



Department of Health and Human Services



Compendium of
Unimplemented
Office of Inspector General
Recommendations

OIG

Office of Inspector General

May 2007

This inaugural edition of the “Compendium of Unimplemented Office of Inspector General Recommendations” combines our previously issued “Red Book” and “Orange Book,” which presented unimplemented monetary and nonmonetary recommendations, respectively. In combining the two publications, our objective is to create a more useful tool for Congress, the Administration, and the Department in their respective efforts to identify ways to contain costs, maximize the effectiveness of programs and services, and improve the efficiency of departmental programs. Full implementation of the recommendations in this document could achieve substantial savings and increase the effectiveness of the Department’s programs.

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Office of Inspector General

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

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for the Department, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement, and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide the Department, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. These investigative efforts lead to criminal convictions, civil False Claims Act recoveries, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. OCIG also represents OIG in the global settlement of cases arising under the civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidance, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Introduction

Purpose

The “Compendium of Unimplemented Office of Inspector General Recommendations” combines the “Red Book” (unimplemented monetary recommendations) and the “Orange Book” (unimplemented nonmonetary recommendations) into one publication. The “Red Book” was a compendium of significant Department of Health and Human Services (HHS), Office of Inspector General (OIG) cost-saving recommendations that had not been fully implemented. The “Orange Book” focused on OIG recommendations to improve the operation of HHS programs.

The “Compendium of Unimplemented Office of Inspector General Recommendations” lists and describes selected significant OIG recommendations that have not been implemented as of December 31, 2006. It does not include all unimplemented OIG recommendations. For example, it does not include recommendations addressed to specific non-Federal entities and recommendations that involve sensitive security issues. Detailed information about the issues examined and the recommendations are available in the relevant OIG audit and evaluation reports. This publication contains citations to those reports.

The estimated value of each monetary recommendation is based on the specifics of each review and is not extrapolated beyond the scope of the original review or adjusted to current-year dollars. For some recommendations, estimated savings are unknown and “TBD” (to be determined) is indicated.

Full implementation of these recommendations could produce substantial savings for the Federal Government and, in turn, the American taxpayer, as well as improve the operation of HHS programs. We hope that this compendium will prove useful to decision makers in the Department and Congress.

Priority Recommendations

Below is a list of unimplemented recommendations that we refer to as “priority recommendations” because they represent, in our view, the most significant opportunities to positively impact the Department’s programs. The priority recommendations are comprised of both monetary and non-monetary recommendations, representing various time frames. The list comprises three categories: savings, integrity and efficiency, and quality of care. These areas reflect OIG’s mission to ensure the appropriate expenditure of Federal dollars; protect the integrity of the Department’s programs against waste, fraud, and abuse; improve program efficiency; and protect the health and safety of program beneficiaries.

Savings:

- Reduce the Rental Period for Medicare Home Oxygen Equipment, savings TBD (p. 2)
- Improve Coding and Reimbursement for Medicare Consultation Services, estimated savings \$1.1 billion (p. 4)
- Reduce Improper Use of Modifier 25, estimated savings \$538 million (p. 5)
- Modify Payment Policy for Medicare Hospital Bad Debts, estimated savings \$340 million (p. 14)
- Establish More Consistent Medicare Outpatient Surgery Rates That Reflect Only Necessary Costs, estimated savings \$1.1 billion (p. 17)
- Ensure the Medical Necessity of Medicare Ambulance Claims, estimated savings \$402 million (p. 26)
- Limit Upper Payment Limit Payments to Cost and Require That Medicaid Payments Returned by Public Providers Used To Offset the Federal Share, estimated savings \$120 million (p. 31)
- Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments, savings TBD (p. 33)
- Require That Medicaid Reimbursement for Brand-Name and Generic Drugs Accurately Reflects Pharmacy Acquisition Costs, estimated savings \$1.08 billion for brand-name drugs (p. 35) and \$470 million for generic drugs (p. 36)
- Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement, estimated savings \$1.15 billion (p. 39)

Integrity and Efficiency:

- Ensure That Prescription Drug Plan Sponsors’ Compliance Plans Address All Requirements (p. 57)
- Improve Centers for Medicare & Medicaid Services Performance Evaluation Process for Program Safeguard Contractors (p. 58)
- Improve Monitoring of Patient Safety Grants (p. 59)
- Update and Maintain an Accurate New Drug Code Directory (p. 60)
- Improve Postmarketing Oversight (p. 61)
- Improve Oversight and Review of Outside Activities of Senior-Level National Institutes of Health Employees (p. 62)
- Improve Oversight of State Standards and Practices for Content and Frequency of Caseworker Visits to Children in Foster Care (p. 68)

Priority Recommendations

Quality of Care:

- Improve Hospital Reporting of Deaths Related to Restraint and Seclusion (p. 49)
- Improve the Availability of Quality-of-Care Data in the Medicare End Stage Renal Disease Program (p. 51)
- Strengthen Food and Drug Administration Oversight of Clinical Investigators (p. 95)
- Protect Human Research Subjects by Strengthening Institutional Review Boards (p. 96)

Department of Health and Human Services

HHS promotes the health and welfare of Americans and provides essential services to people of every age. The Department's major operating divisions are described below:

- The Centers for Medicare & Medicaid Services (CMS) administers the Medicare and Medicaid programs, as well as the State Children's Health Insurance Program (SCHIP) programs. These programs, which account for well over 80 percent of the HHS budget, provide medical care coverage for senior citizens, people who have disabilities or who are economically disadvantaged, and children whose families have limited income.
- The public health operating divisions include the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the Agency for Healthcare Research and Quality (AHRQ), and the Substance Abuse and Mental Health Services Administration (SAMHSA). These divisions promote biomedical research and disease cure and prevention; ensure the safety and efficacy of marketed food, drugs, and medical devices; and conduct other activities designed to ensure the general health and safety of Americans.
- The Administration for Children and Families (ACF) provides Federal direction and funding for State-administered programs, including a variety of social service programs, designed to promote stability, economic security, responsibility, and self-support for the Nation's families.
- The Administration on Aging (AoA) awards grants to States for establishing comprehensive community-based systems that, through services such as congregate and home-delivered meals and in-home care and family caregiver support, assist in maintaining the dignity and quality of life of older Americans and their families.

Organization of the "Compendium of Unimplemented Office of Inspector General Recommendations"

This report is organized as follows: The first section contains monetary recommendations, and the second section contains nonmonetary recommendations. Within both of these sections, the recommendations are organized according to whether they are new or were published in the previous editions and are further subdivided by health and human services issue area.

Each narrative contains a background summary, findings, recommendation(s), status, the report number(s), and the report issue date(s). In the case of monetary recommendations, there is also an estimate of the savings that may be achieved by implementing the recommendations. OIG final reports, including the comments of the cognizant agency, are available upon request and most can be found at <http://www.oig.hhs.gov>. Each report with monetary recommendations also includes a methodology section detailing our process for estimating cost savings. Readers interested in a particular recommendation are encouraged to review the associated report(s).

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New Monetary Recommendations

Medicare and Medicaid

Medicare Hospitals

Improve Management and Oversight of Consecutive Medicare Inpatient Stays

Background: This evaluation assessed the quality of care and the medical necessity of services within sequences of consecutive stays for Medicare beneficiaries. For the purposes of this review, OIG defined “consecutive inpatient stays” as a sequence of three or more individual inpatient facility stays for the same Medicare beneficiary when the admission date for each successive stay occurs within 1 day of the discharge date for the preceding stay. This evaluation focused on consecutive inpatient stays in fiscal year (FY) 2002 involving acute care hospitals and three types of inpatient facilities that may be found within acute care hospitals: rehabilitation units, psychiatric units, and skilled nursing swing beds.

Finding: Twenty percent of consecutive stay sequences were associated with quality of care problems (medical errors, accidents, or patient care that did not meet professionally recognized standards) that contributed to the need for multiple inpatient stays and/or unnecessary fragmentation of health care services across multiple inpatient stays in a sequence. Medicare paid an estimated \$267 million for these stay sequences in FY 2002.

Recommendation(s): CMS should (1) direct the Quality Improvement Organizations (QIO) to monitor the quality of inpatient services provided within sequences of consecutive inpatient stays, (2) encourage the QIOs and fiscal intermediaries to monitor the medical necessity and appropriateness of inpatient services provided within these consecutive inpatient stay sequences, and (3) reinforce efforts to educate providers about the appropriate uses of skilled nursing swing beds.

Savings: *TBD

**In FY 2002, \$267 million was paid in association with quality-of-care problems that significantly contributed to the need for multiple inpatient stays and/or unnecessary fragmentation of health care services across multiple inpatient stays in a sequence. Some portion of this would be saved if our recommendations were implemented.*

Status: CMS concurred with our assessment of consecutive Medicare inpatient stays but believes that existing mechanisms already address the issues. CMS stated that periodic reviews of consecutive inpatient stay sequences are not warranted and contended that current QIO activities functionally cover the first and second of our recommendations. CMS agreed with the third recommendation and will prepare a Medlearn Matters provider education article about the appropriate uses of skilled nursing swing beds.

Report(s): OEI-03-01-00430; issued 08/05

Durable Medicare Equipment

Reduce the Rental Period for Medicare Home Oxygen Equipment

Background: Section 1834(a)(5) of the Social Security Act authorizes Medicare payment for home oxygen equipment under its durable medical equipment (DME) benefit. Medicare covers both stationary and portable oxygen delivery systems, which were payable on a rental-only basis from 1989 (the year in which Medicare implemented the DME fee schedule) until 2006. The current rental period is 36 months and the current rental period for capped rental items is 13 months.

Findings: Based on the 2006 median fee schedule amount, Medicare will allow \$7,215 for 36 months for concentrators that cost \$587, on average, to purchase. Based on our analysis, minimal servicing and maintenance for concentrators and portable equipment are necessary.

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

Savings: TBD

Status: CMS agreed with OIG recommendations. With regard to the first recommendation, there was a proposal in Congress to reduce the monthly rental limit for oxygen from 36 to 13 months, but the bill was never enacted. Concerning the second and third recommendations, both have been implemented by CMS.

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

Other Medicare Reimbursement

Reduce Improper Medicare Payments for Allergen Immunotherapy

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

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

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

Savings: *\$75 million

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

Status: CMS stated that it is prepared to develop and disseminate educational materials and develop new coverage criteria for allergen immunotherapy services. CMS has identified two possibilities for developing national coverage criteria for allergen immunotherapy and either option would require up to 12 months to fully implement.

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

Other Medicare Reimbursement

Improve Coding and Reimbursement for Medicare Consultation Services

Background: Medicare reimbursement for consultations increased from \$3.3 billion in 2001 to \$4.1 billion in 2004. We reviewed Medicare services billed as consultation in 2001. We contracted with certified professional coders to determine whether each service had been billed with the correct code and documented adequately and found a high rate of improper payments.

Finding: Approximately 75 percent of services billed as consultation and allowed by Medicare in 2001 did not meet all applicable program requirements, resulting in \$1.1 billion in improper payments. Services billed as consultations often did not meet Medicare's definition of consultation, were billed as the wrong type or level of consultation, or were not substantiated by documentation.

Recommendation(s): To reduce the incidence of improperly billed consultations through its Medicare carriers, CMS should educate physicians and other health care professionals about the criteria and proper billing for all types and levels of consultations.

Savings: *\$1.1 billion

**This is a national projection based on Medicare claims in 2001.*

Status: CMS agreed with our recommendations and outlined a plan to publish a Special Edition regarding consultations on its Web site. CMS also noted that codes for billing inpatient and confirmatory consultations have been eliminated from the Current Procedural Terminology effective January 1, 2006, which should reduce coding errors.

Report(s): OEI-09-02-00030; issued 03/06

Other Medicare Reimbursement

Reduce Improper Use of Modifier 25

Background: CMS does not generally allow additional payment for separate evaluation and management (E/M) services performed by a provider on the same day as a procedure. However, if on the same day as a procedure, a provider performs an E/M and the E/M service is significant, separately identifiable, and above and beyond the usual preoperative and postoperative care associated with the procedure, modifier 25 may be attached to the claim to allow additional payment for the separate E/M service. In 2002, Medicare allowed \$1.96 billion for approximately 29 million claims using modifier 25.

Finding: Thirty-five percent of claims using modifier 25 that Medicare allowed in 2002 did not meet program requirements, resulting in \$538 million in improper payments. A large number of claims submitted used modifier 25 incorrectly, such as by attaching the modifier to an E/M claim when no other service was performed on the same day. Also, more than one-third of carriers have not conducted oversight related to modifier 25.

Recommendation(s): CMS should work with carriers to reduce the number of claims submitted using modifier 25 that do not meet program requirements.

Savings: *\$538 million

**In 2002, \$538 million was improperly paid based on all Medicare Part B provider claims.*

Status: CMS concurred with the recommendations and plans to educate the provider community about the need for documentation to support services billed to the Medicare program. CMS will inform contractors of our findings so that they can take corrective actions. CMS stated they will also modify the “Medical Claims Processing Manual” to clarify that appropriate documentation must be maintained to support claims for payment, even though providers are not required to submit the documentation with the claim.

Report(s): OEI-07-03-00470; issued 11/05

Other Medicare Reimbursement

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

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

Finding: 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. This study 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, but those that did found providers had an error rate of 40 percent or more for services billed with modifier 59.

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

Savings: *\$59 million

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

Status: CMS concurred with our recommendation to encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59 and to ensure that carriers' claims-processing systems pay claims only when modifier 59 is billed with the secondary code. At this time, CMS is not able to implement an edit to ensure correct coding.

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

Other Medicare Reimbursement

Prevent Overpayments Under Medicare's Inpatient Rehabilitation Facility Transfer Policy

Background: Under the prospective payment system (PPS) for inpatient rehabilitation facilities (IRF), Medicare pays the full prospective payment to an IRF that discharges a beneficiary to home. However, in certain situations, Medicare pays a lesser amount when the IRF transfers the beneficiary to another facility.

Finding: We estimate that during FY 2003, the Medicare program paid approximately \$14.3 million in excessive payments to inpatient rehabilitation facilities as a result of the facilities coding claims as discharges rather than as transfers. Our reviews indicated that the Common Working File did not have the necessary edits in place to detect the miscoded claims and prevent excessive payments.

Recommendation(s): CMS should establish edits in the Common Working File that match beneficiary discharge dates with admission dates to other providers to identify potentially miscoded claims.

Savings: *\$14.3 million

**These estimated savings are based on an audit of FY 2003 claims.*

Status: CMS concurred with our recommendation to establish edits in the Common Working File. CMS expects to implement the edits in 2007.

Report(s): OAS-04-04-00008; issued 9/06

OAS-04-04-00013; issued 11/06

Other Medicaid Reimbursement

Revise and Clarify Average Manufacturer Price Regulation

Background: Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to the CMS the average manufacturer price (AMP) for each covered outpatient drug. CMS uses the AMP to calculate a unit rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States.

The Deficit Reduction Act (DRA) of 2005 required OIG to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006.

Pursuant to the DRA of 2005, CMS was required to promulgate, by July 1, 2007, a regulation that clarifies AMP requirements after considering our recommendations.

Finding: Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. Our previous and ongoing work, which has focused primarily on how manufacturers calculate the AMP, has found that manufacturers interpret AMP requirements differently. Specifically, our findings demonstrated 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. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, they raised additional issues related to the implementation of DRA of 2005 provisions. Because the DRA of 2005 expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

Recommendation(s): The Secretary should direct CMS, in promulgating the AMP regulation, to (1) clarify requirements in 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 AMP; (3) issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA of 2005; and (4) encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Savings: TBD

Status: CMS published a proposed regulation on December 22, 2006, and is currently reviewing comments on the proposed rule. The final rule, which provides clarity to the definition of the AMP, is scheduled to be published in July 2007.

Report(s): OAS-06-06-00063; issued 5/06

Previous Monetary Recommendations

Medicare and Medicaid

Medicare Hospitals

Continue Mandated Reductions in Hospital Capital Costs

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

Finding: 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) was a major reason for this increase. Paying capital costs prospectively, as required by regulation, should assist in curbing escalating costs. However, the prospective rates are based on historical costs that are inflated because (1) excess capacity in the hospital industry has caused more capital costs to be incurred than economically necessary and (2) inappropriate elements, such as charges for depreciation on federally funded assets, are included in the historical costs.

