track available beds and equipment. As of late summer 2008, most of the localities were in the early stages of planning for alternate care sites, and most had not identified guidelines for altering triage, admission, and patient care during a pandemic. Finally, although the localities conducted medical surge exercises, none consistently documented the lessons learned.

Recommendations: We recommend that ASPR, in collaboration with CDC, (1) work with States and localities to improve their efforts within each of the five components of medical surge that we reviewed, (2) ensure that States and localities consistently document the lessons learned from preparedness exercises that address medical surge, (3) address the issue of legal protections for medical professionals and volunteers who respond to public health emergencies,

(4) facilitate the sharing of information and emerging practices among States and localities, and (5) provide training and technical assistance to States and localities on key issues.

Management Response Summary: ASPR concurred with our recommendations. In October 2009, ASPR stated that it had updated its *Medical Surge Capacity and Capability Handbook* and added hospital reporting requirements to aid State health care system planning. ASPR also indicated that it had implemented a standardized reporting template to improve health care systems' statewide and regional exercise documentation and data collection.

Status: We will monitor ASPR's progress in implementing the recommendations made in this report.

Related Report:

2009 SEP *State and Local Pandemic Influenza Preparedness: Medical Surge.*
OEI-02-08-00210 [Report](#)

Ensure That State Public Health Laboratories Meet Cooperative Agreement Requirements on Biological Threats (New)

Background: In 2006, through its Cooperative Agreement, CDC allocated about \$766 million to 62 awardees to meet 9 preparedness goals. Preparedness Goal 3, Detect and Report, is the only goal that focuses on public health laboratory testing and reporting biological threats. This goal contains 2 required critical tasks with 11 requirements. These requirements contain multiple elements that State public health laboratories must meet to decrease the time needed to detect and report biological public health threats. For most of the Preparedness Goal 3 requirements, State public health laboratories must coordinate with private clinical laboratories, known as sentinel laboratories, that perform preliminary testing and ship specimens to the State.

Finding(s): We surveyed public health laboratory officials in 50 States and 3 metropolitan areas to assess the extent to which they have made progress toward meeting 9 of the 11 Cooperative Agreement requirements for State public health laboratory testing and reporting. We found that every State reported meeting at least three of the requirements that we reviewed, but no State met all nine. At least 87 percent of States reported meeting all of the elements in four of the nine requirements. Less than 65 percent of States reported meeting all the elements in 5 of the 9 testing and reporting requirements we reviewed, and less than 10 percent of States reported meeting all elements in two of these five requirements.

Recommendations: CDC should continue to assist States in meeting Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. CDC should place special emphasis on improving performance for the 2 requirements met by less than 10 percent of States by (1) determining why less than 10 percent of States conducted tests of their sentinel laboratories' shipping capabilities outside regular business hours and providing assistance to States on how to increase the number of tests conducted, and (2) ensuring that States use a consistent method to identify sentinel laboratories to be included in their databases and that the databases include all the required elements.

Management Response Summary: CDC concurred with our overall recommendation that it continue to assist States in meeting the Cooperative Agreement requirements to decrease the time needed to detect and report biological public health threats. CDC concurred that it should determine how sentinel laboratories are identified and noted that States should have flexibility in determining the functional criteria for a

facility to be considered a sentinel laboratory. CDC noted that States have until 2010 to meet all the required critical tasks stipulated.

Status: We encourage CDC to continue to assist States with meeting the cooperative agreement requirements.

Related Report:

2008 OCT *Public Health Laboratory Testing To Detect and Report Biological Threats.*
OEI-04-07-00750 [Report](#)

Update and Maintain an Accurate National Drug Code Directory

Background: The Drug Listing Act of 1972, § 3, amended the Food, Drug, and Cosmetic Act (FDCA) to require drug firms that are engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to the 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. FDA enters the full NDC number and information submitted as part of the listing process into a database known as the Drug Registration and Listing System. FDA extracts information from the database several times a year and publishes that information in the *NDC Directory* (the directory). When drug firms introduce a new drug product or discontinue a product, they must report the complete NDC and associated information to FDA as part of the drug-product listing process.

Finding(s): We found that the directory was neither complete nor accurate. An estimated 9,187 prescription drug products were missing from the list, while another 5,150 had not cleared the listing process. 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 instances when drugs are placed on or taken off the market and their failure to provide sufficient and accurate information to complete the listing process.

Recommendations: FDA should (1) finalize the draft listing instructions that are on its Web site, (2) provide greater control over the assignment of NDCs, (3) continue to implement electronic submission of listing forms by firms, (4) implement a mechanism to routinely identify drug product omissions and inaccuracies, (5) resolve the status of pending drug product listings, (6) improve communication with drug firms to facilitate accurate and complete reporting of drug products, and (7) identify and take appropriate action against drug firms that consistently fail to list drug products and update information.

