



AUG 30 2005

TO: Heads of Operating Divisions
Heads of Staff Divisions

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: 2005 Orange Book

Attached for your information is a copy of the Office of Inspector General (OIG) 2005 Orange Book. This document highlights significant nonmonetary recommendations from reports released by OIG over the past several years. For various reasons, these recommendations have not yet been fully implemented.

This edition of the Orange Book contains more than 90 unimplemented recommendations that we feel would improve the efficiency and effectiveness of the Department's programs. The actions needed to implement our proposals are primarily administrative. Upon request, we would be happy to discuss these items with you.

We greatly appreciate your assistance and cooperation in compiling and updating this publication from the previous issue. While we have a number of new items in this edition, many previous items have been removed thanks to action on the part of the operating divisions to implement the recommendations.

We are also distributing copies of the Orange Book to the Secretary and his immediate office, the Office of Management and Budget, and Congress. Additional copies are available on the Internet at <http://oig.hhs.gov>.

Attachment

**Department of Health & Human Services
Office of Inspector General**

*Program and Management Improvement
Recommendations*

The Orange Book



**Daniel R. Levinson
Inspector General**

2005

Office of Inspector General

<http://oig.hhs.gov>

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 all auditing services for HHS, 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 HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts management and program evaluations (called inspections) that focus on issues of concern to HHS, Congress, and the public. The findings and recommendations contained in the inspections generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs. OEI also oversees State Medicaid Fraud Control Units which investigate and prosecute fraud and patient abuse in the Medicaid program.

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. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general 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 HHS. 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 guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

INTRODUCTION

THE ORANGE BOOK

The Orange Book is a compendium of significant, unimplemented, nonmonetary recommendations for improving departmental operations. The Office of Inspector General (OIG) believes that implementation of these recommendations will benefit the Department of Health and Human Services (HHS) and its customers through increased operational effectiveness and assurance that governmental resources are controlled by reliable financial management and accounting systems.

Generally, these recommendations can be implemented by an administrative action, while some call for a change of legislation. Although these recommendations generally have a nonmonetary impact when implemented, HHS may achieve some programmatic savings. The OIG recommendations for proposed legislation are not removed until the law has been enacted—not just proposed. For administrative issues, recommendations are not removed until the action has been substantially completed.

The Orange Book supplements other OIG reports. The Inspector General Act (Act) requires that OIGs' semiannual reports to Congress include "...an identification of each significant recommendation described in previous semiannual reports on which corrective action has not been completed." In compliance with the Act, significant recommendations are highlighted in the semiannual reports. Because of the abbreviated nature of these reports and the potentially significant impact of OIG recommendations, we prepare the Orange Book to elaborate further on our most significant nonmonetary issues. Through the Orange Book, HHS officials, Office of Management and Budget officials, and Congress have in one document significant program and management improvement recommendations. Items added since the previous version of the Orange Book are designated "new" in the Table of Contents.

HEALTH AND HUMAN SERVICES

HHS promotes the health and welfare of Americans and provides essential human services to persons of every age group. It touches every aspect of life for each American citizen. Over 80 percent of the HHS budget provides income support and medical care coverage for elderly, disabled, and poor individuals. The balance of the budget provides research into the causes of disease, promotes preventive health measures, supports the provision of health and social services, and combats alcoholism and drug abuse.

The report is divided into five major areas: Centers for Medicare & Medicaid Services, Public Health, Children and Families, and Older Americans, as well as General Department Management. An overview of these areas and related OIG findings and recommendations are highlighted in separate sections.

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Centers for Medicare & Medicaid Services

Centers for Medicare & Medicaid Services

Overview

The Centers for Medicare & Medicaid Services (CMS) encompasses the Medicare and Medicaid programs and the State Children's Health Insurance Program (SCHIP).

The Medicare program provides health care coverage for individuals through Part A and Part B insurances. Medicare Part A provides hospital insurance protection for covered services to persons age 65 or older and to certain disabled persons. Medicare Part B (supplementary medical insurance) provides insurance protection against most of the costs of health care to persons age 65 and older and certain disabled persons who elect this coverage. The services covered are medically necessary physician services, outpatient hospital services, outpatient physical therapy, speech pathology services, and certain other medical and health services.

The Medicaid program provides grants to States for medical care for more than 42 million low-income people. Federal matching rates are determined on the basis of a formula that measures relative per capita income in each State. Eligibility for the Medicaid program is, in general, based on a person's eligibility for cash assistance programs.

The SCHIP expands health coverage to uninsured children whose families earn too much to qualify for Medicaid but too little to afford private coverage. The program is a partnership between the Federal and State Governments in which States may choose to expand their Medicaid programs, design new SCHIPs or create a combination of both.



Introduction

Related OIG Activities

The Office of Inspector General (OIG) activities that pertain to the health insurance programs administered by CMS help ensure cost-effective health care, improve quality of care, address access to care issues, and reduce the potential for fraud, waste, and abuse. Through audits, evaluations, and inspections, OIG recommends changes in legislation, regulations, and systems to improve health care delivery systems and reduce unnecessary expenses. The OIG's reviews assess the adequacy of internal controls, identify innovative cost containment techniques, probe for improper cost shifting, seek to identify mechanisms to contain increasing Medicare/Medicaid costs, and identify efficiencies in program administration.

Centers for Medicare & Medicaid Services

-Ambulance-

Develop Prepayment Edit to Verify Medical Necessity of Ambulance Claims

Report Number: OEI-09-95-00412 Final Report: 11/1998

Finding

We found that two-thirds of ambulance services that did not result in hospital or nursing home admissions or emergency room care on the same date of services were medically unnecessary. We estimate that Medicare allows approximately \$104 million each year for these medically unnecessary ambulance services.

Current Law

CMS regulations state that ambulance services are covered only if other forms of transportation would endanger a beneficiary's health. The Balanced Budget Act of 1997 mandates that CMS work with the industry to establish a negotiated fee schedule for ambulance payments effective January 1, 2000. CMS issued a proposed rule September 12, 2000. Implementation of the new fee schedule was to begin January 1, 2001. Because of the public interest and comments, CMS did not have sufficient time to implement the final rule. On February 27, 2002, CMS published the final rule establishing a fee schedule for payment of ambulance services under the Medicare program, implementing section 1834(1) of the Social Security Act effective April 1, 2002.

Recommendation

Legislative

Administrative

Material Weakness

CMS should develop a prepayment edit to verify the medical necessity of ambulance claims that are not associated with hospital or nursing home admissions or emergency room care. This proposal would provide a solution for one group of ambulance services until CMS and the industry can better address issues of medical necessity, including clear and consistent definitions.

Status

Management Response

CMS published the final regulation effective February 27, 2002, for ambulance fee schedule, which revised and clarified the requirements at section 410.40(d)(3), Coverage of Ambulance Services. The ambulance supplier must meet all coverage criteria for payment to be made.

Centers for Medicare & Medicaid Services

-Ambulance-

Equalize Medicare Reimbursement for Home Dialysis

Report Number: OEI-07-01-00570 Final Report: 05/2003

Finding

Medicare pays for all dialysis modalities under all payment methods equally, except for continuous cycling peritoneal dialysis under Method II. 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.

Current Law

Section 1881(b)(7) of the Social Security Act allows CMS to pay up to 130 percent of the composite rate amount for continuous cycling peritoneal dialysis.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

CMS did not concur with our recommendations.

Centers for Medicare & Medicaid Services
-Contractor Operations

Strengthen CMS Oversight of Managed Care Organizations

Report Number:	OAS-17-97-00097	Final Report:	04/1998
	OAS-17-98-00098		02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001
	OAS-17-01-02001		02/2002
	OAS-17-02-02002		01/2003
	OAS-17-03-03003		11/2003
	OAS-17-04-02004		12/2004

Finding

Overall the FY 2004 audit results identified improvements in the implementation of formal policies and procedures and documentation to support the processing, approval and acceptance of applications for managed care organizations applying to join the Managed Care program. However, the auditors noted inadequate monitoring of managed care organizations by the central and regional offices. For example, the management system used by central office to monitor the execution and status of managed care organization reviews performed by regional offices was not being updated in a timely manner. In addition, sufficient documentation to evidence the ongoing monitoring of managed care organizations by regional offices was not provided. The audit also identified a lack of tailored policies and procedures to monitor reviews related to demonstration projects.

Current Law

Guidance for the oversight effort is found in instructions issued by the CMS Office of Financial Management. Ensuring that policies and procedures are consistently implemented and the availability of documentation to support management decisions is a requirement of OMB A-123 and GAO's internal control standards.

Recommendation

Legislative **Administrative** **Material Weakness**

CMS should (1) ensure that the management system is updated on a timely basis to provide information for adequate management oversight to be executed, (2) ensure existing policies and procedures for the ongoing monitoring of organizations within the Managed Care program are consistently implemented and that the monitoring of these organizations is documented in accordance with appropriate standards and guidelines, and (3) develop policies that require that the regional office, in its performance of monitoring of demonstration projects, create tailored procedures that contemplate and address the unique requirements or risks of each demonstration project.

Status

Management Response

CMS has continued to improve financial management over the past several years and has developed a comprehensive plan for financial management to address OIG recommendations. CMS will ensure that managed care systems will be updated for any changes in a timely manner and has provided to its regional offices a policy on document retention. In addition, CMS has created or revised monitoring guides to review the various managed care plans.

Centers for Medicare & Medicaid Services
-Contractor Operations

Ensure Accuracy of Carrier Payment Dates

Report Number: OEI-03-00-00350 Final Report: 09/2000

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. However, 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 indicates that data from the National Claims History File may not accurately reflect the carriers' actual date of payment.

Current Law

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

Recommendation

Legislative

Administrative

Material Weakness

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. If there is no correlation between the claims payment date variable and the carriers' actual date of payment, we recommended that CMS: (1) define what data should be entered into this field and how they should be calculated, and/or (2) 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

Management Response

CMS stated that a review to compare data contained in the National Claims History File with data at the carrier level is under way. In addition, CMS has approved two new edits which will enforce the payment floor standards on claims sent to the Common Working File.

Centers for Medicare & Medicaid Services
-Contractor Operations

Strengthen Local Medical Review Policies for Mental Health Services

Report Number: OEI-03-99-00132 Final Report: 05/2002

Finding

Through a review of carriers' local policies for mental health services, we determined that some carriers lacked local policies for psychotherapy, pharmacologic management, or psychological testing. Of those that had local policies, some did not adequately address all the policies specified in the Local Medical Review Policy Format. Significant variations in policies existed between carriers and documentation requirements for therapy and pharmacologic management were not comprehensive and consistent.

Current Law

Exhibit 6 of the Medicare Program Integrity Manual specifies the general format that carriers must use when writing their local policies.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS require carriers to strengthen vague or incomplete sections of their local policies for mental health services and ensure that policies adequately address all of the elements specified in the Medicare Program Integrity Manual.