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

Savings: TBD

Status: CMS did not agree with our recommendations. CMS believed that section 1886(g)(1)(B)(iv) of the Social Security Act, which states that the Secretary of the Department of Health and Human Services 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, it did not include the effects of excess bed capacity and other elements included in the base-year historical costs. The President's FY 2001 budget proposed reducing capital payments and saving \$630 million from FY 2001 through FY 2005. A similar reduction was not included in the President's FY 2007 budget proposal. We plan to perform a follow-up audit of this issue during FY 2007.

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

OAS-14-93-00380; issued 04/93

Medicare Hospitals

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

Background: Under section 1886(d) of the Social Security Act, the Medicare program pays for the operating costs attributable to hospital inpatient services under a PPS. The system pays for care using a predetermined specific rate for each discharge. Public Law 100-203 required the Secretary of the Department of Health and Human Services to establish a PPS for capital costs for cost reporting periods beginning in FY 1992.

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

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

Savings: TBD

Status: CMS agreed that the capital rate reflected an overestimation of base-year costs and that the BBA of 1997 provided for a reduction of 2.1 percent in capital payments for FYs 1998 through 2002. No additional adjustments have been made. CMS is continuing to monitor current capital payment and cost data to determine whether additional adjustments are warranted.

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

Medicare Hospitals

Revise Graduate Medical Education Payment Methodology

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

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

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

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

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

Status: CMS did not concur with our recommendations. Although the BBA of 1997 and the Balanced Budget Refinement Act of 1999 (BBRA) contained provisions to slow the growth in Medicare spending on graduate medical education, we continue to believe that our recommendations should be implemented and that further savings can be achieved.

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

Medicare Hospitals

Modify Payment Policy for Medicare Hospital Bad Debts

Background: Under Medicare's inpatient hospital PPS, hospitals are reimbursed for inpatient services rendered to Medicare beneficiaries by a fixed payment amount based on a diagnosis-related group (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: CMS records showed that total Medicare hospital bad debts increased from \$159 million in FY 1984 to almost \$399 million in FY 1987. During this same period, hospitals continued to earn significant profits. Although regulations provide that hospitals must be able to establish that they made reasonable bad debt collection efforts, such efforts have often been inadequate; hospitals have little incentive to aggressively collect the unpaid deductible and coinsurance amounts when Medicare pays these amounts. As a result, hospitals have received unallowable bad debt payments.

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

Savings: Savings: *\$340 million

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

Status: CMS did not agree with our recommendations. The BBA of 1997 provided for some reduction of bad debt payments to providers. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 subsequently increased bad debt reimbursement. Currently, Medicare pays 70 percent of allowable bad debts for hospitals. Medicare inpatient hospital bad debts totaled \$781 million in FY 2004. Our subsequent work shows hospitals continue to claim unallowable bad debts. Additional legislative changes are required to implement the modifications that we recommended. The President's FY 2008 budget proposes to eliminate Medicare bad debt payments for all providers over a 4-year period.

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

Medicare Hospitals

Recover Overpayments and Expand the Diagnosis-Related Group Payment Window

Background: Under the PPS for inpatient hospital services, Medicare fiscal intermediaries reimburse hospitals a predetermined amount for inpatient services furnished to Medicare beneficiaries depending on the illness and its classification under a DRG. Effective January 1, 1991, separate payments for nonphysician outpatient services (such as diagnostic tests and laboratory tests) provided to a patient during the 3 days immediately preceding the patient's admission are not permitted under the OBRA of 1990, section 4003. Prior to that, separate payments for nonphysician outpatient services provided before admission for an inpatient stay were not permitted.

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

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

Savings:	Diagnostic services provided:	4 - 14 days	\$37.0 million**
	4 - 7 days		\$83.5 million*

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

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

Status: CMS concurred with our recommendation; however, CMS noted that some additional factors would have to be considered before a legislative change could be advanced.

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

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

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

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

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

Savings: TBD

Status: CMS agreed with our recommendations, but no additional analysis has been done to examine the adequacy of base-year costs.

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

Medicare Hospitals

Establish More Consistent Outpatient Surgery Rates That Reflect Only Necessary Costs

Background: The Medicare program covers hospital outpatient department services under the Medicare Supplemental Medical Insurance Program. Medicare reimbursement for services in these settings varies and has evolved over time. Hospital outpatient departments were historically reimbursed for services using a facility fee based on the lesser of costs or charges. In 1980, recognizing that some surgical procedures provided on an inpatient basis could be safely performed in less intensive and less costly settings, Congress added coverage for services provided in ambulatory surgical centers (ASC). In 2000, CMS implemented an outpatient PPS for hospital outpatient services. Medicare regulations establish different reimbursement rates for the same procedures performed in different settings (outpatient or ASC).

Finding: Our review of 424 ASC-approved procedure codes showed that Medicare paid an estimated \$1.1 billion more for services provided in settings with higher reimbursement in 2001. For similar procedures, CMS could have saved an estimated \$1 billion if the lower ASC rate had been used instead of the outpatient department rate. Likewise, CMS could have saved \$100 million if the lower outpatient department rate had been used instead of the ASC rate. Additionally, if CMS had removed 72 procedure codes meeting the criteria for removal from the ASC list, it could have saved almost \$8 million.

Recommendation(s): CMS should (1) seek authority to set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and (2) remove the procedure codes that meet its criteria for removal from the ASC list of covered procedures.

Savings: *\$1.1 billion

**In 2001, an additional \$1.1 billion was paid by the Medicare program because of variations between ASC and the Outpatient Department reimbursement rates for 424 ASC-approved procedure codes.*

Status: CMS agreed to consider seeking authority to set rates that are consistent across sites as it develops its legislative program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to implement a revised payment system for ASCs beginning on or January 1, 2006, but not later than January 1, 2008.

On November 24, 2006, CMS issued a final rule (CMS-1506-FC) for Medicare payments for hospital outpatient services in CY 2007 that implemented new steps to make payments more accurate and to promote higher quality and value in outpatient care. The rule requires reporting of quality measures in CY 2009. CMS also proposed a major revision of payments for ASCs that would better align payments for surgical procedures in ASCs and hospital outpatient departments. The proposed reforms are intended to address rapid growth in hospital outpatient services.

Report(s): OEI-09-88-01003; issued 05/89
OAS-14-89-00221; issued 03/91

OAS-14-98-00400; issued 11/98
OEI-05-00-00340; issued 01/03

End Stage Renal Disease

Limit Payment Under Method II for Continuous Cycling Peritoneal Dialysis to Method I Rates

Background: The Omnibus Budget Reconciliation Act (OBRA) of 1989 amends the Social Security Act to limit payment for continuous cycling peritoneal dialysis under any method other than the composite rate (referred to as Method I) to no more than 130 percent of the composite rate. Under Method I, dialysis facilities receive a set payment for each dialysis treatment and related supplies. Alternately, under Method II, a beneficiary may elect to receive all dialysis supplies from a durable medical equipment (DME) supplier to perform self-dialysis. At 42 CFR § 414.330(c)(2), payment limits for continuous cycling peritoneal dialysis under Method II are established at 130 percent of the national median amount for hospital-based facilities.

Finding: Medicare regulations for reimbursement for home dialysis are inconsistent. Medicare pays for two types of dialysis, hemodialysis and continuous ambulatory peritoneal dialysis, at the same rate, whether payment is made to a dialysis facility under Method I or to a DME supplier under Method II. A third type, continuous cycling peritoneal dialysis, is paid under Method I when payment is made to a dialysis facility. However, when the service is provided by a DME supplier, the supplier may bill under Method II, which permits payment up to 130 percent of the Method I rate. This 30-percent premium resulted in additional annual payments of \$12.2 million for Medicare and \$3.1 million for beneficiaries in CY 2000.

Recommendation(s): CMS should change the regulation to limit payment for Method II continuous cycling peritoneal dialysis supplies to no more than the payment allowed under Method I.

Savings: *\$15.3 million

**This includes potential savings to Medicare and its beneficiaries if continuous cycling peritoneal dialysis kits for Method II were limited to the same payment rate used under Method I in 2000.*

Status: Believing that Congress intended that DME suppliers should have a higher payment limit, CMS does not concur with this recommendation. CMS has eliminated billing for kits under Method II and requires suppliers to itemize supplies, which are reimbursed based on reasonable charges up to a monthly payment limit.

Report(s): OEI-07-01-00570; issued 5/03

End Stage Renal Disease

Reduce Medicare End Stage Renal Disease Payment Rates

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

Finding: Both 1985 and 1988 audited data justify a decrease in the payment rate. The 1985 data showed a median cost, including home dialysis costs, of \$108.19 per treatment. Even after considering the effect of home dialysis services, the in-facility costs decreased from 1980 to 1985 without a corresponding reduction in the prospective rates. In addition, our audit of the 1988 home office costs of a major chain of freestanding facilities showed that its 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.

Savings: \$45 million*

**This estimate, which is based on 2003 Medicare payments for dialysis treatments, represents program savings of \$45 million for each dollar reduction in the composite rate.*

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

Status: CMS agreed that the composite payment rates should reflect the costs of outpatient dialysis treatment in efficiently operated facilities, and the BBA of 1997 required the Secretary of the Department of Health and Human Services to audit the cost reports of each dialysis provider at least once every 3 years. The BBRA of 1999 increased each composite rate payment for dialysis services furnished during 2000 by 1.2 percent above the payment for services provided on December 31, 1999. The Benefits Improvement and Protection Act of 2000 increased the payment rate for services provided in 2001 by 2.4 percent and required the Secretary to develop a composite rate that includes, to the maximum extent feasible, payment for clinical diagnostic laboratory tests and drugs that are routinely used in dialysis treatments but are currently separately billable by dialysis facilities. The MMA of 2003, Title VI, section 623, increased the composite rate by 1.6 percent for 2005, restored the composite rate exception for pediatric facilities, and required the Secretary to establish a basic case-mix adjusted PPS for dialysis services. Once CMS has implemented a bundled PPS for ESRD services, we will reexamine whether the payment rates for outpatient dialysis services reflect current efficiencies and economies in the marketplace.

Report(s): OAS-14-90-00215 Management Advisory Report; issued 7/90

Medicare Durable Medical Equipment

Reduce the Medicare Reimbursement Amount for Category I Enteral Nutrition Formulas

Background: Medicare covers enteral nutrition therapy, commonly called tube feeding, for beneficiaries who cannot swallow because of a permanent medical problem or an impairment of long and indefinite duration. Medicare Part B coverage of enteral nutrition therapy is provided under the prosthetic device benefit for beneficiaries residing at home or in a nursing facility when the stay is not covered by Medicare Part A.

Medicare groups enteral nutrition formula products into seven classes based on their composition. Products falling within these classes are identified by one of seven Healthcare Common Procedure Codes for reimbursement purposes. A wide variety of enteral nutrition formulas are grouped under Category I (code B4150).

Finding: We compared the amount Medicare reimburses for Category I enteral nutrition formulas with prices available to the supplier community in CY 2001. We found that the amount Medicare reimburses for Category I formulas exceeded median contract prices available to suppliers from the sources we reviewed by 70 to 115 percent. We estimate that if Medicare's payment amount for these formulas had been set at the median of purchase prices reviewed, the program and its beneficiaries could have saved over \$82 million in CY 2001.

Recommendation(s): CMS should consider using the inherent reasonableness authority to reduce the Medicare reimbursement amount for Category I enteral nutrition formulas.

Savings: *\$82 million

**Estimated savings are based on the difference between Medicare reimbursement and median contract prices.*

Status: CMS concurred with our recommendation but must wait to initiate inherent reasonableness reviews until written procedures for conducting these reviews are developed according to statute and regulation. In accordance with the MMA of 2003, competitive acquisition of enteral nutrition will be phased in beginning of 2007.

Report(s): OEI-03-94-00021; issued 4/96

OEI-03-02-00700; issued 2/04

Medicare Durable Medical Equipment

Identify Medical Equipment/Supply Claims Lacking Valid, Active Unique Physician Identification Numbers

Background: The OBRA of 1985 required CMS to establish unique physician identification numbers for all physicians who provide services to Medicare beneficiaries. Medicare requires that medical equipment and supplies be ordered by a physician or another qualified practitioner.

Finding: Our review of 1999 claims identified \$32 million in Medicare payments for claims with invalid unique identification numbers (UPIN) listed for the ordering physicians. Another \$59 million was paid for claims with inactive identification numbers. A small number of suppliers accounted for a substantial portion of these claims.

Recommendation(s): CMS should create claims-processing edits to identify medical equipment and supply claims that do not have a valid and active physician identification number listed for the ordering physician.

Savings: *\$91 million

**Estimated savings based on allowed charges for claims with invalid or inactive UPINs in 1999.*

Status: CMS concurred with our recommendation and implemented an edit to reject claims listing a deceased physician's identification number. CMS decided not to implement edits for inactive and invalid physician identification numbers. Instead, the agency initiated provider education efforts and issued two program memorandums.

Report(s): OEI-03-01-00110; issued 11/01

Medicare Durable Medical Equipment

Prevent Medicare Losses Resulting From Early Payments for Medical Equipment

Background: Medicare covers DME, prosthetics, orthotics, and supplies under Medicare Part B. Medicare allowed approximately \$6 billion for these claims in 1998.

Finding: We found that Medicare could have earned an additional \$7.2 million in interest on 1998 payments for claims that were billed before the end of the service period. Only four of seven insurers surveyed did not pay for services before the service period was completed.

Recommendation(s): CMS should not pay for DME, prosthetics, orthotics, and supply claims before the service period has been completed.

Savings: *\$7.2 million

**Estimated savings are based on the difference in interest earned between Medicare payments made at the end of the service period as opposed to payments made prior to the service completed in 1998.*

Status: CMS did not concur with our recommendation and stated that delaying payment of DME, prosthetics, orthotics, and supply claims until the end of the service period would not be a desirable practice.

Report(s): OEI-03-99-00620; issued 6/00

Medicare Reimbursement

Ensure Appropriate Medicare Reimbursement to Ambulatory Surgical Centers for Intraocular Lenses

Background: Section 1833(i)(2)(A)(iii) of the Social Security Act requires that Medicare payment to ASCs for intraocular lenses (IOL) be “reasonable and related to the cost of acquiring the class of lens involved.” The OBRA of 1993 set the price of \$150 per lens for the period from 1994 through 1998. The payment rate has remained unchanged, despite 1994 cost data suggesting that it substantially exceeds the cost of the IOLs. The MMA of 2003 requires CMS to implement revised payment systems for ASCs to be effective no later than January 1, 2008.

Finding: Payment at the time of the evaluation was set at \$150 per lens for all types of lenses except for certain “new technology intraocular lenses.” We found that in 2002, although the average cost of a lens was \$90.30, this varied significantly by the type of material used to make the lens. The cost of soft acrylic lenses averaged \$124.77, silicone lenses averaged \$69.37, and polymethyl methacrylate averaged \$39.10.

Recommendation(s): We recommended that CMS reduce Medicare payment to ASCs for IOLs in a manner that takes into account the different types and costs of intraocular lenses.

Savings: *\$34.8 million

**This estimated savings could have been achieved in 2002 if CMS had reduced Medicare payments to ASCs for IOLs to the weighted 90th percentile for each lens type.*

Status: CMS is deferring action to reduce Medicare payment for IOLs until it can implement section 626 of the MMA, which requires implementation of a revised system of payment for ASC services by January 1, 2008.

Report(s): OEI-06-02-00710; issued 03/04

Medicare Reimbursement

Reinstate the Beneficiary Coinsurance and Deductible Provisions for Laboratory Services

Background: Medicare pays for most clinical laboratory tests based on fee schedules. These schedules, effective July 1, 1984, generally were established by each carrier at 60 percent of the Medicare prevailing charge (the charge most frequently used by all suppliers). Over the years, the Medicare fee schedule has gone through several adjustments. The OBRA of 1993 reduced the cap for the Medicare clinical laboratory fee schedule from 84 percent beginning in 1994 to 76 percent by 1996. The BBA of 1997 reduced fee schedule payments by lowering the cap to 74 percent of the median for payment amounts beginning in 1998, but the Benefits Improvement and Protection Act of 2000 raised the fee schedule amounts to 100 percent of the median for “new tests” performed on or after January 1, 2001. Also, no inflation update was permitted between 1998 and 2002. The MMA of 2003 mandated that the annual adjustment to the clinical laboratory fee schedule for 2004 through 2008 be 0 percent.