Management Response Summary: FDA concurred with our recommendations and requested access to our data files to follow up on identified problems. In comments on our draft report, FDA delineated a number of initiatives to improve the directory's completeness and accuracy, such as conversion to an electronic listing system for use by drug firms.

Subsequent to our report, FDA indicated that it had updated the draft listing instructions on its Web site.

FDA published a proposed rule, 71 Fed. Reg. 51276 (Aug. 29, 2006), to clarify listing requirements, enhance control of the drug establishment registration and drug-listing process, and improve data accuracy and completeness. FDA also said that in December 2006, it held a public hearing on the proposed rule that would change the NDC system. On July 11, 2008, FDA issued *Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing: Availability*.

In addition to requesting comments on the draft guidance, FDA requested comments on the adequacy and usefulness of the technical documents that are available on FDA's Web site. With publication of the guidance, FDA is launching a voluntary pilot program that will enable industry to begin submitting drug establishment registration and drug listing information in electronic format. Based on comments received on the draft guidance and information obtained during the voluntary pilot program, FDA issued final guidance on June 1, 2009.

Status: We continue to recommend that the FDA provide greater control over the assignment of NDCs, implement a mechanism to routinely identify drug product omissions and inaccuracies, resolve the status of pending drug product listings, and identify and take appropriate action against drug firms that consistently fail to list drug products and update information. We also have additional work in the area underway.

Related Report:

2006 AUG *The Food and Drug Administration's National Drug Code Directory.*
OEI-06-05-00060 [Report](#)

Improve Postmarketing Oversight of Drugs

Background: FDA requires all new drugs to undergo clinical testing to demonstrate their safety and efficacy before approval for sale in the United States. FDA has the authority to require postmarketing study commitments in certain situations (e.g., accelerated approval), but most postmarketing study commitments are requested by FDA and agreed to by drug applicants. The Food and Drug Administration Modernization Act of 1997 (FDAMA) 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 in FDA's Center for Drug Evaluation and Research are charged with validating the accuracy of the reports.

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

Recommendations: FDA should (1) instruct drug applicants to provide additional, meaningful information in their ASRs, (2) improve the management information system for monitoring postmarketing study commitments, (3) ensure that postmarketing study commitments are being monitored, and (4) ensure that ASRs are being reviewed.

Management Response Summary: 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 being done. It concurred with our recommendations to improve the management information system for monitoring postmarketing study commitments and to ensure that postmarketing study commitments were being monitored and that the ASRs were validated. Subsequent to our report, FDA told us that it had begun to improve its postmarketing study commitment database and reporting capabilities; to train its review division staff members on ASR validation procedures; to standardize the process by which postmarketing study commitments are requested and reviewed; and to hire contractors to conduct an analysis of the postmarketing commitment process to gain

greater internal consistency on how FDA requires, requests, facilitates, and reviews postmarketing study commitments.

FDA also told us that in February 2006 it issued industry guidance to describe in greater detail the content, form, and timing of postmarketing reports; in July 2006, it enhanced its database to include new functions and improvements. The FDA Amendment Act of 2007 (FDAA), § 921, added a requirement for FDA to review annually the backlog of postmarketing safety commitments to determine which commitments require revision or should be eliminated and to report to Congress on these determinations. In an April 2008 update, FDA told us that it had prepared a report to Congress on postmarketing safety commitments, which was in the clearance process.

Status: Although we acknowledge FDA's efforts to date, we continue to recommend that FDA improve its management information system for monitoring postmarketing study commitments and ensure that ASRs are being validated.

Related Report:

2006 JUN *FDA's Monitoring of Postmarketing Study Commitments.*
OEI-01-04-00390 [Report](#)

Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products (New)

Background: Beginning in 2005, FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. These records enable FDA to trace articles of food through each stage of the supply chain—from retail outlets back to farms—if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat. Traceability is the ability to follow the movement of food products through the stages of production, processing, and distribution. Traceability is often needed to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures. We used two primary data sources for our review: a traceability exercise of 40 selected food products and structured interviews with the managers of the food facilities that handled the selected food products to determine the extent of the information that facilities kept about their sources, recipients, and transporters, which we used to trace the products.

Finding(s): We were able to trace 5 of the 40 products through each stage of the food supply chain. For 31 of the 40 products, we were able to identify facilities that likely handled the products. Most facilities did not maintain lot-specific information in their records and could estimate only a range of deliveries (from one or more facilities) that may have included the products we purchased. Several factors prevented us from tracing the specific products through the food supply chain: processors, packers, and manufacturers did not always maintain lot-specific information as required; products were not labeled with required information; and products from a number of farms were mixed. We found that 59 percent of the facilities did not meet FDA's record requirements about sources, recipients, and transporters. This meant that 70 of the 118 facilities in our sample did not provide required information. We also found that one-quarter of the food facilities were not aware of FDA's records requirements. Others highlighted practices designed to improve traceability.