Status

Management Response

CMS concurred with our recommendations.

Centers for Medicare & Medicaid Services
-Home Health

Improve Physician's Role in Home Health Care

Report Number: OEI-02-94-00170 Final Report: 06/1995

Finding

Agencies and physicians identify some obstacles and issues related to the physician role. Obstacles mentioned by respondents include: (1) 65 percent of agencies and 51 percent of physician respondents find the process of reviewing and signing plans of care burdensome; (2) physicians find it difficult to find important information on the plan of care; and (3) some agencies feel that physicians' awareness and education in home health are inadequate and that they lack an understanding of the home health benefit.

Current Law

Medicare home health agency regulations require physicians to sign a plan of care specifying all services the patient is to receive. This certification must be updated every 60 days, but the physician is not required to see the patient.

Recommendation

Legislative

Administrative

Material Weakness

CMS should continue its efforts to change the plan of care to ensure that it conveys critical information to caregivers and relieves unnecessary burden from physicians. CMS should strengthen its efforts to educate both agencies and physicians about its policies regarding the physician's role in home health care.

Status

Management Response

In October 2000 and February 2001, CMS issued a Program Memorandum, which advised contractors to educate providers through training sessions, provider bulletins, and Web sites. CMS has proposed revised conditions of participation for care planning and coordination of services. Specifically, the revisions would decrease the burden of home health agencies and would allow agency staff to develop care plans in coordination with the physician. The notice of proposed rulemaking (NPRM) was published on March 10, 1997. Public comments were received and revisions to the regulation are in progress. However, § 902(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) established a 3-year window between publication of the proposed rules and final rules. Even though the NPRM was published prior to the MMA's effective date of December 8, 2003, CMS has determined to republish the rule as an NPRM because changes have occurred in the home health industry since the 1997 proposed rule. The new NPRM will take into account public comments submitted on the 1997 proposed rule and is targeted for publication at the end of calendar year 2005.

Centers for Medicare & Medicaid Services

-Hospices-

Strengthen Education of Contractual Relationships Between Hospices and Nursing Homes

Report Number:

OEI-05-95-00251

Final Report:

11/1997

Finding

Some hospice contracts with nursing homes contain provisions that raise questions about inappropriate patient referrals between hospices and nursing homes.

Current Law

Hospice care is a treatment approach that recognizes that the impending death of an individual warrants a change in focus from curative to palliative care. The Medicare hospice benefit program began in 1983 and was extended in 1986 to cover individuals residing in nursing facilities. To qualify, a patient must be certified as terminally ill with a life expectancy of 6 months or less, if the illness runs its normal course.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS work with the hospice associations to educate the hospice and nursing home communities to help them avoid potentially fraudulent and abusive activities that might influence decisions on patient benefit choices and care.

Status

Management Response

CMS concurred with our recommendation. CMS will continue to encourage the regional home health intermediaries to reemphasize the potential fraudulent and abusive activities in their continuing educational efforts. CMS is currently developing a notice of proposed rulemaking for the hospice conditions of participation and expects to publish it in August 2005.

Centers for Medicare & Medicaid Services
- Hospitals -

Improve Oversight of the Rural Health Clinics

Report Number: OEI-05-94-00040 Final Report: 07/1996

Finding

Rural health clinics and associated Medicare and Medicaid expenditures have grown substantially since 1990. Four interrelated factors appear to be driving the recent growth of rural health clinics: providing access to care, reimbursement, managed care, and the certification process. Rural health clinics may be increasing access to care in some areas but not in others. Rural health clinics are 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.

Current Law

The Rural Health Clinic 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 midlevel practitioners in rural communities.

Recommendation

Legislative

Administrative

Material Weakness

CMS should, along with the Health Resources and Services Administration, modify the certification process to increase State involvement and ensure more strategic placement of rural health clinics; CMS should expedite the issuance of the regulations now under development; and CMS should take immediate steps to improve the oversight and functioning of the current cost reimbursement system, with a long term goal of implementing a different method.

Status

Management Response

CMS concurred with the intent of our recommendations. The Balanced Budget Act of 1997 refines the requirements for rural health clinic designations and provider-based reimbursement. CMS developed a program memorandum consolidating and clarifying the policy regarding provider-based and free-standing designation conditions. A rural health clinic final rule was originally published on December 23, 2003. However, section 902(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a 3-year window between publication of proposed rules and final rules, effective for regulations published after December 8, 2003. Because the final rule was published after the MMA's effective date of December 8, 2003, and because the time between the proposed and final rules was greater than 3 years, CMS has determined that the rule needs to be republished as a notice of proposed rulemaking, which is targeted for publication at the end of calendar year 2005.

Centers for Medicare & Medicaid Services
- Hospitals -

Perform Routine Monitoring of Hospital Billing Data to Identify Aberrant Patterns of Upcoding

Report Number:	OEI-03-98-00560	Final Report:	01/1999
	OEI-03-98-00490		04/1999
	OEI-03-99-00370		03/1999

Finding

The diagnosis related group (DRG) system is vulnerable to abuse by providers who wish to increase reimbursement inappropriately through upcoding, particularly within certain DRGs. We identified a small number of hospitals that have atypically high billings for DRGs 416, 296, and 475, but found that CMS performs no such routine, ongoing analysis of hospital billing data to detect possible problems in DRG coding.

Current Law

Under Medicare's prospective payment system (PPS) reimbursement formula for inpatient services, the payment a hospital receives is based upon an individual hospital's payment rate and the weight of the DRG to which a case is assigned. Since 1995, CMS has used two specialized contractors called Clinical Data Abstraction Contractors to validate the DRGs on an annual national sample of over 20,000 claims billed to Medicare. This validation provides CMS with an overall assessment of DRG coding.

Recommendation

Legislative

Administrative

Material Weakness

CMS should perform routine monitoring and analysis of hospital billing and clinical data to proactively identify aberrant patterns of upcoding. This analysis should include identification of hospitals with atypically high billings for certain DRGs.

Status

Management Response

CMS concurred with our recommendation. CMS has established the Payment Error Prevention Program, which monitors all inpatient PPS admissions to hospitals. CMS has established baseline payment error rates by State and is continuing an annual surveillance sample. It is expected that this routine monitoring will continue through future contracts with quality improvement organizations.

Centers for Medicare & Medicaid Services

- Hospitals -

Improve Quality Oversight of Ambulatory Surgical Centers in the Medicare Program

Report Number:

OEI-01-00-00450

Final Report:

02/2002

Finding

Medicare Ambulatory Surgical Centers (ASC) more than doubled in number from 1990 to 2000, and procedures increased by 730 percent. Medicare's system of quality oversight is not up to task, as nearly a third of ASCs certified by State agencies have not been recertified in 5 or more years. CMS does little to hold State certification agencies and accreditors accountable to the Medicare program and the public.

Current Law

Quality oversight of ASCs revolves around the Conditions of Coverage, Medicare's set of minimum health and safety requirements. ASCs must become Medicare certified by a State survey and certification agency or privately accredited to show that they meet the Conditions.

Recommendation

Legislative

Administrative

Material Weakness

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 overseeing ASCs. CMS should ensure that State agency certification and accreditation strike an appropriate balance between compliance and continuous quality improvement.

Status

Management Response

CMS is moving forward with the implementation of the Quality Improvement Evaluation System and the Aspen Complaint Tracking System to continually refine the State survey agencies' performance standards. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directs that a new payment system for Ambulatory Surgical Centers services be implemented no later than January 1, 2008. CMS expects to use this regulatory vehicle to conduct comprehensive reevaluation of the Ambulatory Surgical Centers benefit to include improvement of quality oversight.

Centers for Medicare & Medicaid Services
- Hospitals -

Ensuring Oversight of Prospective Payment System-Exempt Hospitals and Units

Report Number: OEI-12-02-00170 Final Report: 11/2002

Finding

Routine medical reviews of prospective payment system (PPS)-exempt facilities, including psychiatric and rehabilitation units and hospitals, and long term care hospitals, have not been conducted since the fall of 1995. These facilities received approximately \$8.7 billion from Medicare in 2000. Our annual reviews of improper Medicare fee-for-service payments attributed \$800 million of improper payments to PPS-exempt hospitals and units in FY 2000 (A-17-00-02000).

Current Law

Section 1154(a)(1)(A) of the Social Security Act requires quality improvement organizations to review some or all services to determine whether they were reasonable and medically necessary. Section 1816(a)(2)(B) authorizes fiscal intermediaries to audit providers to insure that proper payments are made.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS ensure that oversight of PPS-exempt hospital services is performed.

Status

Management Response

CMS concurred with our recommendations. In February 2002, CMS notified fiscal intermediaries that they are allowed to include these provider types in their medical review functions; however, no additional funding was provided.

Centers for Medicare & Medicaid Services
- Hospitals -

Establish Outpatient Surgery Rates More Consistently Across Sites and Reflect Only the Costs Necessary for the Efficient Delivery of Health Services

Report Number: OEI-05-00-00340 Final Report: 01/2003

Finding

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 ambulatory surgical center (ASC) rate had been used instead of the hospital outpatient department (OPD) rate. Likewise, CMS could have saved \$100 million if the lower OPD 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, CMS could have saved almost \$8 million.

Current Law

The Medicare program covers OPD services, ASC services, and physician office services under the Medicare Supplementary Medical Insurance Program. How Medicare reimburses for services in these settings varies and has evolved over time. Hospital OPDs were historically reimbursed for services using a facility fee based on the lesser of costs or charges. In 2000, CMS implemented an outpatient prospective payment system for hospital outpatient services. In 1980, recognizing that some surgical procedures provided on an inpatient basis could be safely performed in less intensive and less costly settings, the Medicare program began covering services provided in ASCs.

Recommendation

Legislative

Administrative

Material Weakness

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.

Status

Management Response

Section 626 of Public Law 108-173 mandates that the Government Accountability Office conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments. The report will include recommendations that advise CMS regarding payments to ambulatory surgical centers and CMS will implement a new payment system for ambulatory surgical centers beginning on or after January 1, 2006, and not later than January 1, 2008. CMS issued a proposed rule on November 26, 2004, to update the list of Medicare-approved ambulatory surgical centers procedures in 2005. CMS proposed to remove from the ambulatory surgical centers list a number of the codes recommended for deletion by the OIG. Nearly 500 comments were submitted timely and CMS is reviewing those comments and preparing a final rule for implementation in the summer of 2005.

Centers for Medicare & Medicaid Services
- Hospitals -

Medicare-Approved Heart Transplant Centers

Report Number: OEI-01-02-00520 Final Report: 02/2004

Finding

We used initial approval criteria to assess the ongoing performance of Medicare-approved heart transplant centers. 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 a heart transplant did so in a Medicare-approved center that fell below the initial approval performance levels. CMS rarely receives data from heart transplant centers on their volume and survival rate, limiting its ability to detect and address potential quality concerns.