Finding: Our 1996 follow-up report found that, generally, Medicare continued to pay clinical laboratories more than physicians pay for the same tests. Our previous work indicated that the clinical laboratories marketed customized panels to physicians at less than what Medicare paid for the same tests. This contributed to a significant increase in the use of laboratory services. Because of the potential for overutilization and the fact that beneficiaries are not always aware of the tests being performed, we believe that CMS should reconsider our recommendation to study the reinstatement of beneficiary coinsurance and deductible provisions for laboratory services.

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

Savings:	Copayment	*\$1.25 billion
	Fee Schedule Adjustment	TBD

**The savings estimate is based on the 20-percent copay applied to FY 2005 Medicare payments for clinical laboratory services totaling \$6.28 billion.*

Status: Although legislation is reducing prices on individual tests, we continue to recommend that payments for laboratory services be evaluated. CMS has taken corrective actions to reduce payments for laboratory services. A proposal to reduce payment updates from FYs 2003 through 2005 was included in the President’s FY 2001 budget, as was a proposal to reinstate laboratory cost sharing. Neither of these proposals was enacted. In addition, the BBA of 1997 required the Secretary of the Department of Health and Human Services to request that the Institute of Medicine conduct a study of Part B laboratory test payments. As a result of the Institute of Medicine’s recommendations, the MMA of 2003 mandated that CMS conduct a demonstration that applies competitive bidding to clinical laboratory services. CMS awarded a task order contract in September 2004 for the design and operation of the demonstration. The initial report to Congress on the demonstration was submitted in December 2005. The MMA of 2003 also set the laboratory fee schedule updates at 0 percent for 2004 through 2008. The competitive bidding demonstration for independent clinical laboratory services was scheduled to begin April 2007 in one geographic area.

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

Require Physician Examination Before Ordering Home Health Services

Background: Section 1861 of the Social Security Act authorized Medicare payments for home health services. Since October 1, 2000, home health agencies have been reimbursed under a PPS.

Finding: Audits and investigations have identified medically unnecessary care and inappropriate or fraudulent billing by specific home health agencies. We have conducted other studies that describe extreme variations and broad patterns of billing by these agencies, which raise questions about the appropriateness of some billings. We, therefore, find that it is necessary to place systematic controls on the home health benefit to prevent abuse.

Recommendation: CMS should revise Medicare regulations to require that physicians examine patients before ordering home health care. As discussed under “Status,” other recommendations to correct abusive and wasteful practices are being addressed.

Savings: TBD

Status: Although the BBA of 1997 included provisions to restructure home health benefits, CMS still needs to revise regulations to require that physicians examine Medicare patients before ordering home health services. After the enactment of the BBA of 1997, our four-State review found that unallowable services continued to be provided because of inadequate physician involvement. Although agreeing in principle, CMS said that it would continue to examine both coverage rules and conditions of participation to develop the discipline necessary for ensuring proper certification. CMS also provided additional payments for physician care plan oversight and education for physicians and beneficiaries.

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

Medicare Reimbursement

Ensure the Medical Necessity of Ambulance Claims

Background: Medicare-covered ambulance transport must be reasonable and medically necessary. Medicare covers and pays for emergency and nonemergency ambulance transports only when a beneficiary's medical condition, at the time of transport, is such that other means for transportation, such as taxi, private car, wheelchair van, or other type of vehicle, would endanger the beneficiary's health. The beneficiary's medical condition must require both the ambulance transportation itself and the level of service provided for the billed service to be considered medically necessary. That is, the transport must be provided to reach a Medicare-covered service facility or to return from such a service facility.

Finding: We conducted this study as a followup to previous work that identified high payment error rates for ambulance transports. This study indicated that 25 percent of ambulance transports did not meet Medicare's program requirements, resulting in an estimated \$402 million of improper payments in CY 2002.

Recommendation(s): CMS should implement program integrity activities designed to reduce improper payments for ambulance transports at greatest risk of error.

Savings: *\$402 million

**In CY 2002, Medicare paid an estimated \$402 million for improper payments for ambulance transports that did not meet Medicare program requirements based on a sample of Medicare claims.*

Status: CMS concurred with our recommendation. CMS indicated that it will advise all contractors to consider implementing prepayment edits for trips with an origin or destination modifier for a dialysis facility, as well as nonemergency transports to and from a hospital, nursing home, or physician's office. In addition, CMS will encourage contractors to consider obtaining documentation from ambulance suppliers and third party providers to determine that ambulance transports meet program requirements on postpayment review and educating suppliers and third party providers who initiate ambulance transports about the appropriate use of Medicare's nonemergency ambulance transport benefit.

Report(s): OEI-09-95-00412; issued 12/98

OEI-05-02-00590; issued 01/06

Medicare Reimbursement

Recover Overpayments and Prevent Inappropriate Medicare Part B Payments for Nail Debridement and Related Services

Background: Podiatry services, including nail debridement, performed within the scope of applicable State licenses are generally reimbursable under the Medicare program.

Finding: Based on our medical review of CY 2000 claims, we estimated that \$51.2 million was inappropriately paid for nail debridement services. Over half of these nail debridement claims contained related podiatry services. When a nail debridement service is determined to be inappropriate, all podiatry payments for related services are also inappropriate. Medicare paid \$45.6 million for such related services.

Recommendation(s): CMS should (1) require Medicare carriers to recoup the overpayments found in our sample and to carefully scrutinize payments for nail debridement services through medical reviews, (2) require podiatrists to adequately document the medical necessity of all nail debridement services, and (3) require CMS Regional Offices and carriers to educate podiatrists on Medicare payment policies for nail debridement claims.

Savings: *\$96.8 million

**In CY 2000, Medicare inappropriately paid \$96.8 million for nail debridement and related podiatry services based on a projection from a sample of claims.*

Status: CMS concurred with our recommendations. CMS indicated that they will continue to maximize the effectiveness of its medical review strategy and collect the overpayments identified in our sample. CMS prepared a provider education article to educate podiatrists on Medicare policy for paying nail debridement claims.

Report(s): OEI-04-99-00460; issued 06/02

Medicare Reimbursement

Ensure Appropriateness of Medicare Payments for Mental Health Services

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

Finding: We estimated that claim error rates for mental health services have exceeded 34 percent, suggesting widespread problems across a variety of provider types and care settings. Billing abuses involving beneficiaries who are unable to benefit from psychotherapy demonstrate a special need for enhanced program and beneficiary protections. Also, beneficiaries with mental illness sometimes do not receive all the services that they need, so that both underutilization and overutilization problems exist.

“Partial hospitalization” services, which may be provided by both hospitals and community mental health centers, have been particularly troublesome. These intensive services are designed to reduce the need for hospitalization of beneficiaries with serious mental illness. We estimated that payment error rates for partial hospitalization in community mental health centers were as high as 92 percent. A number of these centers were terminated from the program after CMS determined that they did not meet certification requirements. Reviews of outpatient psychiatric services provided by both acute care and specialty psychiatric hospitals also revealed high payment error rates, particularly relating to partial hospitalization services.

Recommendation(s): CMS should ensure that mental health services are medically necessary and reasonable; accurately billed; and ordered by an authorized practitioner by using a comprehensive program of targeted medical reviews, provider education, improved documentation requirements, and increased surveillance.

Savings: *\$725 million

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

Status: Concurring with the individual reports, CMS has initiated some efforts, particularly regarding community mental health centers, such as conducting site visits and terminating noncompliant providers from the Medicare program. Our work indicates that problems continue at community mental health centers.

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

Modify Payments to Managed Care Organizations

Background: The BBA of 1997 established the Medicare+Choice (M+C) program with the primary goal of providing a wider range of health plan choices to Medicare beneficiaries. The Act also modified the payment methodology under the program to correct excess payments, reduce geographic variations in payments, and align payments to reflect beneficiaries' health status. The MMA of 2003 redesignated the M+C program as Medicare Advantage (MA) and increased payments.

Finding: Based on numerous OIG reviews, studies by other agencies, and MA organization data, we concluded that MA organizations receive more than adequate funds to deliver the Medicare package of covered services. The basis used to calculate monthly capitation payments to MA organizations was flawed, resulting in higher-than-necessary payments. Medicare payments funded excessive administrative costs, and MA organizations did not account for investment income earned on Medicare funds.

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

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

Savings: *\$1.97 billion

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

Status: Subsequent to the BBA of 1997, the BBRA of 1999 increased payments to MA organizations. We still have concerns that the Federal payment to MA organizations is excessive because the 1997 base rate was flawed. We will be updating our work to examine MA organization payments as a result of all legislative changes.

Report(s): OAS-14-00-00212; issued 9/00

Medicare Managed Care

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

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

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

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

Savings: TBD

Status: CMS did not agree with our recommendation to institute a ceiling on the administrative costs included in MA organizations' proposals. We will be updating our work to examine administrative costs under provisions of the MMA of 2003.

Report(s): OAS-14-98-00210; issued 1/00 OAS-03-01-00017; issued 11/01
OAS-03-98-00046; issued 1/00

Medicaid Reimbursement

Limit Upper Payment Limit Payments to Cost and Require That Medicaid Payments Returned by Public Providers are 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: Enhanced payments to local-government-owned providers were not based on the actual cost of providing services to Medicaid beneficiaries. In addition, a large portion of the enhanced payments were not retained by the health care facilities to provide services to resident Medicaid beneficiaries. Instead, some funds were transferred back to the States for other uses.

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

Savings: *\$120 million

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

Status: In a Notice of Proposed Rulemaking issued in January 2007, CMS proposed to limit reimbursement for health care providers that are operated by units of government to an amount that does not exceed the provider's costs and to require providers to receive and retain the full amount of total computable payments for services furnished under the approved State plan.

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

Medicaid Reimbursement

Ensure Compliance With Requirements for Medicaid School-Based Health Services

Background: Section 1903(c) of the Social Security Act (the Act) was amended in 1988 to make clear that Medicaid payment was allowable for covered Medicaid services that are included in an individualized education plan or individualized family service plan, as required by the Individuals With Disabilities Education Act (IDEA). Otherwise covered Medicaid services include early and periodic screening diagnosis and treatment services that meet Medicaid requirements and may also be required under IDEA.

Finding: Our reviews identified Medicaid overpayments for school-based health services. The Federal share of the overpayments totaled 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 speech-language pathologist. These unallowable claims generally occurred because States did not provide sufficient guidance to and oversight of local education agencies, and rates were not developed in accordance with applicable Federal cost allocation requirements or CMS program guidelines.

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

Savings: TBD

Status: CMS has begun taking action in individual States to recover overpayments. CMS has recently 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. The President's FY 2007 budget proposes to prohibit Federal Medicaid reimbursement for school-based administrative or transportation costs.

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

Medicaid Reimbursement

Address and Resolve Excessive Medicaid Disproportionate Share Hospital Payments

Background: Section 1923 of the Social Security Act (the Act), as amended by the OBRA of 1993, requires that States make Medicaid disproportionate share hospital (DSH) payments to hospitals that serve disproportionate numbers of low-income patients with special needs. Section 1923(g) of the Act limits these payments to a hospital's uncompensated care costs, which are the annual costs incurred to provide services to Medicaid and uninsured patients less payments received for those patients.

Finding: Nine of the ten States reviewed did not comply with the hospital-specific DSH limits imposed by section 1923(g) of the Act. As a result, payments exceeded the hospital-specific limits by about \$1.6 billion (\$902 million Federal share). About \$679 million of the \$902 million was based on historical costs. States did not later adjust the payments using actual costs. States also made about \$223 million in excess payments because they included unallowable costs in their calculations of hospital-specific limits. In addition, three States required hospitals to return DSH payments totaling approximately \$3.6 billion through intergovernmental transfers.

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

Savings: TBD

Status: CMS agreed with our recommendations and is recovering overpayments from individual States and developing a DSH program regulation. CMS has received comments on a draft regulation and is currently working on issuing the final regulation.

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

Medicaid Reimbursement

Eliminate or Reduce Transition Periods for Compliance With Revised Medicaid Upper Payment Limits

Background: In a final rule published in January 2001, CMS revised the Medicaid UPL regulations to provide for three separate aggregate upper limits—one each for private, State, and non-State-government-owned facilities. The regulation included 5- and 8-year transition periods for States with approved rate enhancement State plan amendments. The applicable transition period depended on the effective date of these amendments.

Finding: We believe that the transition periods included in the regulations are longer than needed for States to adjust their financial operations in response to the new UPLs.

Recommendation(s): CMS should seek authority to eliminate or reduce the 8-year transition period included in the revised upper payment limit regulations.

Savings: TBD

Status: CMS did not concur with our recommendation. According to CMS, the transition periods were established pursuant to either notice-and-comment rulemaking or legislation and offering new proposals at this time would undermine the consensus reached through those processes. CMS anticipates no further action on our recommendation. Five States remain with transition periods through September 1, 2008.

Report(s): OAS-03-00-00216; issued 09/01

Medicaid Reimbursement

Require 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 drug prescriptions. We estimated the actual acquisition cost for 200 brand name drugs with the greatest amount of Medicaid reimbursement for CY 1999.

Finding: State pharmacy reimbursement formulas discount below the AWP averaged 10.31 percent nationally in 1999. We believe that this discount is not sufficient to ensure that a reasonable price is paid for drugs. Our review, based on CY 1999 data, estimated that the actual acquisition cost for brand-name drugs was an average of 21.84 percent below the AWP, an increase of 19.3 percent over our previous estimate based on CY 1994 data. 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 greatest amount of Medicaid reimbursement for CY 1999.

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

Savings: *\$1.08 billion

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

Status: CMS concurred with our recommendation and is 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 price (ASP). The proposal was not included in the President's FY 2007 budget. We will continue to monitor the pricing of Medicaid drug reimbursements for brand-name drugs.

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

Medicaid Reimbursement

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

Background: Most States use the AWP minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. We estimated the actual acquisition cost for 200 generic drugs with the greatest amount of Medicaid reimbursement for CY 1999.

Finding: State pharmacy reimbursement formulas discount below the AWP averaged 10.31 percent nationally in 1999. We believe that this discount is not sufficient to ensure that a reasonable price is paid for drugs. Our review, based on calendar year 1999 data, estimated that the actual acquisition cost for generic drugs was an average of 65.93 percent below the AWP, an increase of more than 55 percent from our previous estimate, based on CY 1994 data. We estimated, that changing the reimbursement policy consistent with our findings could have saved the Medicaid program as much as \$470 million for the 200 generic drugs with the greatest amount of Medicaid reimbursement for CY 1999.

Recommendation: CMS should encourage the States to bring pharmacy reimbursement more in line with the actual acquisition cost of generic drugs being realized by pharmacies in their States. We recommended a four-tier approach to reimbursement as follows: single-source innovator drugs, multiple-source innovator drugs without FULs, multiple-source noninnovator drugs without FULs, and multiple-source drugs with FULs.

Savings: *\$470 million

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

Status: CMS concurred with our recommendation. The agency is working with States to strongly encourage them to review their estimates of acquisition costs and will follow up to ensure that they take our findings into account.

The DRA changes the Medicaid reimbursement rate for drugs to make payments more accurate. For generic drugs, the Federal Government will set a FUL on Medicaid drug payment that is equal to 250 percent of the lowest AMP for a generic version of a drug. The FY 2007 President's budget proposes to build on the DRA changes to the FUL for multiple-source drugs. The budget proposes to limit reimbursement for multiple-source drugs to 150 percent of the AMP. We will continue to monitor the pricing of Medicaid drug reimbursements for generic drugs.

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

OAS-06-02-00041; issued 09/02

Medicaid Reimbursement

Add Qualified Drugs to the Medicaid Federal Upper Limit List

Background: Pursuant to 42 CFR § 447.332, CMS is required to establish FULs to reduce the amount that Medicaid reimburses for multiple-source drugs. Prior to 2007, these regulations set the FUL amount at 150 percent of the published price for the least costly therapeutically equivalent product that can be purchased in quantities of 100 tablets or capsules plus a reasonable dispensing fee. If the drug product is not available in quantities of 100 or if the drug is a liquid, then the FUL amount should be based on a commonly listed size. The regulations further instruct CMS to include a drug on the FUL list if the FDA rates at least three versions of the drug as therapeutically equivalent and the drug has at least three suppliers listed in national compendia. The DRA provides, as of January 1, 2007, that FULs apply to multiple source drugs for which FDA has rated two or more products to be therapeutically and pharmaceutically equivalent and the FUL amount is based on 250 percent of the lowest average manufacturer price of the drug.