Recommendations: We recommend that FDA (1) seek statutory authority, if necessary, to strengthen records requirements regarding lot-specific information; (2) consider seeking additional statutory authority to improve traceability; (3) work with the food industry to develop additional guidance to strengthen traceability; (4) address issues related to mixing raw food products from a large number of farms; (5) seek statutory authority to conduct activities to ensure that facilities are complying with record requirements; and (6) conduct education and outreach to inform the food industry about its records requirements.

Management Response Summary: FDA said that it will consider our first three recommendations regarding seeking wider statutory authority, and it described its efforts in response to our recommendations to work with the food industry to conduct education and outreach. FDA did not say whether it concurred with the other recommendations but noted that it continues to work closely with its food-safety partners to strengthen its ability to protect Americans from foodborne illness, which includes determining whether additional statutory authority is needed to better protect public health.

Status: We continue to recommend that FDA seek statutory authority to strengthen record requirements and compliance and improve traceability.

Related Report:

2009 MAR *Traceability in the Food Supply Chain.* OEI-02-06-00210 [Report](#)

See Also:

2009 MAR OIG Testimony Before the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies: "Traceability in the Food Supply Chain." [Testimony](#)

Ensure That Clinical Investigators Disclose All Financial Interests (New)

Background: Most new drugs, biological products, and medical devices undergo clinical trials on human subjects before they are marketed in the United States. Sponsors, generally pharmaceutical or device companies, oversee trials conducted by clinical investigators. Sponsors must collect financial information from clinical investigators before the trials. However, sponsors submit financial information to FDA only when they submit their marketing applications after clinical trials end. For each clinical investigator, sponsors submit a financial form either certifying that the investigator does not have a financial interest or disclosing the financial interest.

Findings: We found that clinical investigators might not be disclosing all their financial interests. One percent of clinical investigators disclosed a financial interest during the period reviewed. FDA cannot determine whether sponsors have submitted financial interest information for all their clinical investigators. We also found that almost half of marketing applications were missing financial interest information. In almost one-third of marketing applications, FDA reviewers did not document a review of financial interest information, and neither FDA nor sponsors took action for 20 percent of marketing applications with disclosed financial interests.

Recommendations: FDA should (1) ensure that sponsors submit complete financial information for all their clinical investigators, (2) ensure that FDA reviewers consistently review financial information and take action in response to disclosed financial interests by using a review template and providing guidance and training to reviewers, and (3) require that sponsors submit financial information as part of the pretrial application process.

Management Response Summary: FDA generally agreed with our recommendations. However, the agency did not agree with our final recommendation that FDA require sponsors to submit financial information for clinical investigators during the pretrial application process. FDA emphasized that collecting financial information before clinical trials is the sponsors' responsibility. As of February 2009, FDA required entities submitting marketing applications to include a complete list of clinical investigators and either certify to the absence of any financial arrangement or disclose the nature of the financial arrangement. FDA has also updated the *Compliance Program Guidance Manual* chapter entitled "Clinical Investigator Inspections."

Status: We continue to recommend that FDA require sponsors to submit financial information as part of the pretrial application process. Acknowledging the burden to

FDA's administrative and review staff, we encourage FDA to develop a review of financial information that best balances the additional effort with the potential benefits.

Related Report:

2009 JAN *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information.* OEI-05-07-00730 [Report](#)

Minimize Financial Risk in the Food and Drug Administration's Information Technology Contracts (New)

Background: Pursuant to the Federal Acquisition Regulation, agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. Agencies must perform acquisition planning, clearly define what they are buying in the requirements section of a statement of work (SOW), and select an appropriate contract type and method. Agencies must also monitor contractors to ensure quality results.

Finding(s): We found that FDA's Center for Drug Evaluation and Research (CDER) relied primarily on acquisition methods that emphasize speed and flexibility over planning. CDER also relied on time-and-materials contract actions that increase risk for the Government. Because CDER did not clearly define its requirements or performance measures, it also did not apply quality assurance (QA) plans consistently.

Recommendations: We recommend that FDA minimize its contract risk by (1) defining information technology (IT) requirements more clearly, (2) converting ongoing time-and-materials contract actions to fixed-price contract actions when appropriate, (3) using performance incentive plans when appropriate, and (4) using documented QA plans.

Management Response Summary: FDA neither agreed nor disagreed with our recommendation to define its IT requirements more clearly. However, it did identify actions that it is taking that support that recommendation, such as implementing a formal business process model. FDA agreed with our other recommendations to convert time-and-materials contracts to fixed-price contracts when appropriate and to use performance incentives and QA plans, saying that it will use these methods in future contracts when applicable.

Status: We continue to recommend that FDA define its IT requirements in its SOW.