Current Law

CMS has not established ongoing performance standards for Medicare-approved heart transplant centers, since establishing coverage standards in 1987. However, Medicare’s policy for initial approval as a heart transplant center includes requirements that centers perform 12 heart transplant procedures in a 12-month period and achieve a 73 percent 1-year survival rate for recipients.

Recommendation

Legislative

Administrative

Material Weakness

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

Status

Management Response

On February 4, 2005, CMS published proposed rule (70 FR 6140), “Hospital Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplant.” The notice of proposed rulemaking established the requirements for approval and reapproval of transplant centers to perform organ transplants. The approval requirements include data submission, outcome measures, and process requirements. CMS expects to publish the final rule within 1 to 1 1/2 years. HRSA has partnered with CMS in developing outcome measures for the proposed rule and will continue to act as a liaison between CMS and the Scientific Registry of Transplant Recipients to provide assistance to review data on transplant center(s) performance.

Centers for Medicare & Medicaid Services

- Hospitals -

Medicare Reimbursement to Ambulatory Surgical Centers for Intraocular Lenses

Report Number: OEI-06-02-00710 Final Report: 03/2004

Finding

We found that the acquisition cost of these lenses varied according to the type of material used, from an average cost of \$90 for the most expensive type of material to \$39 for the least.

Current Law

Section 1833(i)(2)(A)(iii) of the Social Security Act requires that Medicare payment to ambulatory surgical centers for intraocular lenses be “reasonable and related to the cost of acquiring the class of lens involved.” The Omnibus Budget Reconciliation Act of 1993 set the current price of \$150 per lens for the period from 1994-1998.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS reduce Medicare payment to ambulatory surgical centers for intraocular lenses in a manner that takes into account the different types and costs of intraocular lenses.

Status

Management Response

CMS is deferring action to reduce Medicare payment for intraocular lenses until it can implement section 626 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires implementation of a revised system of payment for ambulatory surgical center services by January 1, 2008.

Centers for Medicare & Medicaid Services
- Hospitals-

Long Term Care Hospitals-within-Hospitals

Report Number: OEI-01-02-00630 Final Report: 07/2004

Finding

We found that 19 of 87 hospitals-within-hospitals (HwH) exceeded the annual 5 percent threshold for readmissions from their host hospitals at least once between September 2000 to December 2002. Currently, CMS lacks a system to detect readmissions over the 5 percent threshold and it has no ongoing mechanism to determine whether HwHs are financially and organizationally separate from their host hospitals.

Current Law

At 42 CFR 412.22(e), HwHs are required to demonstrate organizational and financial separateness from the hospital in which they are located (the host). 42 CFR 413.40(a)(3)(B) establishes a ceiling on payments to HwHs by excluding discharges from the HwH to the host if the patient is subsequently readmitted to the HwH and the number of such cases exceeds 5 percent to the total number of HwH discharges during that cost reporting period.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS (1) develop a system to monitor HwHs' compliance with the 5 percent readmission rule, and (2) require HwHs to demonstrate their organizational and financial independent on a continuing basis.

Status

Management Response

In fiscal year 2004, the Research Triangle Institute International was awarded the contract to implement the 5 percent policy adjustment under the long term care hospital (LTCH) prospective payment system (PPS) (42 CFR section 412.532) for completion by July 1, 2005. Because of the difficulties of an annual verification of organizational and financial independence between a host hospital and its HwH, CMS revised the designation and payment policies for LTCH HwHs, published in the August 11, 2004, inpatient PPS final regulation. CMS still requires the HwH and its host to maintain separate governing bodies and medical staff. CMS no longer requires separate basic hospital functions (15 percent test) based on corporate documentation to indicate compliance with Medicare separateness and control policy. CMS has instituted a payment adjustment under the LTCH PPS when the number of patients shift from the host to the HwH exceeds a specified threshold.

Centers for Medicare & Medicaid Services
-Information and Accounting Systems

Ensure That the Medicare Accounts Receivable Balance Is Fairly Presented

Report Number:	OAS-17-95-00096	Final Report:	07/1997
	OAS-17-97-00097		04/1998
	OAS-17-98-00098		02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001
	OAS-17-01-02001		02/2002
	OAS-17-02-02002		01/2003
	OAS-17-03-03003		11/2003

Finding

The lack of an integrated financial management system and internal control weaknesses identified continued to impair the CMS's and the Medicare contractors' ability to efficiently and effectively support and analyze accounts receivable and other financial reports. The preparation of certain reports and the review and monitoring of individual accounts receivable are dependent on labor intensive manual processes subject to the increased risk of inconsistent, incomplete, or inaccurate information being submitted to CMS. Certain internal control weaknesses continued to persist, such as inadequate independent verification of controls in the contractors' processing and reporting of accounts receivable.

Pending implementation of the integrated general ledger system, strong oversight of the Medicare contractors, and properly trained personnel are needed to (1) reduce the risk of material misstatements in financial data and (2) ensure that periodic analyses and reconciliations are completed to detect and resolve errors and irregularities in a timely manner.

Current Law

Guidance applicable to financial management systems appears in the Federal Financial Management Improvement Act of 1996. Additional guidance for reporting by the Medicare contractors is provided in the Medicare Financial Management Manual instructions issued by the CMS Office of Financial Management. The GAO's Standards for Internal Control in the Federal Government indicate that internal control monitoring should assess the quality of performance over time and ensure that findings of audits and other reviews are promptly resolved. Without appropriate monitoring and oversight of contractor operations, deficiencies in internal controls may allow material misstatements to occur without being identified in a timely manner.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS (1) maintain internal controls to ensure that reported accounts receivable amounts and transactions are valid and documented, (2) establish an integrated financial management system for use by Medicare contractors and the CMS central office, and (3) provide additional guidance and training to contractors, including continuing its efforts to promote uniform reporting procedures by the Medicare contractors.

Status

Management Response

CMS continued to contract with Independent Public Accountants to test and analyze accounts receivable at the Medicare contractors. Furthermore, CMS developed workgroups that are responsible for addressing four key areas: follow up on corrective action plans, reconciliations of funds expended to paid claims, trend analysis, and internal controls. As CMS progresses toward its long term goal of developing an integrated general ledger system, it continues to provide training to the Medicare contractors to promote a uniform method of reporting and accounting for accounts receivable and related financial data.

Centers for Medicare & Medicaid Services
-Information and Accounting Systems

Improve Medicare Information Systems Controls

Report Number:	OAS-17-98-00098	Final Report:	02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001
	OAS-17-01-02001		02/2002
	OAS-17-02-02002		01/2003
	OAS-17-04-02002		12/2004

Finding

In FY 2002, 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 ultimately result in (1) unauthorized access to and disclosure of sensitive information, (2) malicious changes that could interrupt data processing or destroy data files, (3) improper Medicare payments, or (4) disruption of critical operations.

Current Law

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.

Recommendation

Legislative

Administrative

Material Weakness

For its Medicare contractors and system maintainers, CMS should continue to implement (1) consistent adherence to OMB Circular A-130 guidelines for entity-wide security plans to safeguard Medicare data; (2) consistent physical and logical access procedures, including administration and monitoring of access by Medicare contractor personnel; (3) procedures for the implementation, maintenance, access, and documentation of operating systems software products used to process Medicare data; (4) segregation of duties to ensure accountability and responsibility; (5) updated and documented service continuity procedures needed in the event of a system outage; and (6) adequate application controls integrated into all Medicare systems to ensure that beneficiary and related financial databases are updated timely, accurately, and completely.

Status

Management Response

CMS generally concurred with the findings and noted that, although no findings at a single location were considered material, OIG had aggregated the findings at Medicare contractors and the CMS central office into one material weakness. CMS further noted that it was continuing to make progress toward resolving this issue by revising its "core" information systems security requirements for Medicare contractors that adhere to guidelines in OMB Circular A-130 and implement effective control procedures. In FY 2002, CMS completed a prototype of a system security plan methodology for the Medicare contractors and developed new background investigation procedures. CMS also developed policies and procedures for software quality assurance and developed, tested, and implemented a systems software change audit review process.

Improve Quality Improvement Processes in Dialysis Facilities

Report Number: OEI-01-99-00052 Final Report: 01/2002

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.

Current Law

Section 42 CFR 405.2133 requires dialysis facilities to furnish information pertaining to patient care to the Secretary for inclusion in a national medical information system.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS revise the Conditions of Coverage, examine ways to foster the commitment of attending physicians to performance measures, develop more effective intervention strategies for facilities, and work with the corporations to share experiences and minimize reporting burdens on dialysis facilities.

Status

Management Response

CMS concurred with most of our recommendations. The Conditions of Coverage proposed rule was published in February 2005 and has a 90-day public comment period. The proposed conditions would require a facility-level data driven Quality Assessment and Performance Improvement program (QAPI), increased participation of attending physicians in patient care and in supporting the facility QAPI program, increased medical director role, and electronic clinical measure reporting.

Centers for Medicare & Medicaid Services
-Information and Accounting Systems

Improve End-Stage Renal Disease Data Management

Report Number: OEI-07-01-00250 Final Report: 02/2002

Finding

We determined that data sets in the Renal Beneficiary and Utilization System (REBUS) were out of date, incomplete, and inaccurate. Users within and external to CMS have been negatively impacted by system flaws.

Current Law

Section 1881(c)(7) of the Social Security Act requires the Secretary to establish an end-stage renal disease (ESRD) registry to assemble and organize the data reported by network organizations, transplant centers and other sources. Section 42 CFR 405.2133 requires dialysis facilities to furnish information pertaining to patient care to the Secretary for inclusion in a national medical information system.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS develop a strategic plan for addressing ESRD data management, including short and long term remedies for current data problems, reassessment of the data needs of users, improving the efficiency of data distribution, improving ongoing communication with users and data contributors, and better coordination with the Social Security Administration.

Status

Management Response

CMS concurred with our recommendations. As of February 15, 2005, CMS along with the ESRD networks, its contractors, and the renal community worked together to consolidate its three ESRD systems now referred to as CROWN (Consolidated Renal Operations in a Web-enabled Network). The three systems include: (1) the Renal Management Information System (REMIS), (2) the Standard Information Management System (SIMS), and (3) the Vital Information System to Improve Outcomes in Nephrology (VISION). SIMS went into production on January 1, 2000, and REMIS went into production on July 13, 2003. The REMIS application directly addresses concerns raised by OIG. The CROWN is the automated system that combines all of CMS's electronic data on ESRD benefits and utilization. The CROWN provides for the collection, validation, and storage of information about the national ESRD program, its beneficiaries, and the services provided to them.