Finding: We found that 90 drug products that met the established criteria were not included on the FUL list in 2001. If 55 of these drug products had been included on the FUL list, the Medicaid program could have saved about \$123 million in 2001. We also found that CMS does not consistently add qualified drugs to the FUL list in a timely manner. Of the 252 first-time multiple-source drugs approved between January 2001 and December 2003, 109 products met the statutory and regulatory criteria for inclusion. However, only 25 were actually added. We estimated that Medicaid lost \$167 million between 2001 and 2003 because qualified drugs were not added to the FUL list in a timely manner.

Recommendation(s): CMS should take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the FUL list and establish an administrative procedure and schedule to govern the determination and publication of FULs.

Savings: *TBD

**This represents potential Medicaid savings of \$123 million for drug products that met the established criteria but were not included on the FUL list in CY 2001. Qualified drugs that were not added to the FUL list in a timely manner could have resulted in an additional \$167 million in potential savings between CY 2001 and 2003. The calculations were based on the difference between the potential FUL amount and the average Medicaid reimbursement amount.*

Status: CMS did not concur with our finding that 90 drug products that met the established criteria were not included on the FUL list in 2001. They stated that our work did not follow the same procedures CMS uses when establishing the FUL and included drugs for which a FUL is irrelevant (i.e., the FUL exceeds the AWP). Effective January 1, 2007, the DRA sets the FUL on Medicaid drug payment at 250 percent of the lowest AMP for a multiple-source version of a drug and changes the criteria for drugs added to the FUL. CMS added 9 of the 90 products in the report (7 of 9 products accounted for \$94 million of the \$123 million in savings we calculated for 2001). Of the nine products added, CMS added four in August 2003, one in March 2004, and the remaining four in June 2004.

Medicaid Reimbursement

Add Qualified Drugs to the Medicaid Federal Upper Limit List *(continued)*

CMS concurred with the intent of our recommendation to establish an administrative procedure and schedule to govern the determination and publication of FULs and has taken steps to support this objective. However, CMS did not concur with our methodology in performing this review and savings estimates. At a meeting for a follow-up study, CMS explained that it was looking into ways to better identify products that were qualified for the FUL. This includes subscribing to an electronic database that identified drugs that are no longer subject to patents, allowing CMS to anticipate when drugs would qualify.

Report(s): OEI-03-02-00670; issued 02/04

OEI-03-04-00320; issued 12/04

Medicaid Drug Rebates

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

Background: The OBRA of 1990 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Rebates are calculated using the AMP, the manufacturer's best price, and other factors. In contrast, most States reimburse pharmacies for Medicaid prescription drugs based on the AWP of the drug. We calculated the rebates for the 100 brand-name drugs that had the greatest amount of Medicaid reimbursement for 1994 through 1996 using the AWP instead of the AMP.

Finding: Requiring manufacturers to pay Medicaid drug rebates using the same basis as reimbursements made to pharmacies would (1) eliminate inconsistencies in the present methods used by drug manufacturers to calculate AMPs; (2) establish a much-needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursement for drugs at the pharmacy level; and (3) reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

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

Savings:	*100 brand-name drugs All Drugs	\$1.15 billion TBD
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**Basing Medicaid rebates on the AWP rather than the AMP would have resulted in about \$1.15 billion in added rebates for CYs 1994 through 1996 for 100 brand-name drugs that had the greatest amount of Medicaid reimbursement in these years.*

Status: CMS agreed to pursue a change in the Medicaid drug rebate program similar to that recommended. In accordance with the DRA of 2005, CMS provides the States with sales-based sources of drug-pricing information that were not previously available for States' use. Beginning in July 2006, CMS provides States with AMP data on a monthly basis. However, the DRA does not require States to use AMP data to revise their current reimbursement formulas. In the future, States may start using AMP for reimbursement purposes. If they do, this may establish a connection between reimbursement and rebates. We will continue to monitor the issue.

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

Medicaid Drug Rebates

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

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

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

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

Savings: *\$123 million

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

Status: CMS disagreed with this recommendation. We are continuing to monitor the drug rebate program; audits will continue to focus on enhancing the collection of rebates and providing potential savings to the rebate program.

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

Eliminate Excessive Costs in the 340B Drug Discount Program

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

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

Recommendation(s): We recommended that HRSA improve its oversight of the 340B Program to ensure that entities are charged at or below the 340B ceiling price and that it work with CMS to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices. HRSA should take four steps to strengthen its administration of the 340B Drug Discount program: (1) establish detailed standards for the calculation of 340B ceiling prices, (2) institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities, (3) seek legislative authority to establish penalties for violations of the PHS Act, and (4) obtain consistent unit of measure and package size data to accurately calculate 340B ceiling prices.

Savings: *\$46.8 million to federally supported covered entities

**Estimated savings based on \$3.9 million in overpayments by federally supported covered entities in 1 month in 2005, multiplied by 12 to calculate savings for 1 year. Additional indirect savings to the Department are likely but cannot be calculated.*

Status: HRSA has taken steps to more closely monitor the prices paid by 340B entities. HRSA stated that it anticipates promulgating a penny price policy in conjunction with formalizing the instructions for the calculation of 340B ceiling prices. HRSA has requested that manufacturers voluntarily submit their prices for comparison with the agency's ceiling prices and will review the data that manufacturers and entities voluntarily submit, to the extent that resources permit. Additionally, HRSA stated that it will explore the possibility of seeking the authority and resources needed to impose fines and civil penalties for violations of section 340B of the PHS Act.

Health Resources and Services

Eliminate Excessive Costs in the 340B Drug Discount Program *(continued)*

HRSA and CMS negotiated a new Intra-agency Agreement and Data Use Agreement in which HRSA will receive pricing data from CMS effective during FY 2005 but will itself calculate the Government's 340B ceiling price. CMS has agreed to reiterate the 30-day pricing data submission requirement for manufacturers and will consider referring appropriate cases of late submission to OIG to levy penalties. HRSA will work with CMS to maximize the acquisition of manufacturer's data as well as resolve problems related to missing data. HRSA also agreed to publish detailed standards for the calculation of 340B ceiling prices on its Web site.

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

OEI-05-02-00073; issued 07/06

Aging

Use Voluntary Contributions To Expand Services for the Elderly

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

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

Recommendation(s): AoA should revise its regulations in accordance with the Older Americans Act.

Savings: *\$90.8 million

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

Status: The Older Americans Act (OAA) Amendments of 2000 and 2006 (Public Laws 106-501 and 109-365, respectively) changed provisions relating to voluntary contributions. AoA is in the process of determining which regulatory changes are needed for this section, as amended, as well as for other provisions of the Act that were amended.

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

Departmentwide and Cross-Cutting Issues

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

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

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

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

Recommendation(s): ACF and CMS should (1) provide specific guidance to States on collecting Medicaid costs from noncustodial parents who have the financial ability to pay or who do not have affordable employer-sponsored health coverage available, (2) clarify third-party liability regulations to assist State Medicaid agencies in coordinating with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders, and (3) seek legislation that would allow States to accumulate medical support payments to offset Medicaid fee-for-service costs for a reasonable period.

CMS should also (1) issue program guidance to advise States of their authorities under Federal law to collect SCHIP costs from noncustodial parents and (2) determine whether additional Federal funds are needed to assist States in interfacing their Title IV-D and SCHIP databases and implementing a process to collect SCHIP costs from noncustodial parents and, as appropriate, provide such funds.

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

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

Departmentwide and Cross-Cutting Issues

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

Status: On January 17, 2006, ACF shared the results of our review with States. In addition, CMS provided guidance to States on the collection of Medicaid costs from available noncustodial employer-sponsored health care coverage through a series of meetings sponsored by ACF. CMS also agreed to work with OIG to draft legislation to allow States to accumulate medical support payments and to consider whether third-party liability regulations needed clarification; however, we continue to believe there is a need.

As to our recommendations concerning SCHIP costs, CMS did not believe that issuing formal guidance was necessary but did alert States of their option to pursue the Federal and State shares of these costs. As an additional effort to ensure that States are knowledgeable about their authorities under Federal law to collect SCHIP costs from noncustodial parents, CMS participated in the Medical Support Collaboration regional meetings sponsored by the ACF in 2005 and 2006. CMS noted that States already have the ability to fund the administrative costs of building an infrastructure with the State Title IV-D agency under their 10-percent administrative SCHIP cap. We still believe that it may be necessary for CMS to consider alternative methods to ensure that States receive adequate funds especially if States are at or near their 10-percent administrative cap.

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

OAS-01-03-02502; issued 05/05

New Nonmonetary Recommendations

Medicare and Medicaid

Medicare Hospitals

Improve Hospital Reporting of Deaths Related to Restraint and Seclusion

Background: This study determined whether hospitals reported restraint and seclusion related deaths, as required by CMS, and evaluated CMS and State survey agency responsiveness, guidance, and monitoring concerning the reporting requirement. In December 1997, CMS published a proposed rule to revise all existing hospital conditions of participation (CoPs) and included a new Patient's Right. The new CoP was, in part, a response to reports of violations of patients' rights in hospitals. The Patient's Right CoP establishes, among other things, a reporting requirement for all hospital deaths associated with the use of restraints or seclusion for behavior management (42 CFR § 482.13(f)(7)). CMS requirements establish timeframes to ensure that investigations concerning hospital compliance with the Patient's Rights CoP are timely, and information about deaths related to restraint and seclusion is communicated to the protection and advocacy agencies and the CMS central office in a timely manner.

Finding: Hospitals failed to report to CMS 44 of 104 documented deaths related to restraint and seclusion between August 2, 1999, and December 31, 2004. CMS and State survey agencies do not consistently take action in response to reported deaths in a timely manner. State survey agencies did not disseminate information to hospitals about the reporting requirement, which may contribute to hospitals' lack of understanding of the reporting requirements. Also, CMS does not maintain comprehensive and reliable information about reported deaths related to restraint and seclusion.

Recommendation(s): CMS should seek legislation to establish intermediate sanctions for hospitals that fail to report directly to CMS deaths related to restraint and seclusion; consider regulatory changes that would require reporting all deaths related to the use of restraint and seclusion; instruct its regional offices and State survey agencies to adhere to reporting deadlines; encourage State survey agencies to provide to hospitals ongoing training about the reporting requirements; and instruct regional offices to request periodic updates about deaths related to restraint and seclusion from other Federal and State agencies.

Status: CMS generally concurred with our recommendations. On December 8, 2006, the Hospital CoP Patient's Rights was published in the "Federal Register" as a final rule. The rule finalizes the standards for death-reporting requirements. CMS will also issue a Survey and Certification Memorandum to ensure the regional offices and survey agencies receive written instructions that inform hospitals of new death-reporting timelines. However, CMS indicated that to establish intermediate sanctions for hospitals would require legislative changes by Congress.

Report(s): OEI-09-04-00350; issued 9/06

Medicare Hospitals

Improve Carrier Determination of Copayments for Medicare Mental Health Services

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

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

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

Status: CMS agreed to take steps to address our recommendations. CMS plans to issue more precise guidance that will establish policy for application of the outpatient mental health treatment limitation, create and post educational material on its Web sites; and, to the extent operationally feasible, require carriers to reopen and adjust incorrectly processed claims for patients with Alzheimer's disease and related disorders.

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

Medicare Hospitals

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

Background: Patients with ESRD rely on dialysis treatment to compensate for kidney failure. In 2000, both OIG and Government Accountability Office (GAO) issued reports documenting problems with CMS oversight of ESRD facilities. National aggregate data suggest that dialysis care has improved overall. However, questions remain about the quality of care provided at some ESRD facilities. This study assessed the extent to which data were available to assist ESRD Networks in identifying facilities with quality improvement needs.

Findings: We found that although Networks have access to multiple sources of data about quality of care, each has limitations in assisting Networks to identify facilities with quality improvement needs. Limitations include lack of facility-specific, comprehensive, and current clinical performance measures (CPMs). CMS has taken action towards providing a streamlined source of data that could assist Networks in identifying facilities with quality improvement needs; however, it has not yet been implemented. In 2000, CMS stated that it was developing a Core Data Set project that would collect facility-specific data on a comprehensive set of clinical performance measures regularly. CMS has faced technical and resource challenges, and the implementation of Core Data Set is not complete.

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

Status: CMS has made progress in collecting data to improve the quality of care in the ESRD program; however, opportunities for improvement still exist. CMS published proposed revisions to the ESRD Conditions for Participation in February 2005, and a final rule is expected. Steps CMS has taken to improve quality of care for the ESRD program include the development of CPMs, definition of the Core Data Set, and proposed regulations that would require facilities to electronically submit all CPMs on all ESRD patients. CMS has also committed to developing a new information system call Consolidated Renal Operations in a Web-based Network (CROWN), which would consolidate existing data sources into one system. CMS expects the CROWN to be completed in 2008.

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

Nursing Homes

Ensure That States Cease Imposing Fees on Nurse Aides Registration

Background: The OBRA of 1987 includes numerous provisions intended to lead to improvement in the quality of care in long term care (LTC) facilities. The OBRA requires that each State establish and maintain a nurse aide registry. Sections 1819(e)(2) and 1919(e)(2) of the Social Security Act prohibit States from imposing any charges on individuals related to registration in the registry.

Finding: CMS conducted limited oversight of all States regarding imposing registry fees and provided guidance on fees only to States that requested it. Almost half of the States imposed fees related to nurse aide registries, few States required aides to pay for placement on nurse aide registries, and others required fees on nurse aides as a requirement to work in LTC facilities.

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

Status: CMS indicated that it will work through its regional offices to notify States found to impose fees in violation of Federal requirements that such practices must cease and ensure that proper revenue offset was made to claims for Federal financial participation. CMS has also indicated that it will ensure that all State Medicaid agencies review a written reminder of the statutory and regulatory provisions that prohibit the imposition of any charges on nurse aides relating to the nurse aide registry. Additionally, CMS has indicated that it will ensure that the regional offices will periodically perform focused reviews of States' compliance with registry requirements.

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

Nursing Homes

Ensure That Only Registered Nurse Aides Without Substantiated Findings Are Registered

Background: The OBRA of 1987 includes numerous provisions intended to lead to improvement in the quality of care in LTC facilities. Federal regulations (42 CFR § 483.156) require each State to establish and maintain a registry of individuals who have completed training and whom the State finds competent to function as nurse aides. In addition, Federal regulations (42 CFR § 483.13(c)(1)) prohibit LTC facilities from employing individuals who have substantiated adverse findings entered into the State nurse aide registry or who have been found guilty in a court of law for abusing, neglecting, or mistreating LTC facility residents.

Finding: Some States failed to update registries with substantiated adverse findings, and some LTC staff reported checking only their own State’s registries before hiring an employee. 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 longer than the allowed 4 months.

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

Status: CMS developed and disseminated the “Abuse and Neglect Detection and Prevention Training Manual” to provide surveyors and other reviewers with additional resources to support the detection and prevention of abuse and neglect. CMS indicated that it will issue additional communications to States affirming the law, CMS policy, and the importance of the nurse aide registries. CMS indicated that it will also consider a variety of methods of working with States to be effective in implementing background checks.

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

OEI-07-04-00140; issued 07/05

Nursing Homes

Strengthen Oversight of Nursing Home Complaint Investigations

Background: Sections 1819(g)(4) and 1919(g)(4) of the Social Security Act require that each State maintain procedures and adequate staff to investigate and report the nursing home complaints they receive. The CMS “State Operation Manual” (SOM) outlines the process that State agencies must follow when managing complaint investigations.

Finding: We found that CMS oversight of complaint investigations is limited and that State agencies did not investigate some of the most serious complaints within the required timeframes. We also found that State agencies have not taken full advantage of the ASPEN Complaints/Incidents Tracking System (ACTS) and that some of the States’ complaint policies do not incorporate some CMS guidelines for complaint investigations.

Recommendation(s): CMS should strengthen oversight of nursing home complaint investigations by requiring State agencies to meet the 10-day timeframe for investigating complaints alleging actual harm. CMS should conduct additional followup to the State Performance Review and consider eliminating the 2-week advance notice for the Federal Oversight and Support Survey required in the SOM to allow regional offices the option of overseeing complaint investigations for the most serious nursing home complaints. CMS should also offer the State agencies further training targeted to complaint management and continue to train its regional office staff on the ACTS functions, especially related to overseeing State agencies.