Related Report:

2009 JAN *Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research.*
OEI-01-07-00450 [Report](#)

Eliminate Excessive Costs in the 340B Drug Pricing Program

Background: The Public Health Service Act of 1944 (PHS Act), § 340B, created the 340B Drug Pricing program to lower drug prices for more than 12,300 entities, including community health centers, public hospitals, and various Federal grantees. Pharmaceutical manufacturers calculate the 340B discount using a specified formula and must sell their products at or below this ceiling price to continue to have their products covered by the Medicaid program. The Health Resources and Services Administration's (HRSA) Pharmacy Affairs Branch administers the program for the thousands of enrolled entities nationwide, which are estimated to have spent \$3.4 billion on drugs in 2003.

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

Recommendation(s): HRSA should (1) improve its oversight of the 340B Drug Pricing Program to ensure that entities are charged at or below the 340B ceiling price; (2) work with the Centers for Medicare & Medicaid Services (CMS) to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices; and (3) strengthen its administration of the 340B Drug Pricing Program by (a) establishing detailed standards for the calculation of 340B ceiling prices; (b) instituting oversight mechanisms, including technical assistance to validate its 340B price calculations and the prices charged to participating entities; (c) seeking legislative authority to establish penalties for violations of the PHS Act; and (d) providing participating entities with secure access to certain pricing data to help approximate the 340B ceiling prices.

Savings: \$46.8 million by federally supported covered entities.*

**We estimated savings based on \$3.9 million in overpayments by 340B entities in 1 month in 2005, multiplied by 12 to calculate savings for 1 year. More indirect savings to HHS are likely but have not been calculated.*

Management Response Summary: HRSA concurred with our recommendations and said that it had taken steps to monitor more closely prices paid by the 340B program. In its comments on our 2005 report, HRSA said that it anticipated

promulgating a penny price policy in conjunction with formalizing instructions for the calculation of 340B ceiling prices. HRSA indicated that in April 2007, it had implemented a 1-year 340B Drug Pricing Program pilot project requesting manufacturers to voluntarily submit their prices for comparison with the ceiling prices. To the extent that resources permitted, HRSA would review the data that manufacturers and entities voluntarily submitted. HRSA also indicated that oversight mechanisms to validate 340B price calculations and access to certain pricing data by participating entities will be addressed through the initiatives supported by the appropriation funding.

In March 2009, HRSA informed us that it would consider seeking the authority to establish penalties for violations of the PHS Act, § 340B, and is following CMS's practices concerning detailed standards for the 340B price calculations. In a September 2009 followup review, HRSA indicated that it was drafting guidelines for publications for 340B pricing; however, it lacked the resources to complete the project. In September 2009, HRSA reported that its pilot project revealed that apparent price discrepancies between the manufacturer's price and the 340B ceiling price were primarily because of differences in the package size that were being compared.

Status: We continue to encourage HRSA to seek legislative authority to establish penalties for violations of the PHS Act.

Related Reports:

2006 JUL *Review of 340b Prices.* OEI-05-02-00073 [Report](#)

2005 OCT *Deficiencies in the Oversight of the 340b Drug Pricing Program.*
OEI-05-02-00072 [Report](#)

See Also:

2005 DEC *OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: "340B Program."*
[Testimony](#)

Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

Background: The Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) was passed in 1990 and reauthorized in 1996 and 2000. In FY 2001, Congress provided \$597.3 million under Title I and \$977.4 million under Title II of the CARE Act. 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, and Title II provides grants to States to improve the organization of HIV/AIDS-related health and support services. States distribute Title II 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, and grantee applications were not used as management tools). HRSA provided limited support to project officers to systematically monitor grantees (e.g., little guidance/training, lack of corrective action plans, high staff turnover, minimal coordination). Grantees' monitoring of subgrantees was limited (75 percent of the sampled grantees did not have comprehensive documentation to demonstrate that they were monitoring subgrantees).

Recommendations: HRSA should (1) specify and enforce standards and policies about how project officers should monitor grantees, (2) address training of project officers, (3) standardize corrective actions, (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.

Management Response Summary: HRSA concurred with our recommendations and indicated that significant administrative changes had occurred since the studies were conducted. In May 2008, HRSA told the Office of Inspector General (OIG) that it had taken a variety of steps to implement our recommendations. The steps include enhancing training for project officers, developing a site visit protocol for onsite monitoring, and increasing the number of grantee site visits. HRSA reported that in March 2009, it had consolidated its grants operations and project officers and its monitoring of Part A and Part B (formerly Title I and II) grantees and, through its Office of Performance Review, was receiving more information with regard to grantee performance.

In June 2009, OIG conducted a congressionally requested evaluation of HRSA's status in addressing our recommendations related to grantees' monitoring of subgrantees. In December 2009, HRSA stated that it was developing and monitoring standards that may be used by Ryan White HIV/AIDS Part A and Part B grantees.