Centers for Medicare & Medicaid Services
Laboratories-

Ensure CLIA Regulation of Unestablished Laboratory Tests

Report Number: OEI-05-00-00250 Final Report: 07/2001

Finding

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) program has difficulty identifying laboratories that perform unestablished tests. These laboratories often cannot meet CLIA requirements, resulting in laboratories that either fail to register with CLIA or that obtain CLIA certification through improper means.

Current Law

CLIA regulates laboratories that conduct testing on human specimens when the test results are used for the purpose of “diagnosis, prevention, treatment of a disease or impairment of, or assessment of the health of, human beings.”

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS conduct a study of live blood cell analysis, one of the more common unestablished tests. We also recommended that CMS establish procedures for evaluating other unestablished tests, seek new administrative remedies for laboratories that fail to register, require laboratories to disclose any unestablished testing on their application, improve surveyor training on method verification, and provide the public with information about unestablished tests.

Status

Management Response

CMS is in the process of developing an action plan; however, full implementation of any study has been delayed due to priority workload considerations and funding constraints. CMS will reevaluate in FY 2006. Educational information was posted on the CMS CLIA Web site in 2003. CMS has not agreed to seek new administrative remedies for laboratories that fail to register. CMS has agreed to seek more efficient and effective procedures based on the existing authorities and better cooperation with the States.

Centers for Medicare & Medicaid Services
Laboratories-

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

Report Number: OEI-05-00-00251 Final Report: 08/2001

Finding

We found significant vulnerabilities in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification process for laboratories performing waived procedures and provider-performed microscopy. Many certificate of waiver and provider-performed microscopy laboratories do not follow manufacturers' instructions or conduct testing which is beyond the scope of their certification. Moderate and high complexity laboratories also failed to meet requirements for waived testing.

Current Law

The CLIA provides for certificates of waiver for laboratories conducting only simple tests which are specifically designated by FDA, as waived. The statute requires these laboratories to follow manufacturers' instructions and to limit testing to waived tests.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

CMS is working collaboratively with the Centers for Disease Control on developing a document outlining good laboratory practices for waived testing, which will be published in September 2005. CMS will provide the document to all waived testing laboratories and post it on the CLIA Web site when available.

Centers for Medicare & Medicaid Services
-Managed Care

Coordinate Medicaid Managed Care Plans with HIV/AIDS Services

Report Number: OEI-05-97-00210 Final Report: 04/1998

Finding

We found that Medicaid managed care organizations (MCOs) that are paid an AIDS-enhanced rate appear to provide all needed medical services and drugs to AIDS patients. MCOs that are not paid an enhanced rate report they cannot afford to continue providing these services and drugs without adequate financial compensation. In addition, we found that in States visited, the Medicaid managed care and Ryan White programs do not coordinate the services they provide to persons with HIV/AIDS.

Current Law

Under Medicaid, States may choose to exercise any of several options to pay for the care of beneficiaries with AIDS, including: pay MCOs an AIDS-enhanced rate, carve out AIDS patients from managed care, put all AIDS patients in a specified MCO, or put them into the same insurance pool with all Medicaid beneficiaries. There is no Federal requirement that the Medicaid and Ryan White programs coordinate services. Some States have made this a requirement of both programs; many have not.

Recommendation

Legislative

Administrative

Material Weakness

In consultation with HRSA, CMS should develop and disseminate technical assistance and guidance on strategies State Medicaid programs can use to establish appropriate managed care contracts for needed medical services and costs related to these services for beneficiaries with HIV and AIDS. CMS should also urge States to require Medicaid managed care plans to coordinate with Ryan White programs on the services they provide to Medicaid beneficiaries with HIV/AIDS. HRSA should continue to encourage Ryan White grantees to work with Medicaid managed care plans. Together, these agencies should work to develop strategies of coordination for Medicaid managed care and Ryan White programs.

Status

Management Response

CMS Medicaid managed care regulations implemented in 2002 require coordination among programs. Specifically, the Quality Assessment and Performance Improvement subpart of this regulation found at CFR 438.208 requires that managed care plans treating people with special needs establish treatment plans and coordinate their care with other entities. CMS continues to work with HRSA to improve coordination and collaboration between Medicaid MCOs and Ryan White programs and will continue to do so.

Centers for Medicare & Medicaid Services
-Managed Care

Improve Controls to Monitor Chiropractic Care

Report Number: OEI-04-97-00490 Final Report: 09/1998

Finding

We found that Medicare, Medicaid, and private insurers rely on utilization caps, x-rays, physician referrals, copayments, and pre- and postpayment review, in varying degrees, to control utilization of chiropractic benefits. Utilization caps are the most widely used, but these and other controls did not detect or prevent unauthorized Medicare maintenance treatments.

Current Law

In 1972, Section 273 of the Social Security Amendment (P.L. 92-603) expanded the definition of physician under Medicare Part B to include chiropractors. Currently, the only Medicare reimbursable chiropractic treatment is manual manipulation of the spine to correct a subluxation demonstrated by an x-ray. When chiropractors were recognized as physicians and became eligible to participate in Medicare in 1972, chiropractors also became eligible to participate in Medicaid. Under Medicaid, however, chiropractic services are not a mandatory benefit, but rather an optional service. According to Federal policy for Medicaid, chiropractic services should be limited to manual manipulation of the spine and x-ray services. The Balanced Budget Act of 1997 required CMS to establish new utilization guidelines for Medicare chiropractic care by January 1, 2000. It also eliminated the x-ray requirement from the policy.

Recommendation

Legislative

Administrative

Material Weakness

CMS should develop system edits to detect and prevent unauthorized payments for chiropractic maintenance treatments. Examples include: (1) requiring chiropractic physicians to use modifiers to distinguish the categories of the spinal joint problems, and (2) requiring all Medicare contractors to implement system utilization frequency edits to identify beneficiaries receiving consecutive months of minimal therapy.

Status

Management Response

Effective October 1, 2004, CMS began requiring chiropractors to include the Acute Treatment Modifier if active/corrective treatment is being performed, or no modifier if maintenance therapy is being performed. CMS also issued a "Medlearn Matters" Web-based educational article to inform chiropractors and their billing staff of chiropractic billing requirements.

Centers for Medicare & Medicaid Services
-Managed Care

Improve Review and Tracking of Managed Care Marketing Materials

Report Number:	OEI-03-98-00270	Final Report:	02/2000
	OEI-03-98-00271		02/2000

Finding

The goals of Medicare’s National Marketing Guide for managed care—which were to expedite the marketing material review process, reduce resubmissions of material, ensure uniform review across the Nation, and most importantly, provide beneficiaries with accurate and consumer-friendly marketing materials to help them make informed health care choices—were not completely met. Few marketing materials, which had been approved by reviewers in CMS, were in full compliance with the National Marketing Guide. Also, nearly half the materials were not consumer-friendly.

Current Law

CMS has authority to establish how managed care health plans with Medicare contracts provide information to beneficiaries. The health plans are required to submit marketing materials to CMS regional offices for review and approval before distribution. The Medicare Managed Care National Marketing Guide was issued in November 1997. It serves as an operational tool for managed care plans and CMS regional offices, and outlines what information is required or prohibited in marketing materials.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS update the National Marketing Guide to include clarifications of requirements; ensure that model materials are accurate and easy to read; mandate use of standard member materials; develop standard review instruments; establish a quality control system; track marketing-material reviews consistently and uniformly; conduct meetings with noncomplying health plans; and provide training for CMS reviewers and managed care plans.

Status

Management Response

CMS updates the marketing chapter of the Medicare Managed Care Manual on a quarterly basis. It provides models for the Annual Notice of Change, Evidence of Coverage, enrollment form, and many enrollment and disenrollment letters. The 2005 model Evidence of Coverage document can be accessed on the CMS Web site and the agency is receiving feedback on the 2006 model Evidence of Coverage that will be used under the new Part D prescription drug benefit.

Centers for Medicare & Medicaid Services
-Medical Equipment and Supplies-

Require Complete Documentation of Home Oxygen Therapy

Report Number: OEI-03-96-00090 Final Report: 08/1999

Finding

We found that nearly one-quarter of oxygen certificates of medical necessity (CMN) were inaccurate or incomplete. We also determined that 13 percent of beneficiaries reported never using their portable oxygen systems. In addition, 22 percent of sampled suppliers who billed Medicare for portable oxygen systems in 1996 did not provide any refills for them in 1997.

Current Law

The Durable Medical Equipment Regional Carrier Supplier Manuals require suppliers to keep on file complete and accurate CMNs. Section 4552 of the Balanced Budget Act of 1997 requires development of specific service standards for home oxygen suppliers.

Recommendation

Legislative

Administrative

Material Weakness

CMS should delay payment for oxygen equipment claims until complete CMNs are submitted. It should conduct periodic checks to ensure that original CMNs, signed by physicians and kept on file by suppliers, confirm the electronic versions submitted to Medicare carriers. Oxygen equipment should be targeted for focused medical review. Finally, CMS should establish service standards for home oxygen equipment suppliers, as required by the Balanced Budget Act of 1997, and continue to alert physicians to the importance of their role in determining medical need for and utilization of home oxygen equipment.

Status

Management Response

The new provider-based regulation published August 1, 2002 (67 FR 49982) implements procedures with which a provider is required to comply to meet the requirements of being identified as a hospital provider-based entity. The effective date of this regulation was October 1, 2002.

Centers for Medicare & Medicaid Services
-Medical Equipment and Supplies-

Improve Medical Equipment Suppliers' Compliance With Medicare Standards

Report Number: OEI-04-99-00670 Final Report: 08/2001

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.

Current Law

To receive reimbursement from Medicare, business organizations that supply durable medical equipment (DME) to Medicare beneficiaries must meet Medicare's 11 standards required by section 1834 of the Social Security Act. On January 20, 1998, CMS published a proposed rule establishing additional standards for an entity to qualify as a Medicare supplier for purposes of submitting claims for DME, prosthetics, orthotics, and supplies. Suppliers were to achieve compliance with the new standards by December 2000.

Recommendation

Legislative

Administrative

Material Weakness

To improve compliance with Medicare standards, we suggested that CMS could educate suppliers about the requirement to provide beneficiaries with a list of supplier standards, could revise its standards to require suppliers to transmit a copy of the Medicare supplier standards to each beneficiary at the time of each sale or rental, and could institute random, unannounced site inspections of supplier operations.

Status

Management Response

CMS concurred with our findings and has noted improvement in performance of this area since 1997. CMS has implemented rewarding those providers and suppliers that pass inspections and increased site visits to those that do not pass inspection. In addition, CMS plans to assess the impact the new standards have had upon suppliers' compliance and educate suppliers of the requirement to provide beneficiaries with copies of the supplier standards.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Ensure Appropriate Mental Health Services Delivered in Nursing Homes

Report Number: OEI-02-91-00860 Final Report: 05/1996

Finding

A review of nursing home medical records revealed a series of problems in the delivery of mental health services to patients in nursing homes, including (1) not receiving needed care, and (2) fewer skilled individuals providing services.