Status: CMS is planning to release in 2007 a multipurpose video training module that States may use to instruct staff in conducting complaint investigations. In August 2006, CMS revised the language in the State Performance Standard for FY 07 to better reflect the language articulated in the SOM. Namely, according to the policy, the State agency must initiate an onsite survey within 10 working days for nursing home intakes assigned a priority of “Non-Immediate Jeopardy-HIGH.” Additionally, CMS indicated that it will assess the extent to which additional improvements can be made with existing resources and indicated it will assess whether performance expectations for “Non-Immediate Jeopardy” allegations should be adjusted to reflect resource limitations or additions.

Report(s): OEI-01-04-00340; issued 07/06

Nursing Homes

Strengthen Federal Certification Standards for Nursing Home Emergency Plans Including Specific Elements for Emergency Planning Investigations

Background: Sections 1819(b)(c)(d) and 1919 (b)(c)(d) of the Social Security Act establish requirements for nursing home participation in the Medicare and Medicaid programs. Under sections 1819(f)(1) and 1919 (f)(1), the Secretary for the Department of HHS is responsible for ensuring that these requirements and their enforcement are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public monies. Pursuant to Federal regulations 42 CFR § 483.75 (m)(1), certified facilities are required to have “detailed written plans and procedures to meet all potential emergencies and disasters,” and must “train employees in emergency procedures when they begin work in the facility, periodically review procedures, and carry out unannounced staff drills.” The SOM also requires that facilities consider the development of plans and training applicable to the geographic location and the types of residents served.

Finding: We found that although 94 percent of selected nursing homes in the Gulf States affected by hurricanes met Federal emergency plan standards and that 80 percent had sufficient emergency training. All the nursing homes had experienced problems whether they had evacuated or sheltered in place. Nursing homes that evacuated faced problems, such as transportation contracts that were not honored, lengthy travel times, host facilities that were unavailable or inadequately prepared, inadequate staffing, insufficient food and water, and difficult reentry to facilities. We also found that nursing home administrators and staff often did not follow their emergency plans during hurricanes, that the emergency plans were often missing suggested provisions, and that a lack of collaboration between State and local emergency entities and nursing homes impeded emergency planning and response.

Recommendation(s): We recommended that CMS strengthen certification standards for nursing home emergency plans by including requirements for specific elements of emergency planning. We also recommended that CMS encourage communication and collaboration between States and local emergency entities and nursing facilities.

Status: CMS concurred with these recommendations and is exploring ways to strengthen Federal certification standards for emergency preparedness and to promote better coordination between Federal, State, and local emergency management entities. CMS plans to implement a communication strategy to disseminate policies, procedures, interpretive guidance, and other communications to State Survey Agencies, CMS regional offices, and health care facilities. CMS indicated that regulatory changes may be undertaken as a long term strategy while other strategies can be taken in the short term to ensure resident and staff safety. Several CMS workgroups have been reviewing the current Federal emergency preparedness requirements to determine the most appropriate methods of improving the preparedness standards applicable to health care facilities. CMS is also participating in several departmental interagency workgroups that are developing recommendations and guidance for improving coordination and collaboration among Federal, State, and local emergency entities.

Report(s): OEI-06-06-00020; issued 08/06

Medicare Drugs

Evaluate the Calculation of Volume-Weighted Average Sales Prices for Medicare Part B Prescription Drugs

Background: In 2005, Medicare began paying for most Part B drugs using a new pricing methodology based on the ASP. Under Section 1847 (A)(b)(1) of the Social Security Act (the Act), Medicare's payment for most drugs is equal to 106 percent of the volume-weighted ASPs for those drugs. Section 1847A(b)(2) of the Act specifies the unit that manufacturers must use when submitting the ASP data to CMS. This section also specifies the way to calculate a volume-weighted ASP for an HCPCS code based on manufacturer-reported ASP data. Exercising discretion permitted by this section, CMS opted to modify the unit of ASP submission, making it necessary to alter the method for calculating a volume-weighted ASP.

Finding: The method CMS uses to calculate a volume-weighted ASP is mathematically incorrect. Therefore, CMS's equation may not always yield a volume-weighted ASP that is consistent with the volume-weighted ASP derived from the calculation set forth in section 1847A(b)(3) of the Act. Consequently, Medicare Part B prescription drug reimbursement amounts may not be accurate. Furthermore, CMS's calculation affects statutory mandates to monitor and adjust drug reimbursement amounts.

Recommendation(s): We recommended that CMS change its calculation of volume-weighted ASPs and adopt an alternate equation that produces a volume-weighted ASP that is both mathematically correct and consistent with the results of the calculation set forth in section 1847A(b)(3) of the Act.

Status: CMS stated it will consider the report's findings in its ongoing effort to enhance implementation of the new ASP payment methodology. CMS published the current AMP calculation in a final regulation on November 21, 2005, (70 FR 70116, 70218). CMS indicated that as it gains more experience with the ASP and data and other sources of information become available, it may consider altering the methodology of establishing exceptions as suggested by some of the public comments.

Report(s): OEI-03-05-00310; issued 02/06

Medicare Drugs

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

Background: Federal regulations (42 CFR 423.504(b)(4)(vi)) require prescription drug plan (PDP) sponsors, approved to provide Medicare Part D benefits, to establish compliance plans. PDP sponsors' compliance plans must address eight elements as specified in Federal regulations. Additionally, CMS Part D guidance documents state that PDP compliance plans must address 17 requirements regarding the 8 compliance plan elements presented in Federal regulations.

Finding: We found that all PDP sponsors had compliance plans that covered the 79 stand-alone PDP contracts, yet 72 of the 79 compliance plans did not address all of CMS's requirements regarding the eight compliance plan elements. Many compliance plans also lacked detail regarding requirements involving compliance processes and programs. Additionally, we learned that while all compliance plans addressed the fraud and abuse element in some way, only 15 of the 79 plans addressed all 11 CMS recommendations regarding fraud detection, correction, and prevention that were included in the review.

Recommendation(s): We recommended that CMS ensure that PDP sponsors' compliance plans address all requirements within its guidelines regarding the eight elements set forth in the regulations. In addition, CMS should encourage sponsors to provide sufficient detail in their compliance plans to clearly demonstrate how sponsors are actually implementing the compliance plan requirements.

Status: CMS agreed that effective compliance plans are an important tool for monitoring fraud, waste, and abuse in PDP sponsors' Part D plans and concurred with our recommendation. CMS also stated that routine audits, beginning in 2007, will review the required compliance plan elements and that sponsors will be accountable for meeting all requirements.

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

Other Medicare and Medicaid Issues

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

Background: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191), section 202, authorized CMS to contract with entities to fulfill program integrity functions for the Medicare program and required a competitive process for awarding contracts. CMS entered into the first contract under this authority in 1999. Entities awarded such contracts are called program safeguard contractors (PSC). Once under contract, PSCs are then awarded task orders to carry out specific duties.

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

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

Status: CMS concurred with the third and fourth recommendations. CMS partially disagreed with our first two recommendations regarding what should be addressed in PSC performance evaluation reports. With regard to the first recommendation, CMS stated that quantifying results may compromise investigations and create perverse incentives. Our recommendation was not to establish a quota system for performance; rather, we recommended that there should be a combination of qualitative and quantitative results information included in PSC evaluation reports. It would be difficult to determine PSC effectiveness without this information. With regard to the second recommendation, CMS stated that resources sometimes prevent it from addressing all PSC activities in the evaluation reports. We continue to recommend that activities required in PSC task orders should be addressed in evaluation reports.

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

Improve Monitoring of Patient Safety Grants

Background: Congress enacted the Healthcare Research and Quality Act of 1999 (Public Law 106-129), which established AHRQ within HHS. Congress directed AHRQ to designate funds from its appropriation for grants to study patient safety in H.R. Rep. No. 106-645, at 102 (2000). For FYs 2001 through 2003, AHRQ awarded 120 grants totaling \$128 million to conduct research on improving patient safety and reducing medical errors. Federal regulations and departmental policies (e.g., Grant Policy Directives from the Office of Grants) govern HHS grants monitoring.

Finding: We found that based on a sample of 39 grant files, we found that most Financial Status Reports were not received or were late. Of the required reports, 30 percent were not received and 43 percent were not received promptly, representing a combined total of \$50.6 million in dispensed grant funds. In contrast, the submission of the performance reports generally complied with Federal requirements. We also found that AHRQ did not ensure that Federal requirements for grant closeouts were met. Of the sampled grants, seven official grant files were eligible for closeout. Two grants were closed in accordance with Federal requirements. Three grants lacked documentation of required closeout reports, liquidation of assets, and/or results of the final research. The remaining two grant files contained all required closeout documents, although AHRQ staff had not completed the closeout process.

Recommendation(s): We recommended that AHRQ (1) require submission of interim financial information of prior year expenditures before future funding is authorized, (2) establish a tracking system for Financial Status Reports, (3) require grantees with no-cost extensions to submit Financial Status Reports in compliance with Federal requirements, and (4) ensure that grants awaiting closeout are closed promptly.

Status: AHRQ responded that it agrees with the findings in the report and that the recommendations are reasonable. AHRQ indicated that the recommendations reinforce ongoing improvements begun subsequent to the FYs that we reviewed or support ongoing improvement activities.

Report(s): OEI-07-04-00460; issued 06/06

Update and Maintain an Accurate New Drug Code Directory

Background: The Drug Listing Act of 1972 requires drug firms engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to FDA. Drug products are uniquely identified and reported using a three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA assigns the first segment and drug firms assign the other two segments. FDA inputs the full NDC number and information submitted as part of the listing process into a database known as the Drug Registration and Listing System. FDA extracts information from this database several times a year and publishes that information in the NDC Directory. As drug firms introduce a new drug product or discontinue a product, they must report the complete NDC and associated information to FDA as part of the drug product listing process.

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

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

Status: FDA concurred with our recommendations and requested access to our data files to follow up on identified problems. FDA delineated a number of initiatives it expects will improve the Directory's completeness and accuracy, such as conversion to an electronic listing system for use by drug firms. FDA has updated the draft listing instructions referenced on its Web site. FDA published a proposed rule on August 29, 2006, that will clarify listing requirements, enhance control of the drug establishment registration and drug listing process, and improve data accuracy and completeness. In December 2006, FDA held a public hearing on the proposed rule that would change the NDC system. This hearing allowed industries affected by the proposed rule to testify on the impact that NDC system changes would have on their companies or industries.

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

Improve Postmarketing Oversight

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

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

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

Status: FDA agreed with our recommendations to improve the management information system for monitoring postmarketing study commitments and to ensure that postmarketing study commitments are being monitored and ASRs are validated. FDA emphasized the seriousness with which it takes its obligation to monitor the progress of postmarketing study commitments and stressed that it makes some information regarding the commitments publicly available. The agency highlighted ongoing efforts to enhance its postmarketing study commitment database and reporting capabilities, train its review division staff on ASR validation procedures, and standardize the process by which postmarketing study commitments are requested and reviewed. FDA's ongoing efforts are aimed at enhancing the postmarketing commitments (PMC) database and reporting functionalities; completing specialized training for the review division on the overall management of PMCs with the focus on the procedures for validating ASRs; and hiring outside contractors to conduct a thorough analysis of the PMC process to gain greater internal consistency regarding how FDA requires, requests facilitates, and reviews PMCs.

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

Improve Oversight and Review of Outside Activities of Senior-Level National Institutes of Health Employees

Background: Employees of HHS are allowed to work and interact privately with non-Federal entities on their personal time through outside activities, which may require prior approval. These activities must not conflict with employees' official duties and may or may not involve financial compensation. Pursuant to 18 U.S.C. § 208(a), and 5 CFR § 2635.502, an actual conflict of interest arises when an employee personally and substantially participates, in an official capacity, in a particular matter in which he or she has a personal or imputed financial interest if the matter will have a "direct and predictable effect" on that interest. Additionally, pursuant to 5 CFR § 2635.502, the appearance of a loss of impartiality arises when an employee participates, in an official capacity, in a matter in which he has certain defined associations or interests that would "cause a reasonable person to question his impartiality in the matter."

Finding: We found that between 2001 and 2003, 40 percent of NIH senior-level employees at NIH received approval for 319 outside activities. About half of these outside activities involved teaching or consulting and most were compensated. We identified several vulnerabilities that inhibit NIH's ability to effectively review outside activities. Employees submitted limited information regarding their outside activities. There are also several problems in the review process itself, including approvals after the start date, limited use of written recusals, and inadequate followup of ongoing outside activities.

Recommendation(s): We recommended that NIH improve the quality and extent of the information it receives for outside activities and address inadequacies in the review process for outside activities.

Status: HHS and NIH have already undertaken a variety of initiatives to address inadequacies in the review and approval process for outside activities. NIH is in the process of revising procedures for submission and approval of outside activity requests. NIH has increased training and has centralized the review of certain types of outside activity requests. NIH created an Ethics Advisory Committee to centralize the review process and expects to continue the ongoing centralization of the outside activities review process. NIH is updating online training modules to reflect recent ethic program changes. In addition, the NIH Director and Deputy Director forwarded all employees periodic e-mail messages that transmit guidance on the ethics issues and links to ethics related training, FAQs, policies, and regulations. Furthermore, in February 2005, HHS issued an interim final rule that placed several restrictions on the types of outside activities in which NIH employees are allowed to participate and placed a limit on the outside activity approval period of 1 year.

Report(s): OEI-01-04-00150; issued 02/06

Health Resources and Services

Improve Health Resources and Services Administration Alert List Practices

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

Finding: We found that HRSA does not consistently follow Alert List policies including placing, checking, consulting, monitoring, and justifying retaining grantees on the Alert List. Specifically, we determined that HRSA does not (1) consistently place grantees on the Alert List, (2) consistently check the Alert List or accurately document checking it, (3) regularly consult with other agencies to obtain information about grantees, (4) consistently document certain monitoring activities for Alert List grantees, (5) provide justification for retaining grantees whose names appear on the Alert List for more than 2 years, or (6) use the information on the Alert List to make grant decisions.

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

Status: HRSA believes that the consolidation of its grants management operations into a single operating unit, with standardized operating procedures and uniform guidance, will prevent a recurrence of the types of adverse findings identified in the report. HRSA intends to continue to adhere to departmental guidance on the Alert List and is working closely with grants officers to ensure that Alert List procedures are followed.

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

Health Resources and Services

Report Medical Malpractice Cases to the National Practitioner Data Bank

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

Finding: 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: IHS, 290 cases; HRSA, 179 cases; and NIH, 5 cases.

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

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

Status: The HRSA Administrator, who responded on behalf of the Secretary, indicated that HHS is working to develop a final action plan that will include policy decisions relating to future reporting, including ensuring agency compliance.

As of February 2007, IHS had submitted 205 additional reports of practitioners to the NPDB, HRSA had submitted 121 reports, and NIH had not submitted any reports. NIH indicated that it will not submit reports until a revised departmental policy is issued. All cases submitted by IHS and HRSA involve practitioners who did not meet the standard of care. Neither agency is submitting cases where the standard of care was met.

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

Children, Families, and Aging

Administration on Aging

Increase Participation in Cost Sharing of Older Americans Act Services

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

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

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

Status: AoA has implemented actions to address our recommendations. AoA senior staff meet regularly with the six AoA Regional Administrators. Past discussions focused on technical assistance that has been made available to States. AoA is also communicating with each of the 12 States identified in the study to review OAA cost-sharing requirements and establish the need for technical assistance. In addition, letters of guidance have been sent to all State Units on Aging assuring them that technical assistance regarding OAA cost sharing is readily available to all States. AoA did not concur with the recommendation to improve the quality of the NAPIS/SPR data. AoA has made several improvements to NAPIS/SPR over the last 5 years, many of which are noted in the report. Although we recognize these improvements, we found that States participating in cost sharing report their participation data in the NAPIS/SPR differently and include different populations in their counts. Therefore, this issue remains important because it has implications beyond cost sharing, particularly because these data provide essential information for AoA, including performance outcome information required by the Government Performance and Results Act and the Performance Assessment Rating Tool.

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

Other Children, Families, and Aging Issues

Foster Care

Improve Children's Use of Health Care Services While in Foster Care Series

Background: The Medicaid program provides health care to low-income persons and long term care to persons with disabilities and low-income elderly individuals. It is administered by CMS and jointly funded by the Federal and State governments. Section 1902(a)(10)(A)(i)(I) of the Social Security Act (the Act) states that children in foster care who are covered under Title IV-E of the Act are eligible for Medicaid. Children in foster care who are not eligible for Title IV-E usually qualify for Medicaid through other eligibility categories set forth by each State. Federal Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) guidelines require each State to make preventive health care services available to Medicaid-eligible individuals under the age of 21 at intervals that meet reasonable State medical and dental practices, as outlined in sections 1902(a)(43) and 1905(r) of the Act.