Status: We continue to recommend that HRSA set standards for grantees' monitoring of subgrantees and increase its efforts to monitor grantees' oversight of subgrantees. We continue to monitor HRSA's progress in implementing the recommendations.

Related Reports:

2004 MAR *Monitoring of Ryan White CARE Act Title I and Title II Grantees.*
OEI-02-01-00640 [Report](#)

2004 MAR *Ryan White CARE Act Title I and Title II Grantees' Monitoring of Subgrantees.*
OEI-02-01-00641 [Report](#)

Increase Reporting of Medical Malpractice Cases to the National Practitioner Data Bank

Background: Pursuant to a Department of Health & Human Services (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 the National Institutes of Health (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 policy); and (4) the failure to replace a key Program Support Center claims official or to reassign the person's reporting duties.

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

Management Response Summary: There was partial concurrence with our recommendations. Before OIG issued its October 2005 report, IHS started reporting cases in which standards of care were not met. HRSA started reporting such cases soon thereafter. In comments on our draft report, HRSA's Administrator indicated that HHS was developing a policy on reporting cases in which standards of care were not met.

As of April 2008, IHS had submitted 205 more reports of practitioners to NPDB; HRSA had submitted 297 reports. As of April 2008, NIH had not submitted any reports. In March 2009, HRSA informed OIG that it had submitted 17 medical malpractice payment reports between January 1 and December 31, 2008. For the same period, IHS reported to OIG that it had submitted 33 malpractice payment reports and assigned a specific risk-management team to address complaints and questions and perform data entry of NPDB reports. IHS also told us that it had a risk management and medical liability manual and had established file management controls.

In December 2009, IHS indicated that 21 medical malpractice payment reports were submitted for FY 2009. NIH stated that it will not submit reports to NPDB until a revised departmental policy is issued.

Status: We will continue to monitor (1) implementation of new processes to address unreported cases and (2) improvements in internal controls.

Related Report:

2005 OCT *HHS Agencies' Compliance With the National Practitioner Data Bank Malpractice Reporting Policy.* OEI-12-04-00310 [Report](#)

Improve Reporting by Hospitals to the National Practitioner Data Bank

Background: The Health Care Quality Improvement Act of 1986 (HCQIA), § 423, (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 NPDB.

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

Recommendation: HRSA should more fully encourage hospitals to follow the intent of section 423 of the HCQIA 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.

Management Response Summary: HRSA concurred with our recommendations and indicated that its legislative proposal would cover reporting by all health care entities (including managed care organizations (MCO)). In March 2009, HRSA told us that it is developing a legislative proposal to provide for a civil monetary penalty of up to \$11,000 for each instance of a hospital's failure to report to the NPDB. On August 26, 2009, a final regulation from HRSA was distributed throughout HHS for review. It contained language that addresses our recommendation. As of November 2009, the proposed regulation had not been finalized.

Status: We will continue to monitor the proposed regulation and HRSA's development of a legislative proposal.

Related Report:

1999 JUL *Legislative Recommendation To Improve Hospital Reporting to the National Practitioner Data Bank.* OEI-12-99-00250 [Report](#)

Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services (New)

Background: Contract Health Services (CHS) contracts with private providers, such as hospitals and physicians, to deliver emergency or specialty services to eligible Indians when an IHS or tribal facility is unable to provide the necessary care. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and its implementing regulations, all Medicare-participating hospitals must accept reimbursement no greater than the Medicare rate as payment in full for patients eligible for CHS. Nonhospital providers, including physicians, are not covered by the MMA provision. We reviewed the extent to which IHS and tribes paid above the Medicare rate for CHS hospital claims.

Finding(s): We found that IHS and tribes paid above the Medicare rate for 22 percent of hospital claims. As a result, IHS and tribes overpaid \$1 million for hospital claims between January and March 2008. We also determined that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million between January and March 2008. Savings from claims over the Medicare rate could have paid for about 41,000 more nonhospital claims between January and March 2008 that might otherwise have been deferred or denied. Moreover, IHS and tribes paid above Medicare rates for 71 percent of nonhospital claims, most of which were for physician services.

Recommendations: IHS should (1) resolve overpaid CHS hospital claims, (2) direct its fiscal intermediary (FI) to ensure that all future CHS claims are paid at or below the Medicare rate, (3) provide technical assistance to tribes to ensure proper payments of hospital claims, and (4) seek legislative authority to cap payments for CHS nonhospital services.

Savings: TBD*

**We estimated that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million between January and March 2008.*

Management Response Summary: IHS concurred with our recommendations. IHS said that the agency will direct the FI to review the claims identified by OIG as overpaid and, where appropriate, seek refunds in accordance with the Debt Collection Procedures Act within 1 month of receipt of the final report. IHS will also review and monitor the FI's claims-processing and payment policies, procedures, and pricing software accuracy

to ensure that claims processed during the period under review have been paid in accordance with the Medicare rate requirements.