Current Law

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.

Recommendation

Legislative

Administrative

Material Weakness

CMS should take a series of steps to ensure appropriate services are delivered, including educational activities and guidelines.

Status

Management Response

CMS concurred with the recommendation. It is taking steps to ensure that appropriate services are delivered. The Carriers Medical Directors workgroup developed and distributed a final model medical review policy to address Medicare coverage of psychiatry and psychology services. A final rule for coverage of clinical psychological services is pending. 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 Quality Improvement Organizations will increase focus on depression management and treatment beginning August 2005.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Develop Nurse Staffing Standards for Nursing Homes

Report Number: OEI-02-98-00331 Final Report: 03/1999

Finding

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

Current Law

The Omnibus Budget Reconciliation Act 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.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS develop staffing standards for registered nurses and certified nurse assistants in nursing homes to assure sufficient staff on all shifts and to enable residents with 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

Management Response

At the request of Congress, CMS has 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. It indicated a strong relationship between staffing ratios and quality of nursing home care outcome. In addition, the report has 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 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 OSCAR-based reporting system, which will enable better nurse staffing reporting on Nursing Home Compare. Currently, CMS is reviewing a comprehensive study identifying longer-term options for a fully adequate system for public reporting.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Improve Resident Assessment Instruments

Report Number:	OEI-02-99-00040	Final Report:	01/2001
	OEI-02-99-00041		01/2001

Finding

Discrepancies exist between Minimum Data Set (MDS) data and resident medical records. Some of these discrepancies could affect care planning. We also found coding problems with some MDS elements, especially the number of minutes of therapy and the activities of daily living.

Current Law

The Nursing Home Reform Act mandates that nursing homes use a clinical assessment tool called the Resident Assessment Instrument. MDS is a subset of information from the Resident Assessment Instrument. Under the prospective payment system, some elements of the MDS affect Medicare payments to skilled nursing facilities.

Recommendation

Legislative

Administrative

Material Weakness

CMS should more clearly define MDS data elements and work with States to train nursing home staff. We also recommended that CMS establish an audit trail to validate the 108 MDS elements that affect facility reimbursement by Medicare.

Status

Management Response

CMS generally concurred with our recommendations for improved data definitions and training, but did not concur with our recommendation to establish an audit trail. In 1998, CMS devoted significant resources to the development of an accuracy improvement program by letting a contract develop MDS accuracy review protocols. Once the protocols were developed, CMS funded a program safeguard contractor in September 2001, known as the data assessment and verification system (DAVE), to audit and verify MDS data. In January 2004, CMS developed and implemented the DAVE project onsite and off-site audit process of the MDS in long term care facilities to assess the accuracy and reliability of assessment data submitted.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Improve Assessments of Mental Illness

Report Number: OEI-05-99-00700 Final Report: 01/2001

Finding

Less than half of the nursing home residents reviewed had Preadmission Screening and Resident Review (PASRR) Level I assessments completed in compliance with Federal law. Residents with mental illness often did not have Level II assessments in their records and were rarely reassessed when their conditions changed. Some States defined serious mental illness and specialized services in ways that reduce the effectiveness of the assessment process. CMS provides little oversight and guidance to States on the PASRR process.

Current Law

The Omnibus Budget Reconciliation Act of 1987 (OBRA-87) mandated PASRR to ensure that only individuals with serious mental illness, who are in need of nursing facility care, be admitted and continue to reside in nursing facilities and to determine the need for specialized mental health services.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS work with States to improve the assessment of persons with serious mental illness and use survey and certification to monitor compliance. We also recommended that CMS define specialized services that are to be provided by the State to nursing home residents with mental illness.

Status

Management Response

CMS concurred with most of our recommendations, and, as a result, CMS has made revisions to its training curriculum for nursing home surveyors. In addition, CMS offered several national satellite broadcasts in 2001 and 2004 to increase surveyor knowledge and ability to recognize mental illness, to educate surveyors on PASRR implementation and oversight, and to improve surveyors' abilities to determine facility compliance with assessment and care requirements. CMS has also held several training conferences for Resident Assessment Instrument (RAI) coordinators to improve the identification of mental illness symptoms in nursing facilities. CMS will convene an expert panel of PASRR in 2005 to assess the PASRR program and determine what opportunities may exist through guidance or interpretation of statute and regulations to help States. CMS is also exploring the role State surveyors may have in identifying compliance with PASRR Level II assessment requirements.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Identify Nursing Home Residents With Serious Mental Illness

Report Number: OEI-05-99-00701 Final Report: 01/2001

Finding

Data from the Medicaid Statistical Information System, the Minimum Data Set (MDS), and certification surveys were insufficient to identify the number of nursing home residents between the ages of 22 and 64 who are seriously mentally ill. We could not determine the amount of Medicaid expenditures for this group. States were unable to determine where these individuals are receiving long term care.

Current Law

The Omnibus Budget Reconciliation Act of 1987 (OBRA-87) mandated that individuals with serious mental illness should only be admitted and continue to reside in nursing facilities if they are in need of nursing facility care. The State is responsible for providing any specialized mental health services.

Recommendation

Legislative

Administrative

Material Weakness

CMS should improve the quality and usefulness of these data sources by requiring the use of a unique provider number across systems, requiring reporting of resident data by age and diagnosis, and encouraging States to use these data in demonstrating their progress in placing disabled persons in the most integrated settings. We also recommended training to improve data collection and accurate coding.

Status

Management Response

CMS concurred with most of our recommendations, except for reporting the MDS records by primary, secondary, and tertiary diagnoses. In February 2005, CMS issued a letter to State Medicaid directors indicating that it will begin to release MDS data to States with Americans with Disabilities Act compliance activities. CMS will also require States to evaluate the Preadmission Screening and Resident Review outcomes, further obligating States to develop accurate data systems useful for identifying serious mental illness in nursing facility residents. In addition, CMS is planning to implement the use of a unique provider number on or before May 2007.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Update Nursing Homes Nurse Aide Training Curriculum

Report Number: OEI-05-01-00030 Final Report: 11/2002

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 Omnibus Budget Reconciliation Act of 1987. 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 too short, and in-service training may not be meeting Federal requirements.

Current Law

The Omnibus Budget Reconciliation Act of 1987 mandated the Nurse Aide Training and Competency Evaluation Program to establish minimum requirements for nurse aide competency.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS improve nurse aide training and competency program requirements to ensure that content of training curriculum and testing remain relevant to today's complex resident care needs. We also recommended that CMS continue to work with States to assure that training is effective and efficient, and to ensure that nursing homes are in compliance with in-services training requirements.

Status

Management Response

CMS concurred with our recommendations and intends to use its current contract to more extensively document the problem and develop specific policy and program options for improvement. 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 to be completed by the end of FY 2005.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Improve Guidance to State Agencies on Citing Nursing Home Deficiencies

Report Number: OEI-02-01-00600 Final Report: 03/2003

Finding

Using the Online Survey and Certification Reporting (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 received at least one deficiency. We also found that wide variation exists among States in the number of deficiencies they cite and that the average deficiency rate for nursing home surveys in 2001 was 6.2 per nursing home. Also, States differ in determining specific deficiency citations with four major factors contributing to the variation, including: (1) inconsistent survey focus, (2) unclear guidelines, (3) lack of a common review process for draft survey reports, and (4) high surveyor turnover.

Current Law

The Omnibus Budget Reconciliation ACT (OBRA) of 1987 (P.L. 100-203) 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.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

CMS concurred with our recommendations and recognized that surveying the quality of life area has been ill defined regarding the nature and severity of harm, or potential harm, to residents caused by facility failures to provide optimal psychosocial care and services. In August 2003, CMS revised interpretive guidance for specific deficiency tags and developed severity guidance for those tags to be used to provide more instruction to States for selected quality of care and quality of life tags. The first guidance was issued in November 2004. CMS is continuing with the development of new guidance for several other tags. Each will be issued after completion of work by CMS with expert panels. CMS expects issuance through FY 2005.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Strengthen Oversight of Nursing Home Psychosocial Services in the Resident Assessment Process

Report Number: OEI-02-01-00610 Final Report: 03/2003

Finding

Almost all Medicare skilled nursing facility (SNF) beneficiaries have at least one psychosocial services need; however, 39 percent of those with needs have inadequate care plans and 46 percent of those with care plans do not receive all planned services. We found that over 15 percent of the facilities have been cited for psychosocial deficiencies and just over 1 percent of Ombudsman complaint data relates to psychosocial services.

Current Law

The Omnibus Budget Reconciliation ACT (OBRA) of 1987 requires SNFs to provide medically related social services to attain and maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Recommendation

Legislative

Administrative

Material Weakness

We recommend that CMS should strengthen its oversight process associated with the psychosocial services portion of the resident assessment and the resulting care plans to ensure that SNF residents receive necessary and appropriate care.

Status

Management Response

CMS concurred with our recommendations. During 2004, CMS convened a panel of experts to develop a guide for surveyors in evaluating the negative psychosocial outcomes related to a facility's deficient practices as part of the Scope and Severity project. The guidance on the Psychosocial Outcomes Severity Guide is expected to be issued in 2005.

Centers for Medicare & Medicaid Services
-Nursing Homes-

Improve Accuracy of Nursing Home Compare

Report Number: OEI-01-03-00130 Final Report: 06/2004

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 on State survey documentation. These inaccuracies leave consumers with incomplete information about nursing homes' survey and complaint histories.

Current Law

In 1998, HHS launched the Nursing Home Compare Web site with CMS operating the site. The purpose of the site is to provide detailed information about the past performance of certified nursing homes in the country and to allow beneficiaries and their care givers to access individual nursing home quality information.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS requires 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

Management Response

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

Centers for Medicare & Medicaid Services
-Physicians/Allied Health Professionals-

Eliminate Inappropriate Payments for Hyperbaric Oxygen Therapy

Report Number: OEI-06-99-00090 Final Report: 10/2000

Finding

A medical review of hyperbaric oxygen therapy (HBO2) determined that \$19.1 million (of an approximately \$49.9 million allowed charges for outpatient hospitals and physicians) was paid for inappropriate or excessive treatments. An additional \$11.1 million was paid for treatments with questioned quality. These reimbursements resulted from confusion over or abuse of the current coverage policy, medical opinions that do not align with CMS guidelines, and inadequate documentation. Failure by contractors to implement appropriate edits and medical review standards further contributes to inappropriate payments.