Finding: We evaluated and issued reports for eight States (Georgia, Kansas, Illinois, New Jersey, New York, North Dakota, Oregon, and Texas), which together represented 24 percent of the total foster care population. We found that, even though sampled States utilized differing approaches to provide Medicaid services to children in foster care, all of the 400 sampled children included in these studies were covered by their States' Medicaid program and that most had made Medicaid claims for health care services. Through our use of mixed methods, in which we reviewed both Medicaid claims and case-file documentation in five of the eight States, we found that the experiences of sampled children varied in the receipt of required services. Mental health screening requirements also varied, ranging from generally requiring that legal custodians provide for the mental health of children in their custody to specifically requiring that a developmental or psychological evaluation be completed within specific timeframes. Many foster care providers (i.e., foster parent or residential care facility staff) interviewed reported not receiving medical histories or other medical information about children in their care.

Recommendation(s): We made various recommendations calling generally for ACF and CMS to work with each State to improve foster care children's access to State Medicaid services, provide medical services in a timely manner, and help States ensure that the most complete medical histories are shared with the children's caregivers.

Status: In general, ACF and CMS agreed with the recommendations of the report series. Both noted that they were willing to work with all the States evaluated in our series to ensure the implementation of our recommendations. There is some evidence of action by ACF and CMS in addressing these issues. ACF, for example, noted that it is actively working with the North Dakota Division of Medical Services to promote the importance of obtaining medical histories and providing medical information to foster care providers. ACF also said that it is working with Texas to accomplish goals established in its Program Improvement Plan developed because of a Child and Family Services Review (CFSR). Similarly, CMS indicated that it is available to provide technical assistance to Texas to promote provider education regarding the frequency schedule requirements and appropriate documentation of vision and hearing screenings. Despite these efforts, however, the statuses of the implementation for some of the recommendations offered remain unclear. CMS, for instance, presented no plan of action

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for addressing our recommendations for New York, Kansas, and North Dakota. Moreover, we have no knowledge of proactive steps taken by ACF or CMS to implement our recommendations beyond the States studied in the report series.

Report(s): OEI-02-00-00360; issued 07/03	OEI-02-00-00363; issued 06/04
OEI-07-00-00640; issued 08/03	OEI-07-00-00643; issued 08/04
OEI-07-00-00641; issued 02/04	OEI-07-00-00644; issued 01/05
OEI-07-00-00642; issued 03/04	OEI-02-00-00362; issued 06/05

Foster Care

Improve Oversight of State Standards and Practices for Content and Frequency of Caseworker Visits to Children in Foster Care

Background: Caseworker visits are critical elements in maintaining the safety and well-being of children in foster care. There are no Federal requirements regarding specific activities that caseworkers must perform during visits with children in foster care. However, ACF reviews caseworker visits as part of its CFSRs. During CFSRs, ACF determines, for approximately 50 cases per State, whether the frequency of caseworker visits with children was sufficient to ensure adequate monitoring of the child's safety and well-being and whether visits were focused on issues pertinent to case planning, service delivery, and goal attainment. Our evaluation focused exclusively on State standards for children in foster care, including an analysis of States' written standards for the content and frequency of visits, as well as reported content activities for States without written standards and State capacity to produce statewide reports on the frequency of caseworker visits.

Finding: We found that nearly all States have statewide written standards addressing the frequency of caseworker visits with children in foster care. In 43 States, standards call for caseworkers to visit children at least once a month. Twenty States demonstrated their ability to produce statewide reports detailing how often children were visited by caseworkers in FY 2003. Seven of those 20 reports indicated that fewer than half of children were visited monthly on average during FY 2003.

Forty-one out of 51 States reported having statewide written standards addressing the content of caseworker visits. Three of the 41 States reported having written documents addressing the content of caseworker visits as part of broader program areas. Ten States did not have written standards.

Recommendation(s): ACF should promote the development of automated systems, such as the Statewide Automated Child Welfare Information System, for those States with limited or nonexistent automated capacity to record the frequency of caseworker visits and produce statewide reports. For States that already have this capacity, we recommended that ACF work with them to ensure that visitation data are recorded in automated systems. Such automated reports could be particularly useful for States cited during the ACF CFSRs as needing improvement in the area of frequency of caseworker visits.

Status: ACF participated in a national conference call with States in which our report findings and recommendations were outlined, along with information regarding technical assistance available from States already capturing visitation data and producing reports. In addition, following the issuance of this report, the Child and Family Services Improvement Act (CFSI) of 2006 (Public Law 109-288) added new provisions to Title IV-B, subpart 1, related to caseworker visits with children in foster care.

First, the new law adds a new Title IV-B, subpart 1, State plan requirement at section 422 of the Social Security Act, which requires that States and Tribes describe standards for the content and frequency of caseworker visits for children in foster care, which, at a minimum, must be monthly and focus on case planning and service delivery (effective October 1, 2007, section, 422(b)(17) of the Social Security Act.)

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Second, the CFSI Act added section 424(e) to Title IV-B, subpart 1, of the Social Security Act. Section 424(e)(1) and (2) of the Act requires that States submit data to ACF, which, for FY 2007, show the percentage of children in foster care visited monthly by their caseworkers and the percentage of visits that occurred in the children's residences in order to receive Title IV-B, subpart 1, funds for FY 2008.

Furthermore, the new law requires that States develop and achieve annual goals to ensure that 90 percent of the children in foster care are visited by their caseworkers monthly by October 1, 2011. State funds are reduced if a State does not achieve its annual goal or the goal of 90 percent by 2011.

Guidance has been issued to States in the form of an informational memorandum, ACYF-CB-IM-06-05, and a program instruction, ACYF-CB-PI-07-02, concerning the CFSI Act. The new provisions to Title IV-B, subpart 1, related to caseworker visits with children in foster care, are described in those documents.

Report(s): OEI-04-03-00350; issued 12/05

OEI-04-03-00351; issued 12/05

Previous Nonmonetary Recommendations

Medicare and Medicaid

Hospitals

Improve Oversight of Rural Health Clinics

Background: The Rural Health Clinic (RHC) program created in 1977 by Public Law 95-210 is intended to increase access to health care for rural medically underserved areas and to expand the use of mid-level practitioners in rural communities. In 1996, OIG and GAO issued reports that raised concerns about the inappropriate growth and locations of RHCs. Both offices recommended changes that would ensure that RHCs are located in areas that would otherwise be underserved.

Finding: We found that RHCs and associated Medicare and Medicaid expenditures have grown substantially since 1990. Four interrelated factors appear to be driving the recent growth of RHCs: providing access to care, reimbursement, managed care, and the certification process. RHCs may be increasing access to care in some areas but not in others. They paid based on their costs, which may be inflated or inappropriate but are difficult and sometimes impossible to verify or audit without significant resource expenditure by the Government.

Sixty-one percent of RHCs are located in areas that are not designated as shortage areas and 39 percent are located in urbanized areas.

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

Status: CMS concurred with the intent of our recommendations. The BBA of 1997 refines the requirements for RHC designations and provider-based reimbursement. CMS developed a program memorandum consolidating and clarifying the policy regarding provider-based and free-standing designation conditions. CMS published a final rule amending, among other things, the criteria for designating a clinic as an RHC. However, because the date on which CMS published this rule was 3 years beyond that of the proposed rule, contrary to statutory requirement, CMS determined that the rule needed to be republished as a notice of proposed rulemaking. The proposed rule is currently in the Department for clearance and publication.

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

OEI-05-03-00170; issued 08/05

Hospitals

Improve Quality Oversight of Ambulatory Surgical Centers in the Medicare Program

Background: ASCs are one of the fastest growing settings for ambulatory surgery in the Medicare program. CMS is responsible for the oversight of care provided in this health care setting. The quality of oversight is determined by how well an ASC meets Medicare's Conditions of Coverage, an established set of minimum health and safety standards with which ASCs must comply to qualify for Medicare reimbursement. ASCs must become Medicare certified by a State survey and certification agency or be privately accredited to show that they meet the Conditions of Coverage. ASCs are free to choose either a State agency or a private agency to become certified.

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

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

Status: CMS has reported significant progress implementing the Quality Improvement Evaluation System and the Automated Case Tracking System to continually monitor and refine the State survey agencies' performance standards. The MMA of 2003 directs that a new payment system for ASC services be implemented no later than January 1, 2008. Pursuant to the MMA, CMS expects to conduct a comprehensive reevaluation of the ASC benefit including the improvement of quality oversight.

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

Hospitals

Improve Oversight of Medicare-Approved Heart Transplant Centers

Background: CMS has not established ongoing performance standards for Medicare-approved heart transplant centers since establishing coverage standards in 1987. The 1987 coverage decision stated that CMS's policy regarding the initial approval as a heart transplant center was to require that centers perform 12 heart transplant procedures on 12 patients in each of the two preceding 12-month periods and on 12 patients prior to that. It also required centers to have achieved a 73-percent 1-year survival rate and a 65-percent 2-year survival rate for recipients.

Finding: We used initial approval criteria to assess the ongoing performance of Medicare-approved heart transplant centers. We found that from 1987 to 2000, 68 of 90 Medicare-approved heart transplant centers failed, at least once, to meet the initial approval criteria for volume and/or survival rate. From 1992 to 2000, 15 percent of Medicare beneficiaries who received heart transplants did so in Medicare-approved centers that fell below the initial approval performance levels. CMS rarely received data from heart transplant centers on their volume and survival rate, limiting its ability to detect and address potential quality concerns.

Recommendation(s): CMS should develop standards for continuing approved centers as well as for levels of performance that trigger specific responses from CMS. In the short term, we also recommended that CMS improve its oversight of centers by entering into an arrangement with HRSA for regular exchange of volume and survival rate data.

Status: On February 4, 2005, CMS published proposed rule (70 FR 6140), "Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplant." The notice of proposed rulemaking established the requirements for approval and reapproval of transplant centers to perform organ transplants. The approval requirements include data submission, outcome measures, and process requirements. CMS's projected publication date for the final rule is 2007. HRSA has partnered with CMS in developing outcome measures for the proposed rule and will continue to act as a liaison between CMS and the Scientific Registry of Transplant Recipients to provide assistance to review data on transplant center(s) performance.

Report(s): OEI-01-02-00520; issued 02/04

Nursing Homes

Develop Nurse Staffing Standards for Nursing Homes

Background: The OBRA of 1987 requires nursing facilities to have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Finding: We found that many of the most frequently cited nursing home deficiencies are directly related to reported shortages of direct care staff. The failure to provide proper treatment to prevent or treat pressure sores illustrates the lack of direct care staff to ensure that residents are properly hydrated, nourished, and turned frequently.

Recommendation(s): We recommended that CMS develop staffing standards for registered nurses and certified nurse assistants in nursing homes to ensure sufficient staff on all shifts and to enable residents to receive proper care. Staffing standards should account for the intensity of care needed, qualifications of the staff, and the specific characteristics of both the nursing home and the residents.

Status: At the request of Congress, CMS conducted a study examining the relationship of staffing levels to the quality of care received by nursing home residents. A Phase I Report to Congress was delivered in July 2000. A Phase II Report to Congress was delivered in 2002. Phase II indicated a strong relationship between staffing ratios and quality of nursing home care outcomes. In addition, the report identified staffing thresholds that maximize quality outcomes. Although many States will look to the report for standards upon which to base minimum staffing requirements under their respective State licensure authority, CMS does not think there is currently sufficient information upon which to base a Federal requirement for all certified nursing homes. CMS identified a number of short-term, interim options for improving the current Online Survey and Certification Reporting (OSCAR) reporting system, which will enable better nurse staffing reporting on Nursing Home Compare. CMS is reviewing a comprehensive study identifying longer-term options for an adequate system for public reporting.

Report(s): OEI-02-98-00331; issued 03/99

Nursing Homes

Update Nursing Home Nurse Aide Training Curriculum

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

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

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

Status: CMS concurred with our recommendations and intends to use its current contract with Abt Associates to more extensively document the problem and develop specific policy and program options for improvement. Phase I of the contract assessed existing State programs. Phase II is underway to develop specific training programs for States. CMS also proposed to add a requirement to the conditions of participation that nursing homes document when in-service training is conducted to address the weaknesses identified in nurse aides' performance reviews. CMS's research revealed several areas for policy improvement and development that will be addressed in a report currently under clearance.

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

Nursing Homes

Improve Guidance to State Agencies on Citing Nursing Home Deficiencies

Background: The OBRA of 1987 expanded requirements that nursing homes must comply with prior to Medicare certification and defined the State survey and certification process for determining compliance with Federal standards of care.

Finding: Using the OSCAR data system, we found that nursing home deficiencies have increased by 8 percent since 1998. We found that 89 percent of the nursing homes had at least one deficiency. We also found that wide variation exists among States in the number of deficiencies they cite. The average deficiency rate indicated in nursing home surveys in 2001 was 6.2 percent. Also, States differ in determining specific deficiency citations with four major factors contributing to the variation: (1) inconsistent survey focus, (2) unclear guidelines, (3) lack of a common review process for draft survey reports, and (4) high surveyor turnover.

Recommendation(s): We recommended that CMS should continue to improve guidance to State agencies on citing deficiencies by providing guidelines that are both clear and explicit. We also recommended that CMS, together with States, should develop common review criteria for draft survey reports.

Status: CMS concurred with our recommendations and recognized that the standard of quality has been ill-defined, particularly with regard to the nature and severity of harm, or potential harm, to residents caused by the failure to provide optimal psychosocial care and services. In August 2003, CMS provided additional guidance regarding specific types of deficiencies. In November 2004, CMS also issued guidance on assessing the severity of deficiencies relating to quality of care and quality of life. CMS is currently developing guidance for other deficiencies.

Report(s): OEI-02-01-00600; issued 03/03

Nursing Homes

Improve Accuracy of Nursing Home Compare

Background: In 1998, the HHS launched the Nursing Home Compare Web site. The site is maintained by CMS. Nursing Home Compare provides information about the past performance of all Medicare - and Medicaid-certified nursing homes in the country. The site also serves as a source of public information on nursing home quality. Consumers can use the information provided on the site to help them choose the nursing home that best fits their needs. Therefore, it is important that the site accurately portray all Medicare-and Medicaid-certified nursing homes.

Finding: We determined that Nursing Home Compare contains nearly all Medicare- and Medicaid-certified nursing homes. However, Nursing Home Compare did not include one or more surveys for 19 percent of nursing homes. Furthermore, one or more deficiencies were missing from the inspection results of 11 percent of nursing homes. For 15 percent of nursing homes, Nursing Home Compare presented deficiencies not found in State survey documentation. These inaccuracies leave consumers with incomplete information about the nursing homes' survey results and complaint histories.

Recommendation(s): We recommended that CMS require State agencies to verify that the most recent inspection results are in CMS databases and establish a single point of contact for reporting discrepancies on the Web site.

Status: CMS agreed with our first recommendation. CMS indicated that it will consider adding regional office contact information to Nursing Home Compare to facilitate corrections to the Web site. CMS is currently working with the Web site designers and the regional offices to develop the most efficient means of providing CMS oversight of State survey agency data entry.

Report(s): OEI-01-03-00130; issued 06/04

End Stage Renal Disease

Improve Quality Improvement Processes in Dialysis Facilities

Background: This study presented lessons learned by the five largest dialysis corporations regarding the use of clinical performance measures to hold facilities accountable for the quality of care provided to dialysis patients.

Finding: Based on the experiences of large dialysis corporations in using performance data to support quality improvement in dialysis facilities, we learned that medical directors and attending physicians are vital to successful quality improvement programs. Collecting a broad set of measures, establishing minimum performance standards, disseminating timely comparative feedback data, stressing facility-level projects, and using performance data to identify possible problems in facilities were also key concepts in successful quality improvement programs.

Recommendation(s): We recommended that CMS revise the Conditions for Coverage to require facility medical directors to exercise leadership in quality improvement, require dialysis facilities to conduct their own quality of improvement projects, examine ways to foster the commitment of attending physicians to performance measures, develop more effective intervention strategies for facilities, and work with the corporations to share experiences and minimize reporting burdens on dialysis facilities.