IHS directed the FI to ensure that current and future claims are paid at or below the Medicare rate and will continue to monitor the FI's claims-processing performance to ensure that claims are paid in accordance with regulations and instruct the FI to conduct random claims sampling for financial and claims-processing accuracy. To provide technical assistance, IHS shared the findings and recommendations of our final report with the tribes. IHS will continue to meet with tribes and tribal organizations to develop a plan to cap payments for nonhospital services.

In its December 2009 followup comments, IHS indicated that it had taken multiple steps to address our recommendations, including the FI's completing a review of the CHS claims, continuing to monitor processing and payments policies, directing FIs to ensure that all future claims are paid at or below the Medicare rate, conducting random claims sampling, and providing OIG reports to tribes.

Status: We will continue to monitor IHS's implementation of our recommendations to ensure that the recommendations have been fully instituted by IHS.

Related Report:

2009 SEP *IHS Contract Health Services Program: Overpayments and Potential Savings.*
OEI-05-08-00410 [Report](#)

Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations

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

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

Recommendations: NIH should (1) increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations; (2) require grantee institutions to provide details of the nature of financial conflicts of interest and how they are managed, reduced, or eliminated, (3) work with the Secretary of HHS to amend the regulation to require submission of such details; (4) require institutes to forward to OER all the financial conflict-of-interest reports that they receive from grantee institutions, and (5) ensure that OER's conflict-of-interest database contains information on the reports.

Management Response Summary: NIH did not concur with our recommendation to require grantee institutions to provide details about the nature of financial conflicts of

interest, saying that grantee institutions are responsible for identifying and managing financial conflicts of interest.

NIH issued an Advance Notice of Proposed Rulemaking, *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors*, 74 Fed. Reg. 21610 (May 8, 2009), to gain public input on whether modifications are needed to 42 CFR Part 50, Subpart F. NIH invited public comments on the potential regulation of this area, particularly on (1) expanding the scope of the regulation and disclosure of interests, (2) defining “significant financial interest,” (3) identifying and managing conflicts by grantee institutions, (4) assuring grantee institution compliance, (5) requiring grantee institutions to provide more information to NIH, and (6) broadening the regulation to address institutional conflicts of interest.

NIH indicated in its December 2009 comments that the proposed regulation will be published in the Federal Register in 2010 and that it is considering OIG’s recommendation along with the public comments.

Status: We continue to recommend that NIH collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions. We will continue to monitor the progress of the rulemaking. In the interim, OIG recommends that NIH use its authority pursuant to 42 CFR § 50.604(g)(3) to request details on the nature and management of financial conflicts of interest at grantee institutions.

Related Report:

2008 JAN *National Institutes of Health: Conflicts of Interest in Extramural Research.*
OEI-03-06-00460 [Report](#)

Human Services Recommendations

Use Voluntary Contributions To Expand Services for the Elderly

Background: 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 of 1965 (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.

Recommendations: AoA should revise its regulations in accordance with the OAA.

Savings: \$90.8 million*

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

Management Response Summary: AoA concurred with the recommendation. AoA subsequently told us that because the OAA Amendments of 2006 changed provisions relating to voluntary contributions, it was determining the kinds of regulatory changes needed as a result. As of October 2009, no regulatory changes had been made.

Status: We will continue to monitor any regulatory changes in relation to AoA's progress on implementation of this recommendation.

Related Report:

2001 FEB *States' Use of Voluntary Contributions Under Title III of the Older Americans Act.* OAS-12-00-00002 [Report](#)

Ensure That States' Cost-Sharing Practices Comply With Requirements and Improve Data Quality

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 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.

Recommendations: AoA should (1) ensure that States’ cost-sharing practices comply with OAA requirements, (2) provide more guidance to States about cost sharing, and (3) improve the quality of its data so that any effects of cost sharing can be determined.

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

Status: We continue to recommend that AoA improve the quality of participation data. We also continue to recommend that AoA ensure that States’ cost-sharing practices comply with OAA requirements.

Related Report:

2006 SEP *Cost Sharing for Older Americans Act Services.* OEI-02-04-00290 [Report](#)

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

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

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

Recommendations: ACF should (1) enforce documentation requirements to ensure that children's needs are assessed and care is provided, (2) define and enhance field staff roles in oversight to ensure that each child is safe and is receiving needed care, and (3) establish a memorandum of understanding (MOU) between HHS and DHS to clearly delineate the roles and responsibilities of each Department.

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

Status: We continue to recommend that documentation requirements be enforced and that an MOU between HHS and DHS be implemented.