Current Law

Hyperbaric oxygen therapy provides a therapeutic dose of oxygen by creating a pressurized environment in which patients intermittently breathe 100 percent oxygen. This procedure was originally developed for the treatment of decompression sickness; but the primary usage in the United States currently is for wound care. CMS has established 14 conditions in its Coverage Instruction Manual, Section 35-10, for which hyperbaric therapy is reimbursable.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS initiate its national coverage decision process for HBO2; improve policy guidance (e.g., practice guidelines/physician attendance policy); and improve oversight by requiring contractors to initiate edits and consistent medical review procedures, and by exploring the establishment of a registry of facilities and/or physicians providing HBO2.

Status

Management Response

CMS generally concurred with our recommendations and reported several ongoing efforts to address concerns raised in this report. CMS is currently working to correct fiscal intermediary payments for HBO2 services in noncovered provider settings, and edits will be issued shortly to deny payments to providers where HBO2 is not a covered service. CMS also issued billing instructions, in January 2005, for providers paid under the hospital outpatient prospective payment system that furnish HBO2 services to Medicare beneficiaries. These instructions clarify components of HBO2 which may be included in calculating the total number of 30-minute intervals billable under C1300.

Centers for Medicare & Medicaid Services
-Physicians/Allied Health Professionals-

Ensure that Physician Identification Numbers Listed on Durable Medical Equipment Claims are Valid and Active

Report Number: OEI-03-01-00110 Final Report: 11/2001

Finding

We identified \$32 million in Medicare reimbursement for durable medical equipment (DME) claims that listed invalid physician identifiers in 1999. Another \$59 million was paid for DME ordered by physicians with inactive identifications.

Current Law

The Consolidated Omnibus Budget Reconciliation Act of 1985 requires CMS to establish unique physician identification numbers (UPIN) for all physicians who provide services to Medicare beneficiaries. Section 1834(a)(11)(B) of the Social Security Act authorizes the Secretary to require that suppliers receive an order from a physician before delivering medical equipment or supplies.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS revise its claims processing edits to ensure that physician identification numbers listed on medical equipment and supply claims are valid and active.

Status

Management Response

CMS concurred with our recommendations. CMS issued a program memorandum to carriers concerning the use of deceased physicians' UPINs on DME claims. Effective April 1, 2002, the common working file began rejecting DME claims that list a dead physician's UPIN in the ordering UPIN field if the date of service is after the physician's date of death. The deceased UPIN file will be updated for the common working file every 15 months.

Centers for Medicare & Medicaid Services
-Physicians/Allied Health Professionals-

Ensure Appropriate Use of Surrogate Physician Identification Numbers

Report Number: OEI-03-01-00270 Final Report: 08/2002

Finding

For a sample of services for which a surrogate number was used for billing durable medical equipment 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 services billed with surrogate numbers that had incomplete documentation in 1999.

Current Law

Medicare beneficiaries covered under Part B are eligible to receive medical equipment 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 unique physician identification number, the supplier must use a temporary or surrogate number when submitting claims.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

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 unique physician numbers for placement in Intermediary and Carrier bulletins and Web sites.

Centers for Medicare & Medicaid Services
-Prescription Drugs

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

Report Number: OAS-06-91-00092 Final Report: 11/1992

Finding

Although manufacturers' best price determinations were acceptable, calculations of average manufacturer price (AMP) were inconsistent. The variations occurred because CMS had not provided to manufacturers sufficiently detailed instructions on acceptable methods for calculating AMP. The method used affects the AMPs; the resulting rebates; and the accuracy, reliability, and consistency of the pricing information provided to CMS.

Current Law

Section 1927 of the Social Security 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, manufacturers are required to report their AMP to CMS for each covered outpatient drug for a base period. On a quarterly basis, the manufacturer is then required to report the AMP and the best price for each covered outpatient drug.

Recommendation

Legislative **Administrative** **Material Weakness**

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

Status

Management Response

CMS did not concur, stating that the drug rebate law and the rebate agreements already established a methodology for computing AMP. CMS officials also indicated that they have reexamined their policy to assure that they have made it clear that manufacturers are not to inappropriately exclude prices from AMP. We continue to believe that CMS should implement our recommendation. The rebate law and agreements defined AMP, but did not provide specific written methodology for computing AMP. In previous discussions, CMS informed us that the Medicaid drug rebate regulation would provide additional guidance in calculating AMP, but that regulation has not yet been published. Although CMS does provide individual guidance to drug manufacturers, our concern is that the guidance might not be consistent. Our audits point out this inconsistency.

Centers for Medicare & Medicaid Services
-Prescription Drugs

Implement Proper Accountability Over Billing and Collection of Medicaid Drug Rebates

Report Number:

OAS-06-92-00029

Final Report:

05/1993

Finding

None of the eight States reviewed maintained general ledger control accounts for Medicaid drug rebates, and only four States maintained even informal receivable listings for each manufacturer. Additionally, it did not appear that the States reviewed were generally applying their best efforts to collect the billings or resolve disputes with manufacturers. Also, these States had virtually no system of internal controls in place for drug rebate program funds.

Current Law

Federal regulations at 45 CFR, part 74, require that States meet certain standards for grant financial management systems which provide for (1) accurate, current, and complete disclosure of the financial results of programs; (2) accounting records which adequately identify the source and application of program funds; and (3) effective internal controls and accountability over all grant cash, property, and other assets so that these assets are safeguarded.

Recommendation

Legislative



Administrative

Material Weakness

CMS should ensure that States implement accounting and internal control systems in accordance with applicable Federal regulations for the Medicaid drug rebate program. Such systems must provide for accurate, current, and complete disclosure of drug rebate transactions and provide CMS with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program.

Status

Management Response

CMS agreed with the recommendation and set up a reporting mechanism to capture drug rebate information. The agency still needs to make certain that States establish and maintain adequate accounting and internal control systems to ensure the reliability of the information reported by States. We are currently updating our audit work involving Medicaid drug rebate collections. We issued a final report to CMS in July 2005 and are awaiting final comments.

Centers for Medicare & Medicaid Services
-Prescription Drugs

Lower Medicaid Expenditures on HIV/AIDS Drugs

Report Number: OEI-05-99-00611 Final Report: 07/2001

Finding

Medicaid pays up to 33 percent more than other Federal Government drug discount programs for HIV/AIDS drugs. Differences in Federal drug pricing formulas are partially responsible for cost discrepancies. State reimbursement formulas also affect the magnitude of the gap between Medicaid and other government drug purchasers. Medicaid could have saved \$102 million if the 10 States surveyed purchased the 16 antiretrovirals at Federal ceiling prices.

Current Law

Title XIX of the Social Security Act established Medicaid as a jointly funded, Federal/State health insurance program to provide medical services to low-income persons. Medicaid's net spending on prescription drugs, the most frequently used benefit in the Medicaid program, was estimated to be \$16.4 billion in FY 2000. CMS spent \$617 million on antiretrovirals in FY 1999. As the largest source of public coverage for prescription drugs, Medicaid strives to be a prudent purchaser of pharmaceuticals by limiting drug reimbursement to pharmacies and by receiving quarterly rebates from drug manufacturers.

Recommendation

Legislative

Administrative

Material Weakness

For the 16 HIV/AIDS drugs examined in our study, we recommended that CMS review the current reimbursement methodology and work with States to find a method that more accurately estimates pharmacy acquisition cost. For this recommendation, we suggested three options: that CMS develop safeguards to protect Medicaid from average wholesale price (AWP) manipulations, create a national estimated acquisition cost for the States based upon the average manufacturers price (AMP), or share AMP data with States so they can accurately set Medicaid reimbursement amounts. We also recommended that CMS should initiate a review of Medicaid rebates for the 16 HIV/AIDS drugs examined. For this recommendation, we suggested that CMS increase the rebate percentage of AMP or base the rebates on AWP rather than AMP.

Status

Management Response

CMS agreed with the overall intent of our recommendations but expressed reservations with many of the specific suggestions offered for achieving them. CMS continues to believe that it does not have the statutory authority to make the suggested changes. CMS has encouraged States to review their estimates of acquisition costs for drugs. Additionally, CMS monitors States' estimated acquisition costs and provides a quarterly update by State that is listed on the CMS Medicaid Drug Rebate Program Web site. These actions have resulted in a number of State plan amendments submitted to and approved by CMS requesting a change in methodology for the States' estimates of acquisition costs. With regard to initiating a review of Medicaid rebates, the President's FY 2006 budget proposes a flat rebate, eliminating best price and using a better measure for drug payments. No further actions are planned.

Centers for Medicare & Medicaid Services
-Prescription Drugs

Improve Beneficiary Educational Efforts for Medicare Health Maintenance Organization Prescription Drug Benefits

Report Number: OEI-03-00-00430 Final Report: 05/2002

Finding

The information health maintenance organizations (HMOs) provide to beneficiaries about available drug benefits is inconsistent, incomplete, and confusing. Many HMOs did not provide beneficiaries with the specific pricing methods for commonly used drugs, which is important for calculating dollar limits for each prescription. Additionally, information differed between HMOs and CMS's Plan Benefit Package (PBP) database.

Current Law

CMS does not require Medicare+Choice organizations—managed care organizations servicing beneficiaries—to report drug pricing information for beneficiaries.

Recommendation

Legislative

Administrative

Material Weakness

Our prior studies have shown that prescription drug coverage is one of the main factors that attracts beneficiaries to enroll in a managed care option under Medicare. To allow beneficiaries to make more informed choices, CMS should enhance and validate the drug limit information that is collected from plans for the PBP database, and enhance current educational efforts to ensure the plans' drug benefits are clearly explained.

Status

Management Response

CMS responded that beginning in 2006, this recommendation will no longer be relevant because prescription drug benefits will no longer be a non-Medicare benefit offered by Medicare Advantage (MA) plans as they were at the time this report was written. Rather, MA plans must offer prescription drug benefits under Part D of Medicare, as enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In connection with offering Medicare Part D benefits, beginning in 2006 the Medicare statute requires the Secretary to provide comparative information on benefits, premiums, and cost sharing. CMS also intends to publish extensive comparative information, including drug pricing, in standardized formats.

Centers for Medicare & Medicaid Services
-Prescription Drugs

Variation in State Medicaid Drug Prices

Report Number:

OEI-05-02-00681

Final Report:

09/2004

Finding

We determined that the highest paying State's unit reimbursement price ranged from 12 to 4,073 percent more per drug than the lowest paying State for 28 drugs. Medicaid could have saved \$86.7 million in FY 2001 if all States had reimbursed at the same price as the lowest paying State for each of the 28 drugs. Even States with the same formula for estimating pharmacy acquisition costs demonstrated variation in their average annual reimbursement prices.

Current Law

Under section 1902(a)(30)(A) of the Social Security Act, CMS has the authority to set upper payment limits for services available under the Medicaid program. For Medicaid, CMS sets maximum drug reimbursement limits to ensure that the Federal Government acts as a prudent buyer of drugs. Within these Federal parameters, each State determines its own pharmacy reimbursement formula(s).