Status: CMS concurred with most of our recommendations. The Conditions for Coverage proposed rule was published in February 2005, had a 90-day public comment period, and has not yet been published as a final regulation. The proposed conditions would require an outcome-oriented Quality Assessment and Performance Improvement (QAPI) program, increased participation of attending physicians in patient care and in supporting the facility QAPI program, an increased medical director role, and electronic clinical measure reporting.

Report(s): OEI-01-99-00052; issued 01/02

Medicare Durable Medical Equipment

Improve Medical Equipment Suppliers' Compliance With Medicare Standards

Background: CMS reported that payments for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) reached \$10 billion in FY 2005. DMEPOS suppliers must enroll in the Medicare program and comply with Medicare supplier standards pursuant to 42 CFR § 424.57(c) to sell or rent medical equipment and supplies to Medicare beneficiaries and to submit claims for Medicare reimbursement. There were only 11 standards at the time of this study.

Finding: Less than 1 percent of medical equipment suppliers did not have a physical presence at their business address of record. In addition, all suppliers complied with delivery, warranty, repairs, returns, complaints, and disclosing ownership standards. Finally, some suppliers failed to comply with inventory, liability insurance, and licensure standards; and half of the suppliers did not comply with the standard to provide consumer information.

Recommendation(s): OIG recommended that CMS strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards.

Status: CMS concurred with our recommendations and stated they would consider the options outlined by OIG for strengthening the Medicare DMEPOS supplier enrollment process and ensuring that supplies meet Medicare supplier standards.

Report(s): OEI-04-99-00670; issued 08/01

Medicare Durable Medical Equipment

Ensure Appropriate Use of Surrogate Physician Identification Numbers

Background: Medicare beneficiaries covered under Part B are eligible to receive medical equipment that is ordered by a physician or nonphysician provider and furnished by a supplier who has been issued a billing number by Medicare. If the ordering physician has not been assigned a UPIN, the supplier must use a temporary or surrogate number when submitting claims.

Finding: We found that for a sample of services for which a surrogate number was used for billing DME claims, 61 percent of services should have been ordered using the prescribing physician's permanent identification number rather than a surrogate. Further, supporting documentation was missing or incomplete for 45 percent of the sampled services. Medicare paid an estimated \$61 million for such improperly billed services in 1999.

Recommendation(s): CMS should perform targeted reviews of claims for medical equipment ordered with surrogate numbers and should continue to educate suppliers and physicians about the use of accurate identification on claims.

Status: CMS concurred with our recommendations. In September 2002, CMS issued to intermediaries and carriers a program memorandum that contained specific instructions on the proper use of surrogate UPINs for placement in intermediary and carrier bulletins and Web sites.

Report(s): OEI-03-01-00270; issued 08/02

Medicare Reimbursement

Ensure That Appropriate Mental Health Services Are Delivered in Nursing Homes

Background: Medicare covers mental health services delivered to beneficiaries, subject to a 20-percent coinsurance by beneficiaries. Such services are covered when medically necessary and rendered by a psychiatrist, clinical social worker, or psychologist.

Finding: Our review of nursing home medical records revealed a series of problems in the delivery of mental health services to patients in nursing homes, including patients not receiving needed care and fewer skilled individuals providing services.

Recommendation(s): CMS should take a series of steps to ensure that appropriate services, including educational activities and guidelines, are delivered.

Status: CMS concurred with the recommendation and has taken several steps to ensure that appropriate services are delivered. The Carrier Medical Directors workgroup developed and distributed a final model medical review policy to address Medicare coverage of psychiatry and psychology services. CMS has also made revisions to its training curriculum for nursing home surveyors. In addition, CMS offered a national satellite broadcast, “Mental Illness in Nursing Homes,” in 2001. The QIOs increased the focus on depression management and treatment beginning August 2005.

Report(s): OEI-02-91-00860; issued 05/96

Medicare Reimbursement

Equalize Medicare Reimbursement for Home Dialysis

Background: Section 1881(b)(7) of the Social Security Act allows CMS to pay for continuous cycling peritoneal dialysis that is purchased from a DME supplier an amount up to 130 percent of the composite (Method I) rate applicable to other forms of dialysis services.

Finding: We found that Medicare pays for all dialysis modalities under all payment methods at the same rate, with the exception of continuous cycling peritoneal dialysis purchased from a DME supplier. This payment inequity caused Medicare and its beneficiaries to pay \$15.3 million more for dialysis in calendar year 2000 than would have been paid for the same services under payment Method I.

Recommendation(s): We recommended that CMS revise its regulation to limit payment for continuous cycling peritoneal dialysis under Method II to the amount paid under Method I.

Status: CMS did not concur with our recommendation of changing regulations to limit payment for Method II continuous cycling peritoneal dialysis supplies to that under Method I. CMS believes the statute clearly intends that payment limits for continuous cycling peritoneal dialysis supplies should be set at a higher level than that under the composite rate methodology. CMS agreed to take corrective action to ensure that claims are not paid unless a valid method selection form has been recorded and that improper overpayments should be recovered.

Report(s): OEI-07-01-00570; issued 05/03

Medicare Reimbursement

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

Background: The CMS Medicare benefits expense is composed of two major components: fee-for-service and managed care. Fee-for-service expenditures are processed and paid for by Medicare contractors, whereas managed care expenditures are processed and paid for by the central office. In January 2006, CMS completed a system conversion to the Medicare Advantage Prescription Drug System (MARx) for payments to the managed care organizations and for the Medicare prescription drug program, which resulted in the accrual of more than \$1 billion in liabilities and receivables and the disclosure of a gain contingency.

Finding: The FY 2006 financial statement audit noted that CMS lacked a comprehensive control environment related to the managed care benefits payment cycle and the oversight of managed care contractors, which include MA organizations. The existence of a payment process outside of CMS's Office of Financial Management and the lack of integration of accounting processes within operation procedures related to MCOs creates an environment in which the risk of inaccurate payment is not sufficiently mitigated. Also, the auditors noted additional inadequacies with lack of documentation and procedures to determine eligibility of organizations and with oversight and monitoring of managed care organizations by the central and regional offices. In addition, the regional offices did not retain documentation to support exception items in reviews of MCOs. Finally, the audit identified a lack of tailored policies and procedures to monitor reviews related to demonstration projects.

CMS policies and procedures were not sufficient to adequately reduce the risk of benefit payment errors or their timely correction. Systems errors have gone for more than 7 months without being rectified. In addition, CMS's policies and procedures to review and process managed care and prescription drug payments were inadequate. However, MARx payment errors have been identified and were in the process of being corrected or accrued at the plan level during FY 2006.

Recommendation(s): CMS should (1) ensure that the management system is updated in a timely manner in order to provide the information necessary for adequate management oversight; (2) ensure that established policies address standard documentation and retention requirements for regional office monitoring reviews of the managed care organizations; (3) establish policies for regional office monitoring of demonstration projects that include tailored procedures to address the unique requirements or risks of each demonstration project; (4) perform extensive beneficiary data and payment information analysis to identify potential errors, unusual variances, or inappropriate payment trends; (5) perform a timely reconciliation of authorized payments made by Treasury and establish a log to document anomalies and errors that are resolved as part of the authorization process to further support decisions made as part of the authorization process; and (6) develop a process to perform reconciliations of beneficiary-level data to plan payments, including plan-level adjustments.

Status: During FY 2006, CMS achieved the following: (1) developed a number of tools to oversee the Medicare Prescription Drug Benefit, including a Part D audit guide, audit checklists and worksheets, a Part D audit discussion guide, a Part D audit standard operating

Medicare Reimbursement

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

procedure, and a Part D Health Plan Management System audit module; (2) moved forward in the development of error rates for Part C, Part D, and Retiree Drug Subsidy programs and developed policies and procedures to document core and critical elements of managed care operations; and (3) executed protocols with Medicare Health Support and the Care Management for High Cost Beneficiary organizations that outline CMS activities to monitor programs and services.

Nonetheless, CMS lacks a comprehensive control environment related to the managed care and prescription drug benefits cycle and the oversight of managed care contractors which include MA Organizations. The existence of a payment process outside of the Office of Financial Management and lack of integration of accounting processes within operating procedures related to managed care organizations and prescription drug plans contribute to furthering an environment where the risk of inaccurate payments is not sufficiently mitigated.

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

Medicare Reimbursement

Eliminate Inappropriate Payments for Mental Health Services

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

Finding: We found that Medicare may have inappropriately paid over \$200 million for mental health services in nursing homes, physicians' offices, beneficiaries' homes, community mental health centers, and custodial care facilities. Claims were found to be inappropriate because of a lack of medical necessity, poor documentation, lack of records, incorrect billing, and unqualified providers. We noted particular problems with inappropriate and excessive psychological testing and with provision of services to beneficiaries whose level of cognitive impairment rendered them unable to benefit from psychotherapy services.

Recommendation(s): CMS should promote provider awareness of documentation and medical necessity requirements; develop a comprehensive list of psychological testing tools that can be correctly billed; target problematic services for prepayment edits or postpayment medical review; and encourage carriers to take advantage of the Minimum Data Set, a standard form that includes a mental health evaluation and establishes the need for psychological services especially for its assessment of patient cognitive level.

Status: CMS generally concurred with our recommendations. It plans to explore a variety of educational efforts and refer the reports to the carrier clinical workgroup on psychiatric services. According to CMS, carriers will conduct data analysis of psychological testing and psychotherapy claims and conduct medical reviews, if indicated. CMS provided training for providers concerning Medicare payments for Part B mental health services via Medlearn in April 2003.

Report(s): OEI-03-99-00130; issued 05/01

OEI-02-99-00140; issued 01/01

Medicare Reimbursement

Ensure Accuracy of Carrier Payment Dates

Background: Pursuant to the “Medicare Carriers Manual,” certain claims-processing standards must be met by the carriers, including a “payment floor” standard. Under these standards, carriers are instructed to hold payment of electronic claims for 13 days; claims should not be paid before the 14-day floor.

Finding: According to CMS’s National Claims History File data, it appears that Medicare paid over 80 percent of Part B claims prior to the 14-day floor requirement. Contrary to this, CMS’s Contractor Reporting of Operational and Workload Data (CROWD) system shows that payments for less than 1 percent of these Part B claims were made prior to the 14-day floor. Information from both CMS and carrier staff indicated that data from the National Claims History File did not accurately reflect the carriers’ actual dates of payment.

Recommendation(s): CMS should conduct a review of the carriers’ claims-processing data to examine the scheduled date of payment entered on claims sent to the Common Working File. We recommended that if there is no correlation between the claims payment date variable and the carriers’ actual date of payment, CMS should define what data should be entered into this field and indicate how they should be calculated and/or revise the current variable definition to clarify for National Claims History data users that the scheduled date of payment is not an accurate reflection of the actual date of the payment. CMS should also review the carriers’ claims-processing data to determine the accuracy of the information contained in the CROWD system.

Status: At the time we issued our report, CMS stated that a review to compare data contained in the National Claims History File with data at the carrier level was underway. In addition, CMS has approved two new edits that will enforce the payment floor standards on claims sent to the Common Working File.

Report(s): OEI-03-00-00350; issued 09/00

Medicare Managed Care

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

Background: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established quality standards for all laboratory testing to ensure the accuracy and timeliness of test results. The CLIA waives the standards for laboratories that use only tests that the Secretary has determined have insignificant risk of erroneous result. Laboratories conducting only such simple tests must apply for a certification of waiver from the Secretary. Regulations require that laboratories eligible for a certification of waiver follow the manufacturer’s instructions when conducting waived tests.

Finding: We found significant vulnerabilities in the CLIA certification process for laboratories performing waived procedures and provider-performed microscopy. Many certificates of waiver and provider-performed microscopy laboratories do not follow manufacturers’ instructions or conduct testing that is beyond the scope of their certification. Moderate and high complexity laboratories also failed to meet requirements for waived testing.

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

Status: CMS concurred with all OIG recommendations to decrease vulnerabilities in the CLIA enrollment and certification processes; however, it noted that resource limitations could affect implementation. CMS worked collaboratively with CDC on developing a document outlining good laboratory practices for waived testing, which was published in November 2005 in the “Morbidity and Mortality Report.”

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

Prescription Drugs

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

Background: Section 1927 of the Social Security Act (the Act) requires drug manufacturers to enter into and comply with rebate agreements with the Secretary for States to receive Federal funds for a manufacturer's covered outpatient prescription drugs. The Secretary may also authorize States to enter into agreements with drug manufacturers directly. In accordance with section 1927 of the Act, manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period. On a quarterly basis, the manufacturer is required to report the AMP and the best price for each covered outpatient drug. 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.

Finding: We found that although manufacturers' best price determinations were acceptable, calculations of AMPs were inconsistent. The variations occurred because CMS had not provided manufacturers with sufficiently detailed instructions on acceptable methods for calculating the AMP. The method used affects the AMP; the resulting rebates; and the accuracy, reliability, and consistency of the pricing information provided to CMS.

Recommendation(s): CMS should survey manufacturers to identify the various calculation methods used to determine AMPs. CMS also should develop a more specific policy for calculating AMPs that would protect the interests of the Federal Government and be equitable to the manufacturers.

Status: CMS did not concur, stating that the drug rebate law and the rebate agreements already established a methodology for computing AMPs. CMS officials also indicated that they had reexamined their policy to make it clear that manufacturers are not to inappropriately exclude prices from AMPs. We continue to support our recommendation. In addition, based upon ongoing audits, the method to determine the AMP still varies among manufacturers. The rebate law and agreements defined the AMP but did not provide specific written methodology for computing it. A proposed rule issued in December 2006 modified the definition of AMP to remove customary prompt pay discounts extended to the wholesalers from the AMP calculation. The proposed rule also appears to allow for the AMP to be a more transparent calculation. However, CMS still needs to provide oversight to determine whether the methods used to calculate AMPs are consistent among manufacturers.

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

Other Medicare and Medicaid Issues

Establish a National Medicaid Credit Balance Reporting Mechanism

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

Finding: Previous OIG reports indicated that significant outstanding Medicaid credit balances existed nationwide. Currently, many State agencies' efforts are inadequate to ensure that, nationwide, providers are identifying the majority of Medicaid credit balances and remitting overpayments in a timely manner.

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

Status: CMS agreed to recover estimated outstanding credit balances and to evaluate State agencies' oversight activities. Initially, CMS also agreed with the recommendation to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. Upon reexamination, CMS decided not to do so, citing the uncertain but minimal savings potential and the administration's commitment to enhancing States' flexibility and, specifically, to avoiding the imposition of an unfunded mandate.

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

OAS-05-93-00107; issued 05/95

Other Medicare and Medicaid Issues

Increase the Accountability of Dialysis Facilities for Quality of Services

Background: Section 1881(c) of the Social Security Act established ESRD Networks to ensure the “effective and efficient administration of the ESRD benefits.” Also, State agencies assess compliance of ESRD facilities with Medicare Conditions for Participation, listed at 42 CFR § 405, subpart U.

Finding: We found that CMS needs to improve its quality oversight of ESRD facilities through greater accountability of the facilities, ESRD Networks, and State agencies that contract with CMS to provide oversight.

Recommendation(s): We recommended that CMS hold ESRD facilities more accountable through the following actions: revising the conditions of participation to promote accountability and quality of care, strengthening the complaint system, instituting minimum cycle times for surveys, requiring Network/State agency joint initial surveys, and facilitating a method for public accountability regarding serious medical injuries. We recommended that CMS improve Network and State agency accountability by developing performance-based evaluations of Networks, improving assessment of surveys, and increasing public disclosure of both.

Status: CMS generally concurred with our recommendations. Since 2002, CMS has surveyed dialysis facilities every 3 years. In addition, CMS provides facility data reports and ESRD Network data to State survey agencies to assist them in targeting facilities for surveys. CMS has also worked to improve the relationship and cooperation between the ESRD Networks and State survey agencies. In 2002, CMS hosted a joint meeting of 154 representatives from the State survey agencies and the ESRD Networks to help them understand their roles and responsibilities and to discuss collaboration and information sharing. CMS continues to facilitate discussions between the State agencies and ESRD Networks. The proposed ESRD Notice of Proposed Rulemaking was published in the “Federal Register” on February 4, 2005 (70 FR 6183), with a 90-day comment period. Final regulations are pending. The proposed conditions require an internal facility complaint/grievance process and posting the ESRD Network and State Survey Agency’s complaint phone numbers and list of patient rights in a prominent area. In addition, the proposed facility-level quality assessment and performance improvement program must address medical injuries and medical errors identification.