Related Report:

2008 MAR *Division of Unaccompanied Children's Services: Efforts To Serve Children.*
OEI-07-06-00290 [Report](#)

Departmentwide 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 nursing homes, psychiatric facilities, and intermediate care facilities for persons with mental retardation—CMS has established CoPs requiring that residents and patients be protected from abuse or neglect. ACF and the Substance Abuse and Mental Health Services Administration (SAMHSA) provide States with grants to establish protection and advocacy systems for investigating allegations of abuse or neglect. Also, FDA oversees the regulation of medical devices, including physical restraints, and receives information on deaths that occur during the use of restraints.

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

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

Management Response Summary: 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.

Status: We continue to monitor the progress made on these recommendations.

Related Report:

2001 MAY *Reporting Abuses of Persons with Disabilities.* OAS-01-00-02502 [Report](#)

Improve Financial Analysis and Reporting Processes

Background: The Government Management Reform Act of 1994 (GMRA) requires that many Federal agencies, including HHS, prepare annual financial statements. GAO's *Government Auditing Standards* and the Office of Management and Budget's (OMB) Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, provide auditors with guidance about 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 2009 financial statement audit noted that internal control weaknesses continued in HHS's financial management systems and financial analyses and oversight. HHS's lack of an integrated financial management system impaired its ability to support and analyze account balances. Manual intervention was required to correct transactions that did not post in accordance with standards and to transfer information between systems that did not interface electronically.

In addition, certain reconciliations and account analyses were not adequately or promptly performed to ensure that differences were identified and resolved and that invalid or old transactions were identified and closed. Also, management has not implemented corrective action for some longstanding deficiencies in internal control. 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.

Furthermore, general control issues related to the design and operation of key controls related to security management, access controls, configuration management, segregation of duties, and contingency planning were noted. In addition, weaknesses were noted in general controls, business process controls, interface controls, and data management system controls for specific financial applications.

Recommendations: HHS should (1) continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity and (2) provide a secure computing environment for critical applications throughout all the operating divisions.

Management Response Summary: In the *FY 2009 Agency Financial Report*, issued in November 2009, HHS acknowledged that it continued to have material weaknesses in internal control relating to financial reporting system analytics and oversight and in financial management information systems. HHS indicated that it plans to resolve these weaknesses by continuing its efforts to improve financial management processes and oversight and to strengthen information technology systems.

Status: We continue to monitor the HHS's progress in improving its financial analysis and report processes and related controls as part of the annual audit of the HHS's financial statements.

Related Report:

2009 NOV *Department of Health and Human Services Fiscal Year 2009 Agency Financial Report*. Section II. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2009*. OAS-17-09-00001 (pp. II-7, II-14) [Report](#)

Appendix: Acronyms and Abbreviations

The *Compendium of Unimplemented Office of Inspector General Recommendations* (Compendium) includes the following acronyms and abbreviations— first, a list for terms and organizations, followed by a second list for public laws.

Terms and Organizations

ACF	Administration for Children and Families
ACR	adjusted community rate proposals
AFR	Agency Financial Report
AMP	average manufacturer price
AoA	Administration on Aging
APC	Advanced Primary Care
ASC	ambulatory surgical center
ASP	average sales price
ASPR	Assistant Secretary for Preparedness and Response
ASR	annual status report
AWP	average wholesale price
CBO	Congressional Budget Office
CDER	Center for Drug Evaluation and Research
CERT	Comprehensive Error Rate Testing (program)
CFC	Conditions for Coverage
CDC	Centers for Disease Control and Prevention
CHIP	Children’s Health Insurance program (AKA SCHIP)
CHS	Contract Health Services
CMS	Centers for Medicare & Medicaid Services
CMS-ARTS	CMS Analysis, Reporting, and Tracking System
CoP	Conditions of Participation
CPI	Consumer Price Index
CPM	clinical performance measure
CY	calendar year
DHS	Department of Homeland Security
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DPNA	denial of payment for new admissions
DRG	diagnosis-related group
DSH	disproportionate share hospital
DUCS	Division of Unaccompanied Children’s Services
E&M	evaluation and management
EBDP	Entitlement Benefits Due and Payable
ESRD	end stage renal disease
FACS	Financial Accounting Control System
FDA	Food and Drug Administration
FFS	fee for service
FI	fiscal intermediary
FUL	Federal upper limit