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS share more accurate drug pricing information with States, conduct further research on the factors that affect States' drug prices, and annually review States' reimbursement data to target technical assistance to higher paying States.

Status

Management Response

CMS plans to follow up with States that paid higher relative drug prices, particularly States with prices above the upper payment limit.

Centers for Medicare & Medicaid Services
-CMS Administration-

Establish a National Medicaid Credit Balance Reporting Mechanism

Report Number:	OAS-05-93-00107	Final Report:	05/1995
	OAS-04-92-01023		03/1993

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 are remitting overpayments in a timely manner.

Current Law

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

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

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 unfunded mandates.

Centers for Medicare & Medicaid Services
-CMS Administration-

Increase the Accountability of Dialysis Facilities for Quality of Services

Report Number: OEI-01-99-00050 Final Report: 06/2000

Finding

CMS needs to improve its quality oversight of end-stage renal disease (ESRD) facilities through greater accountability of the facilities, ESRD Networks, and State agencies who contract with CMS to provide oversight.

Current Law

Section 1881(c) of the Social Security Act established ESRD Networks to assure the “effective and efficient administration of the [ESRD] benefits.” State agencies assess compliance of ESRD facilities with Medicare Conditions for Participation, listed at 42 C.F.R. § 405, subpart U.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS hold ESRD facilities more accountable through the following actions: revising the conditions of participation, strengthening the complaint system, instituting minimum cycle times for surveys, requiring Network/State agency joint initial surveys, and facilitating publicly accountable means for identifying 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

Management Response

CMS generally concurred with our recommendations. Since 2002, CMS surveys 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 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 in order 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 NPRM was published in the Federal Register on February 4, 2005, (70 FR 6183) and has a 90-day comment period. 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.

Centers for Medicare & Medicaid Services
-CMS Administration-

Increase Organ Donation

Report Number: OEI-01-99-00020 Final Report: 08/2000

Finding

Hospitals and organ procurement organizations (OPO) have made progress in implementing the donation rule. However, hospitals and OPOs have not taken full advantage of the donation rule. Hospitals are not consistently notifying their OPOs of all deaths or imminent deaths. Despite projections of a 10 percent increase, the number of organ donors rose by less than 1 percent in the first year of the donation rule. CMS does not obtain routine data to assess how well the donation rule is working.

Current Law

In June 1998, CMS changed the Medicare Conditions of Participation to spur an increase in organ donation. The new donation rule required hospitals to contact their OPO in a timely manner about individuals whose death is imminent or who die in the hospital. In addition, only OPO staff or trained hospital staff may approach families about organ donation.

Recommendation

Legislative

Administrative

Material Weakness

CMS should revise the Medicare conditions for coverage for OPOs to make them more accountable for implementing the new donation rule. CMS should require OPOs to provide hospital-specific data on referrals and on organ recovery. HRSA should require that OPOs submit hospital-specific data on referrals and on organ recovery. HRSA should support demonstration projects on how to effectively train and make use of designated requestors.

Status

Management Response

CMS concurred with the recommendations and indicated it will explore ways in which additional data can be used to assess OPO effectiveness and hospital compliance with the donation rule. CMS published a Notice of Proposed Rulemaking (NPRM) on February 4, 2005, (70 FR 6068) establishing new conditions of coverage for OPOs. The NPRM included proposed requirements for OPOs to report hospital-specific organ donation, including organ donor potential and the number of actual donors, at least annually to the public. HRSA, through its contract for operation of the Organ Procurement and Transplantation Network, requires OPOs to submit hospital-specific data on organ recovery.

Centers for Medicare & Medicaid Services
-CMS Administration-

Improve the Medicare Beneficiary Complaint Process

Report Number: OEI-01-00-00060 Final Report: 08/2001

Finding

We found that the beneficiary complaint process in Medicare peer review organizations (PROs) is ineffective. Its accessibility is questionable, interventions are rarely triggered by substantiated complaints, and beneficiaries do not receive meaningful responses to their complaints.

Current Law

Section 1154(a)(14) of the Social Security Act requires PROs to “...conduct an appropriate review of all written complaints about the quality of services...” which are payable under Medicare.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS provide Medicare beneficiaries with an effective complaint process, either within or outside of the PRO program. The complaint process should be accessible, responsive, timely, and objective. The organizations handling beneficiary complaints should have adequate investigative capacity, effective interventions and follow-through, a quality improvement orientation, and public accountability.

Status

Management Response

The review process was revised to emphasize effective handling of an responsiveness to beneficiary complaints with the addition of case management and mediation. A focus on quality improvement rather than punitive actions was developed as well. CMS also implemented a more comprehensive and informative approach toward resolving complaints and enhancing beneficiary information activities by utilizing a Medicare Beneficiary Protection Quality Improvement Organization support center to help achieve optimal implementation among quality improvement organizations nationwide.

Centers for Medicare & Medicaid Services
-CMS Administration-

CMS Oversight of Cost-Avoidance Waivers

Report Number: OEI-03-00-00031 Final Report: 02/2004

Finding

We found that six out of seven CMS regional offices approved cost-avoidance waivers that did not include criteria for proving cost-effectiveness. Specifically, for 20 of the 46 waiver requests approved, States did not compare the cost-effectiveness of pay and chase to that of cost avoidance. Further, CMS does not require States to report the data necessary to determine cost-effectiveness, thus preventing CMS from making informed decisions when approving cost-avoidance waivers.

Current Law

When State Medicaid agencies receive claims that have a liable third-party payer, they are required to cost avoid by returning the claim to the provider so the provider can bill the liable third party. Under 42 CFR 433.138, CMS regional offices may grant cost-avoidance waivers if States demonstrate that pay and chase is as cost-effective as cost-avoidance. Under pay and chase, States pay the provider's claim upfront and then seek recovery from the liable third party.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS approve only waivers that meet the criteria for cost-effectiveness as set forth by Federal regulations, strengthen oversight activities through improved document retention, and collect information from States regarding recovery rates from pay and chase activities.

Status

Management Response

CMS concurred with our recommendation that it approve only cost-effective waivers. CMS continues to address the oversight of and/or need for cost-avoidance waivers. CMS central and regional offices continue to work closely with States to identify circumstances for which cost-avoidance waivers are not necessary (i.e., Medicaid services not covered by third parties or benefits not directly available to the provider). CMS has also worked with States to diminish the need for waivers by frequently encouraging States to eliminate paying and chasing of claims and relying instead on cost-avoidance. CMS has made substantial progress on Medicaid pharmacy claims. In August 2001, we reported only 17 States were cost-avoiding (in part or whole) pharmacy claims. A recent CMS survey indicated that 40 States currently meet that description and an additional 4 States are planning systems conversions. CMS plans to follow up with remaining States to consider what further assistance should be offered. Where waivers continue to be necessary, CMS will continue to emphasize cost-effectiveness and proper document retention.

Centers for Medicare & Medicaid Services
-State Administration

Reduce the Number of Uninsured Children Through State Children's Health Insurance Programs (SCHIP)

Report Number: OEI-05-03-00280 Final Report: 08/2004

Finding

OIG reviewed States' progress in reducing the number of uninsured low-income children as reported in their 2002 Annual Reports for SCHIP and consulted data on national insurance rates. We found that: (1) 44 of 46 States provided some response to the requirement that all States describe their progress in their Annual Reports; (2) 22 of these States directly addressed the CMS regulation; (3) 17 of the 22 States reported a reduction in the number of uninsured children, 3 States reported an increase and 2 States reported no change; (4) 19 other States responded to CMS's requirement by reporting on SCHIP enrollment, and 3 States reported on something other than the number of uninsured children or SCHIP enrollment; and (5) 2 States submitted Annual Reports that did not provide any response to CMS's requirement. Finally, data indicate that the rate of uninsured children nationally has declined.

Current Law

The Balanced Budget Refinement Act of 1999 requires that every 3 years OIG (1) evaluate whether States are enrolling Medicaid eligible children in SCHIP, and (2) assess the progress made by States in reducing the number of uninsured low-income children, including their progress in meeting the strategic objectives and performance goals included in the State child health plan.

Recommendation

Legislative

Administrative

Material Weakness

CMS should resolve the inconsistency between the requirement that States report on changes in the number of uninsured children and the practice of accepting enrollment data as a proxy, and ensure the integrity, validity, and usefulness of the SCHIP Annual Report and SCHIP enrollment data.

Status

Management Response

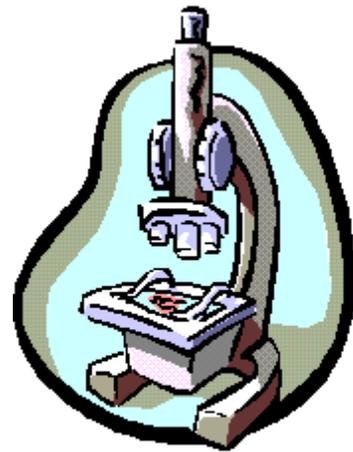
CMS concurred with several of our specific recommendations and has already implemented steps to improve the integrity of the State Annual Report submissions. In addition, CMS has taken steps to enhance technical assistance (TA) to States to improve their measurement capabilities and held a TA session at the National Academy for State Health Policy's annual conference in August 2004. CMS is currently reviewing all State reports on progress towards covering the uninsured and providing State-specific TA to the States not measuring progress.

Public Health

Public Health

Overview

The activities of HHS's Public Health agencies and programs represent this country's primary defense against acute and chronic diseases and disabilities. They provide the foundation for the Nation's efforts in promoting and enhancing the continued good health of the American people. The Public Health agencies encompass: (1) the National Institutes of Health (NIH) supports some 35,000 research projects nationwide in diseases like cancer, Alzheimer, diabetes, arthritis, heart ailments, and AIDS; (2) the Food and Drug Administration (FDA) assures the safety of foods and cosmetics and the safety and efficacy of pharmaceuticals, biological products and medical devices; (3) the Centers for Disease Control and Prevention (CDC) is responsible for protecting the health and safety of people—at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships, and serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States; (4) the Health Resources and Services Administration (HRSA) helps provide health resources for the medically underserved, works to build and maintain the health care workforce, oversees the Nation's organ transplantation system, works to decrease infant mortality and improve child health, and provides services to people with AIDS through the Ryan White CARE Act programs; (5) the Indian Health Service (IHS) improves the health status of Native Americans; (6) the Agency for Healthcare Research and Quality (AHRQ) supports cross-cutting research on health care systems, health care quality and cost issues, and effectiveness of medical treatments; (7) the Agency for Toxic Substances and Disease Registry (ATSDR) works with States and other Federal agencies to prevent exposure to hazardous substances and conducts environmental public health assessments, health studies, surveillance, and health education training in communities; and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA) provides leadership in mental health and substance abuse treatment and prevention.