Report(s): OEI-01-99-00050; issued 06/00

Other Medicare and Medicaid Issues

Improve Medicare Information Systems Controls

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

Finding: In FY 2006, CMS continued to make progress in identifying and addressing weaknesses in its automated Medicare processing systems. Although our review disclosed no exploitation of any identified vulnerability, the weaknesses noted could result in unauthorized access and updates to sensitive systems, programs, and data without proper authorization. For example, the auditors noted that employees who did not require direct access to data and application software programs to perform their job responsibilities had inappropriate standing update access to Medicare data and application software programs. In addition, the auditors noted that application changes were, in some cases, being implemented without documented testing and approval and that application change control procedures were not followed at all sites tested. We noted no change in the controls for the Entitywide Security Program and Service Continuity Planning and Testing areas when compared with FY 2005; in these areas, CMS sustained, but did not improve upon, the FY 2005 audit results. The auditors noted slippage from FY 2005 with controls over systems software, including the change control process for the MARx system.

Recommendation(s): For its Medicare contractors and system maintainers, CMS should continue to (1) target contractor access control policies and procedures to ensure their sufficiency and enforcement; (2) ensure the proper segregation of duties for application and system programmers by limiting update access to Medicare data and/or programs; (3) continue to assess the enforcement of change request (CR) 3862 with regard to the approval of changes to the shared system coded edits and CR 3011 with regard to maintaining audit trails, testing, and approval of program code; and (4) encourage the use of automated tools to monitor, detect, and report to the CMS Information Security Office all noncompliance by contractors and maintainers with CMS headquarters platform security configuration standards for distributed servers.

Status: During the FY 2006 audit, we noted that CMS continued to make improvements regarding the assessment of risks, the identification of controls to reduce risk, overall security policies and procedures, and the training of security personnel. Also, CMS continued to review contractors through SAS 70 audits, an extensive contractor self-assessment program and reporting process, and greater central oversight by contractor management. In addition, the FY 2006 audit noted that CMS had made significant progress by continuing its reviews of contractors, including penetration tests and reviews of configuration setting on servers. Finally, CMS undertook a campaign to review, analyze, and thoroughly discuss the proposed corrective action plans of contractors and CMS headquarters. However, CMS sustained but did not improve upon the FY 2005 audit results. Numerous issues were noted in the areas of direct update access to Medicare claims data and controls over changes to edits and proper edit settings for the Fiscal Intermediary Shared System, Multi-Carrier System and Viable

Other Medicare and Medicaid Issues

Improve Medicare Information Systems Controls *(continued)*

Information Processing Systems' Medicare Systems were not in use during the most of the period under audit. In addition, no change in the controls for Entitywide Security Program and Service Continuity Planning and Testing areas were noted. In the area of systems software, security settings for platforms were not consistent with NIST standards and failed to provide sufficient security settings for computer platforms.

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

Strengthen Food and Drug Administration Oversight of Clinical Investigators

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

Finding: We found that in general, oversight of clinical investigators by sponsors, institutional review boards (IRB), and FDA is limited and problematic. We found that data integrity concerns, more than human subject protections, drive FDA's oversight of clinical investigators and that the bioresearch-monitoring program lacks clear and specific guidelines.

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

Status: FDA has completed a number of activities to strengthen institutional review board (IRB) oversight, but acknowledges that efforts are ongoing. In July 2004, FDA issued a proposed rule to require institutional review boards (IRBs) to register at sites maintained by HHS (69 FR 40556). In 2003 and 2004, the Office for Human Research Protections (OHRP), partnering with FDA and other Federal agencies and departments, sponsored national and regional training conferences for IRBs, clinical investigators, clinical staff, and institutional officials on good clinical practice and human subject protection issues. FDA also provided faculty for outreach programs and other activities with universities and professional societies and has created a Web site to provide current information about FDA requirements and guidance for the conduct of clinical studies. FDA and OHRP are also working to develop a coordinated process for joint review of protocols under subpart D regulations of 21 CFR § 50.54 and 45 CFR § 46.407, regarding the funding of research not approved by an IRB. FDA has established a new unit, the Good Clinical Practice (GCP) Program, within the Office of Science Coordination in the Commissioner's Office, to coordinate and direct human subject protection, GCP, and bioresearch-monitoring program policy. In June 2006, FDA announced an initiative to strengthen its oversight and protection of subjects in clinical trials and the integrity of resulting data as part of the Critical Path Initiative. As part of this initiative, FDA intends to define cross-center goals and develop a quality system for the bioresearch-monitoring program. FDA has also established a working group to examine the process for disqualification of clinical investigators and develop internal guidelines on the threshold for disqualification. In December 2006, FDA and OHRP published guidelines describing a coordinated process for joint review of protocols under subpart D regulations of 21 CFR § 50.54 and 45 CFR § 46.407 (<http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0172-gdl0002.pdf>). Other highlights of the Bioresearch-Monitoring Initiative include the issuance of guidance documents in 2006 on using a centralized IRB process in multicenter clinical trials; the establishment and operation of clinical trial data monitoring committees; and the publication of information sheet guidance for IRBs, clinical investigators, and sponsors.

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

Protect Human Research Subjects by Strengthening Institutional Review Boards

Background: In June 2000, Office for Protection from Research Risks moved from NIH to the Office of the Secretary and is now housed in OHRP. OHRP provides leadership for all 17 Federal agencies that carry out federally funded research under the Common Rule. OHRP works with NIH and FDA in new initiatives for research involving human subjects. FDA retains its enforcement authority to ensure researcher compliance with HHS patient protection and patient consent requirements in FDA-authorized drug and medical device clinical trials.

Finding: We found that the effectiveness of IRBs is jeopardized by inadequate review time, unavailability of subject matter expertise, inadequate continuing reviews of approved research, conflicts that threaten IRB independence, and inadequate training for investigators and board members.

Recommendation(s): We recommended jointly to NIH, OHRP, and FDA that they: (1) recast Federal IRB requirements so that they grant IRBs greater flexibility and hold them more accountable, (2) strengthen continuing protections for human subjects participating in research, (3) enact Federal requirements that help ensure that investigators and IRB members are adequately educated about and sensitized to human subject protection, (4) help insulate IRBs from conflicts that can compromise their mission in protecting human subjects, (5) recognize the workload pressures that many IRBs face and take actions to moderate them, and (6) reengineer the Federal oversight process.

Status: As part of the Federal-Wide Assurance (FWA) process, OHRP recommended that institutions and their designated IRBs establish educational training and oversight mechanisms to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, written IRB procedures, OHRP guidance, other applicable guidance, State and local laws, and institutional policies for the protection of human subjects. OHRP recommends that IRB members, staff, and research investigators complete relevant educational and institutional training before reviewing or conducting human subject research. In April 2001, FDA published an interim final rule when establishing additional safeguards for children in clinical trials involving FDA-regulated products (66 FR 20598). In addition, FDA has created a new Office of Pediatric Therapeutics, as well as a full Pediatrics Advisory Committee. NIH now requires Data and Safety Monitoring Boards to share summary information with IRBs and has implemented the requirement for monitoring plans for Phase and Phase II trials, and FDA has issued new draft DSMB guidance. In 2003 and 2004, OHRP, FDA, and other Federal agencies sponsored regional training workshops for IRBs, clinical investigators, and clinical staff on good clinical practice and human subject protection issues. In May 2004, to address conflict-of-interest concerns, HHS issued a final guidance document, “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection,” (69 FR 226393). In July 2004, OHRP and FDA simultaneously issued proposed rules to require IRBs to register at sites maintained by HHS (69 FR 40556 and 69 FR 40584, respectively). In February 2005, HHS announced new electronic FWA forms required for OHRP approval to simplify the registration process.

Biomedical Research

HHS agencies also worked with the Office for Civil Rights on guidance related to HIPAA privacy issues. In February 2006, FDA announced the Information Sheet Guidance Initiative to update its process for developing, issuing, and making available guidance intended for IRBs, clinical investigators, and sponsors. These guidances, known as “Information Sheets,” provide recommendations for IRBs, clinical investigators, and sponsors to assist them in carrying out their responsibilities to protect human subjects who participate in research regulated by FDA. As part of the initiative, FDA plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidance that address current issues, and develop new Information Sheet Guidance as needed. As of December 2006, FDA and OHRP were working to develop a coordinated process for joint review of protocols under subpart D regulations of 21 CFR § 50.54 and 45 CFR § 46.407. FDA is also announcing the availability of five revised Information Sheet Guidances.

Report(s): OEI-01-97-00193; issued 06/98

OEI-01-97-00197; issued 04/00

Health Resources and Services

Improve Hospital Reporting to the National Practitioner Data Bank

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

Finding: We found that there are indications that hospitals may not be complying with the reporting requirements of the NPDB and that approximately half of hospitals have never reported an adverse action to the NPDB.

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

Status: HRSA fully supported the recommendations and awarded a contract to PricewaterhouseCoopers to look at the feasibility of assessing compliance with the NPDB reporting requirements. The results of the PricewaterhouseCoopers studies clearly indicated that the vast majority of hospitals and other health care entities, specifically managed care entities, would not release the professional review materials supporting their actions in the absence of clear legal authority requiring them to do so. According to HRSA, the existing legislation is inadequate to force NPDB reporters to reveal information needed to allow audits of reporting compliance. Without voluntary cooperation from reporters, adequate audits of reporting compliance cannot be performed.

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

Health Resources and Services

Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

Background: The Ryan White Comprehensive AIDS Resources Emergency Act (Public Law 101-381) was passed in 1990 and reauthorized in 1996 and 2000. Most recently, Congress enacted the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Public Law 109-415). Title I provides emergency relief grants to cities disproportionately affected by HIV/AIDS. Title II provides grants to States to improve the organization of health and support services. States distribute Title II funds to subgrantees. In FY 2001, \$597.3 million was provided under Title I and \$977.4 million under Title II.

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

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

Status: HRSA concurred with our recommendations and indicated that significant administrative changes had occurred since the study had been conducted. For example, HRSA consolidated its grants management offices, relocated most Title II monitoring responsibilities from regional offices to headquarters, and redefined the Office of Field Operations as the Office of Performance Review.

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

OEI-02-01-00641; issued 03/04

Children, Families, and Aging

Children, Youth, and Family Services

Improve Methods of Recruiting Foster Parents

Background: The Administration for Children and Families (ACF) has regulatory oversight of the Title IV-E Foster Care program, an entitlement program. It is designed to assist States in covering the costs for children in foster care by providing States with unlimited matching funds for children who meet income eligibility and other program requirements.

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

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

Status: Although ACF concurred with our findings and recommendations, it did not indicate how it planned to address them. ACF noted that States may use some Federal funds for child care and respite care services. In addition, ACF supplied relevant adoption rate data.

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

Departmentwide and Cross-Cutting Issues

Update Cost Principles for Federally Sponsored Research Activities

Background: The cost principles at 45 CFR, Part 74, Appendix E, were published more than 25 years ago when the research environment and Federal funding rules were less complex.

Finding: HHS's hospital cost principles for federally sponsored research activities contained in Appendix E of Part 74 are not current and do not always provide clear guidance for determining the allowable costs and their allocation.

Recommendation(s): The Assistant Secretary for Resources and Technology (ASRT) should modernize and strengthen the cost principles applicable to hospitals by either (1) revise Appendix E (known as OASC-3) where applicable, for consistency with Office of Management and Budget (OMB) Circular A-21 or (2) working with OMB to extend Circular A-21 coverage to all hospitals.

Status: ASRT is working on an update to hospital cost principles.

Report(s): OAS-01-92-01528; issued 05/93

Departmentwide and Cross-Cutting Issues

Improve Financial Analysis and Reporting Processes

Background: The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. Government Auditing Standards and OMB Bulletin 06-03, “Audit Requirements for Federal Financial Statements,” provide auditors with guidance 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: The FY 2006 financial statement audit noted that the lack of an integrated financial management system(s) and weaknesses in internal controls made it difficult for HHS to prepare timely and reliable financial statements. For example, the CORE accounting system, which supports net outlays in excess of \$93 billion, is a legacy accounting system and does not support all functionality required by the United States General Legend and Joint Financial Management Improvement Program standards. Also, CMS’s Medicare contractors continue to rely on labor-intensive manual processes that are subject to an increased risk of inconsistent, incomplete, or inaccurate information being submitted to HHS. In addition, HHS compiles its financial statements through a multistep process using a combination of manual and automated procedures, as a result of system limitations that have many components recording accounting entries outside the general ledger system and using spreadsheets and database queries to prepare financial statements.

Recommendation(s): HHS should continue its efforts to establish an integrated financial management system to promote consistency and reliability in recording and reporting financial information. Also, HHS should establish appropriate policies, procedures, and protocols to address situations or transactions that require cross-functional involvement to determine the appropriate accounting treatment. In addition, HHS should update the policies and procedures for the preparation of the financial statements to ensure compliance through a monitoring process.

Status: HHS acknowledged that it continues to have internal control weaknesses in its financial systems and processes. HHS’s long-term strategic plan to resolve these weaknesses is to replace the existing accounting systems and certain other financial systems with a Unified Financial Management System (UFMS). The UFMS will be implemented in accordance with the approval implementation plan, allowing HHS to comply with the requirements for the Federal Financial Management Improvement Act by the end of FY 2009. HHS plans to implement the UFMS departmentwide by 2009.

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

Departmentwide and Cross-Cutting Issues

Strengthen State Protections for Persons With Disabilities in Residential Settings

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

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

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

Status: We received positive feedback from the responsible operating divisions that detailed actions that they were taking or planning to improve safeguards. For example, SAMHSA has a grant program, begun in FY 2001, to identify effective alternative practices, (e.g., training efforts,) to reduce restraint and seclusion practices and will promote the application of the findings from these grants.

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

Departmentwide and Cross-Cutting Issues

Improve Safeguards for Long Term Care Residents

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

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

Recommendation(s): We recommended that (1) CMS and AoA work collaboratively with the States to improve the safety of LTC residents and to strengthen safeguards against the employment of abusive workers, (2) CMS consider establishing Federal requirements and criteria for performing criminal checks, and (3) CMS consider developing a national abuse registry or expanding the current State registries to include all workers in facilities receiving Federal reimbursement.

Status: CMS and AoA agreed with our recommendations and have planned or taken some actions to improve safeguards for LTC residents in nursing homes. For example, the MMA of 2003 established the framework for a program to evaluate national and State background checks on direct patient access employees of LTC facilities or providers. The program, which may include up to 10 States, will identify efficient, effective, and economical procedures for LTC facilities or providers to conduct background checks.

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

List of Acronyms

Acronyms

ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AMP	Average Manufacturer Price
AoA	Administration on Aging
ASC	Ambulatory Surgical Centers
ASP	Average Sales Price
AWP	Average Wholesale Price
BBA	Balanced Budget Act of 1997
BBRA	Balanced Budget Refinement Act of 1999
CFSR	Child and Family Service Review
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CY	Calendar Year
DME	Durable Medical Equipment
DRA	Deficit Reduction Act of 2005
DRG	Diagnosis-Related Group
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
FUL	Federal Upper Payment Limits
FY	Fiscal Year
GAO	Government Accountability Office
GCP	Good Clinical Practice
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IRB	Institutional Review Board
LTC	Long Term Care
MCO	Managed Care Organization
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NIH	National Institutes of Health
NPDB	National Practitioner Data Bank
OAA	Older Americans Act
OBRA	Omnibus Budget Reconciliation Act of 1981
OBRA	Omnibus Budget Reconciliation Act of 1986
OBRA	Omnibus Budget Reconciliation Act of 1987/9
OBRA	Omnibus Budget Reconciliation Act of 1989
OBRA	Omnibus Budget Reconciliation Act of 1990
OBRA	Omnibus Budget Reconciliation Act of 1993
OHRP	Office for Human Research Protection
OIG	Office of Inspector General
OMB	Office of Management and Budget
OSCAR	Online Survey and Certification Reporting
PPS	Prospective Payment System
QIO	Quality Improvement Organization
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
SOM	State Operations Manual
TBD	To Be Determined
UPIN	Unique Physician Identification Number
UPL	Upper Payment Limit



Department of Health and Human Services
Office of Inspector General

330 Independence Avenue, S.W.
Washington, D.C. 20201

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