FY	fiscal year
GAO	Government Accountability Office
GME	graduate medical education
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HHA	home health agencies
HHS	Department of Health & Human Services
HIGLAS	Healthcare Integrated General Ledger Accounting System
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IOM	Institute of Medicine
IT	information technology
JOM	<i>Joint Operations Manual</i>
LCD	local coverage determinations
LTC	long term care
M+C	Medicare+Choice
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MCO	managed care organization
Medi-Medi	Medicare and Medicaid data matches
MEDIC	Medicare prescription drug integrity contractor
MDS	minimum data set
MOU	memorandum of understanding
MLN	Medicare Learning Network
MSIS	Medicaid Statistical Information System
NAPIS/SPR	National Aging Program Information System/State Program Reports
NCCI	National Correct Coding Initiative
NDC	National Drug Code
NF	nursing facility
NLA	National Limit Amount
NIH	National Institutes of Health
NPDB	National Practitioner Data Bank
NPI	national provider identifiers
NSC	National Supplier Clearinghouse
OACT	Office of the Actuary
OER	Office of Extramural Research (NIH)
OFM	Office of Financial Management
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPPS	Outpatient Prospective Payment System
ORR	Office of Refugee Resettlement (ACF)
PCS	personal care services
PDE	prescription drug event
PDP	prescription drug plan
PERM	Payment Error Rate Measurement (program)
POS FE	Point-of-Sale Facilitated Enrollment
PPS	prospective payment system
PSC	program safeguard contractor
QA	quality assurance
QAPI	Quality Assurance and Performance Improvement

QIO	quality improvement organization
RAC	Recovery Audit Contractor
RHC	rural health clinic
RVU	relative value unit
SAMHSA	Substance Abuse and Mental Health Services Administration
S&C	survey & certification letter
SCHIP	State Children’s Health Insurance program (AKA CHIP)
SNF	skilled nursing facility
SOW	statement of work
TBD	to be determined
TrOOP	True out-of-pocket costs for Part D
UPIN	unique physician identification number
UPL	Upper Payment Limit
ZPIC	Zone Program Integrity Contractor

Public Laws

The *Compendium* refers to the following acronyms and abbreviations for Public Laws (P.L.).

BBA	Balanced Budget Act of 1997, P.L. No. 105-33.
BBRA	Balanced Budget Refinement Act of 1999, P.L. No. 106-113.
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, P.L. No. 106-554.
CARE Act	Ryan White Comprehensive AIDS Resources Emergency Act of 1990, P.L. No. 101-381.
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. No. 99-272.
DRA	Deficit Reduction Act of 2005, P.L. No. 109-171.
FDAA	FDA Amendment Act of 2007, P.L. No. 110-85.
FDAMA	Food and Drug Administration Modernization Act of 1997, P.L. No. 105-115.
FDCA	Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717.
FFMIA	Federal Financial Management Improvement Act of 1996, P.L. No. 104-208.
FMFIA	Federal Managers’ Financial Integrity Act of 1982, P.L. No. 97-255.
GMRA	Government Management Reform Act of 1994, P.L. No. 103-356.
HCQIA	Health Care Quality Improvement Act of 1986, P.L. No. 99-660.
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191.
HSA	Homeland Security Act of 2001, P.L. No. 107-296.
IDEA	Individuals With Disabilities Education Act, so named by the Education of the Handicapped Act Amendments of 1990, P.L. No. 101-476. Formerly, Education of the Handicapped Act Amendments of 1983, P.L. No. 98-199.
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275.
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173.
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173.
OAA	Older Americans Act of 1965, P.L. No. 89-73.
OAAA	OAA Amendments of 2006, P.L. No. 109-365.
OBRA 1981	Omnibus Budget Reconciliation Act of 1981, P.L. No. 97-35.

OBRA 1986	Omnibus Budget Reconciliation Act of 1986, P.L. No. 99-509.
OBRA 1987	Omnibus Budget Reconciliation Act of 1987, P.L. No. 100-203.
OBRA 1990	Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508.
OBRA 1993	Omnibus Budget Reconciliation Act of 1993, P.L. No. 103-296.
PHS Act	Public Health Service Act of 1944.
PRIOA	Peer Review Improvement Act of 1982, P.L. No. 97-248.
Recovery Act	American Recovery and Reinvestment Act of 2009, P.L. No. 111-5.
TRHCA	Tax Relief and Health Care Act of 2006, P.L. No. 109-432.
(Not abbreviated)	Drug Listing Act of 1972, P.L. No. 92-387.
(Not abbreviated)	Education of the Handicapped Act Amendments of 1983, P.L. No. 98-199. and of 1990, P.L. No. 101-476 (AKA Individuals With Disabilities Education Act (IDEA)).
(Not abbreviated)	Rural Health Clinic Services Act of 1977, P.L. No. 95-210.
(Not abbreviated)	Ryan White HIV/AIDS Treatment Modernization Act of 2006, P.L. No. 109-415.
(Not abbreviated)	Social Security Act of 1935, P.L. No. 96-212.
(Not abbreviated)	Supplemental Appropriations Act of 2008, P.L. No. 110-252.
(Not abbreviated)	Trafficking Victims Protection Reauthorization Act of 2008, P.L. No. 110-457.
(Not abbreviated)	U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, P.L. No. 110-28.