Introduction

Related OIG Activities

The Office of Inspector General (OIG) continues to increase oversight of Public Health program activities and ensure that research funds are monitored properly. OIG concentrates on such issues as biomedical research and human subject protections, substance abuse, acquired immune deficiency syndrome, and medical effectiveness. In addition, OIG conducts audits of colleges and universities that are awarded contract and grant funding by HHS. Other areas of review include grants management in general, information resource management, food and drug programs, community health programs, and IHS financial management.

Public Health Service Agencies
-Biomedical Research

Improve Recruiting Practices for Human Research Subjects

Report Number:	OEI-01-97-00195	Final Report:	06/2000
	OEI-01-97-00196		06/2000

Finding

Recruitment is a major bottleneck in the flow of drugs developed by industry. Therefore, there is significant pressure for research investigators to recruit subjects quickly. Sponsors and investigators use a variety of recruitment methods (many of which raise concerns) including offering incentives, targeting their own patient bases, seeking additional patient bases, and advertising and promoting their research. Oversight of these recruitment methods is limited.

Current Law

In June 2000, the Office for Human Research Protections (OHRP) was established within the Office of the Secretary and took over many of the responsibilities of the former NIH Office for Protection from Research Risks. OHRP is charged with oversight of all research involving human subjects that is conducted or funded by HHS and conducts investigations at research institutions that have signed assurances. Under this new structure, NIH will continue its involvement in the funding and oversight of clinical trials and will coordinate with OHRP in activities related to the protection of 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.

Recommendation

Legislative

Administrative

Material Weakness

We recommended jointly to FDA, NIH, and the Assistant Secretary for Health that FDA, NIH, and OHRP clarify institutional review boards' (IRB) authority to review recruiting practices and work with industry, researchers, and ethicists to develop guidelines on appropriate practices. Also, FDA, NIH, and OHRP should require investigator and IRB education and strengthen their oversight.

Status

Management Response

In 2001, FDA published an interim final rule establishing additional safeguards for children in clinical trials involving FDA-regulated products (Federal Register, 66 FR 20598). NIH also requires data and safety monitoring boards (DSMBs) to share summary information with IRBs and has implemented the requirement for monitoring plans for Phase I and Phase II trials, and FDA has issued new draft DSMB guidance. FDA is currently updating its human subject protection information sheets to reflect current policies, and as part of this effort, the information sheet guidance on Recruiting Human Subjects will clarify that IRBs should review the recruitment methods and materials proposed by investigators. HHS is considering implementation of new requirements for continuing education in human subject protection for IRB members and staff and institutional officials as part of the Federal-Wide Assurance (FWA) process. OHRP and FDA recently simultaneously issued rules to require IRBs to register at sites maintained by HHS (69 FR 40556 and 69 FR 40584, respectively). In 2003 and 2004, OHRP, partnering with FDA and other Federal agencies, sponsored national and regional training conferences for IRBs, clinical investigators, clinical staff, and institutional officials on good clinical practice and human subject protection issues. 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," in the Federal Register [69 FR 226393] in May 2004. HHS agencies worked with the Office for Civil Rights to develop guidance related to HIPAA privacy issues.

Public Health Service Agencies
-Biomedical Research

Strengthen FDA Oversight of Clinical Investigators

Report Number: OEI-05-99-00350 Final Report: 06/2000

Finding

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.

Current Law

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

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

In July 2004, FDA issued a proposed rule to require IRBs to register at sites maintained by HHS (69 FR 40556). HHS simultaneously published a similar IRB registration proposal applicable to research supported or conducted by HHS. In 2003 and 2004, 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. FDA has established a new unit, the Office for Good Clinical Practice, within the Office of Science Coordination and Communication in the Commissioner's Office to coordinate and direct human subject protection and good clinical practices issues. The Bioresearch Monitoring Program policy and coordination function has been elevated to this Office, and it is responsible for addressing issues identified in the OIG recommendations, specifically defining cross-center goals for the program and developing criteria to determine whether the program is achieving these goals. FDA has also begun implementing an initiative to develop better communication with the European Medicines Agency (EMA) with the goal of improving coordination and communication between FDA and EMA, which would allow information sharing on inspections of clinical study sites.

Public Health Service Agencies
-Food and Drug Safety-

Enforce State Pharmacy Boards' Oversight of Patient Counseling Laws

Report Number: OEI-01-97-00040 Final Report: 08/1997

Finding

OIG found that: (1) State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws; (2) the boards' enforcement of the counseling laws has been minimal; and (3) the boards identified major obstacles to the successful implementation of patient counseling laws.

Current Law

In 1990, Congress required pharmacists to offer counseling to Medicaid beneficiaries who present prescriptions and that States establish counseling standards. Nearly all States responded by passing laws that extend patient counseling to all patients, not just Medicaid beneficiaries. State pharmacy boards oversee compliance with these laws.

Recommendation

Legislative

Administrative

Material Weakness

OIG recommended that: (1) FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to individuals receiving new prescriptions; (2) CMS should facilitate State efforts to enforce the Medicaid patient counseling mandate; (3) CMS should develop and assess State progress toward a patient counseling performance objective; and (4) CMS should develop guidelines on State oversight of the Federal patient counseling mandate.

Status

Management Response

In early 2001, FDA contracted with the National Association of Boards of Pharmacy (NABP) to conduct an evaluation of the written medication information given to simulated patients, together with new prescriptions at 380 randomly selected pharmacies across the country. The results of this study showed that 89 percent of consumers received some form of written information about their prescription medications. However, an expert panel found that the usefulness of the information remains variable, with risk information often lacking. FDA has also conducted periodic telephone surveys since 1982 to measure patient-reported receipt of oral and written information about newly prescribed medicines at prescribers' offices and pharmacies. Each of the studies has evaluated reports of about 1,000 patients receiving new prescriptions. The most recent survey, conducted in late 2001, showed results consistent with the previous survey and the NABP study. In June 2002, FDA's Drug Safety and Risk Management Advisory Committee suggested that FDA take a more active role in encouraging the private sector to meet the 2006 legislative goal for distribution of useful written medication information. In 2003, FDA held a public meeting to hear reports of private sector progress in meeting the 2006 goals. FDA plans to conduct a follow-up survey in 2006-2007 to determine the usefulness of written information being supplied at that time.

Public Health Service Agencies
-Food and Drug Safety-

Strengthen FDA Oversight of State Food Firm Inspections

Report Number: OEI-01-98-00400 Final Report: 06/2000

Finding

FDA's current oversight of both the contracts and partnership agreements is insufficient to assure the quality of State inspections carried out on its behalf. Under contract, FDA's on-site audits, the core of its oversight, have dropped by more than half over the past 5 years. Under partnership agreements, FDA lacks leverage to require States to submit information and to assess State performance. Finally, its periodic performance evaluations lack substantive review of State performance, and its feedback to States is based largely on informal communication.

Current Law

During the past 25 years, FDA has extended its inspection coverage by contracting with States to conduct food firm inspections under FDA authorities. In recent years, FDA has further extended its inspection coverage by initiating partnership agreements with many States under which they agree to conduct inspections under State authorities, without Federal funding, and to share the results with FDA.

Recommendation

Legislative

Administrative

Material Weakness

We made several recommendations based on a template of effective oversight, which apply to both the contracts and partnership agreements. In particular, we emphasized the need for FDA to strengthen its system of on-site audits and to develop meaningful channels to provide States with useful feedback on their performance. As a long term objective, we recommended that FDA work with States to achieve basic equivalency in food safety standards, laws, and inspection practices as a basis for future work with States.

Status

Management Response

In response to OIG's review of FDA's oversight of State food firm inspections in June 2000, FDA has implemented several new programs and activities. FDA and State representatives developed a standardized audit form and training for its investigators and inspectors, and FDA is currently compiling data to track frequency of audits. The Division of Federal-State Relations (DFSR) has been working with the American Association of Feed Control Officials to modify the audit program to address bovine spongiform encephalopathy (BSE) concerns and presented a specialized training on these issues in March 2005. FDA audits of the feed/BSE contract are scheduled to begin in FY 2006. The DFSR has also established a committee of FDA/State representatives to develop guidance for States for a quality assurance program element. Standards are being finalized which will be issued for comment in the Federal Register in FY 2005. Finally, in collaboration with the State of New York, FDA conducted a 2-year pilot study to advance the audit (quality assurance) process. The pilot was successfully completed in 2004, and in FY 2005, States may bid on the option to develop their own audit (QA) program that will receive "program" audits by FDA personnel.

Public Health Service Agencies
-Food and Drug Safety-

Improve Oversight of Tissue Banking

Report Number: OEI-01-00-00441 Final Report: 01/2001

Finding

Some tissue banks have never been inspected by FDA. FDA lacks a prescribed cycle for reinspection of tissue banks. In addition, information is lacking on the number of tissue banks in operation and the products they produce and distribute. Many tissue banks do not seek accreditation.

Current Law

Oversight of tissue banks takes place at three levels. FDA focuses on preventing transmission of communicable diseases by requiring donor screening and testing; the American Association of Tissue Banks conducts a voluntary accreditation program. New York and Florida are the only two States to license and inspect tissue banks.

Recommendation

Legislative

Administrative

Material Weakness

FDA should expedite publication of its regulatory agenda that requires registration of tissue banks and enhance donor suitability screening and testing and the use of good tissue practices. It should set a realistic, yet aggressive, date by which it would complete an initial inspection of all tissue banks. FDA should determine the appropriate minimum cycle for tissue bank inspections. It should work with States and professional associations that have inspection and accreditation programs to determine in what areas, if any, oversight activities could be coordinated.

Status

Management Response

The Deputy Secretary concurred that FDA should expedite its planned rulemaking activities related to tissues, specifically the final rule to require registration of tissue banks. HHS also found “considerable merit” in OIG’s recommendation for an intensified inspection program directed toward entities that procure, process, and store human tissues. In congressional testimony, FDA said that all three of the proposed rules have been published, and one rule (Establishment Registering and Listing) was finalized. FDA has completed contacting the 36 uninspected tissue banks. The results were: 31 inspections were completed, 3 firms were out of business, 1 firm could not be located, and 1 firm was not an FDA obligation because it handles only vascularized organs. FDA issued a final rule on November 24, 2004, requiring human cell, tissue, and cellular and tissue-based product establishments to follow current good tissue practices that govern manufacturing, record keeping, and quality programs.

Public Health Service Agencies
-Food and Drug Safety-

Improve Effectiveness of FDA's Adverse Event Reporting System for Dietary Supplements

Report Number: OEI-01-00-00180 Final Report: 04/2001

Finding

Unlike new prescription and over-the-counter drugs, FDA does not have authority to require dietary supplements to undergo premarket approval for safety and efficacy. It relies mostly on its adverse event reporting system to identify safety problems. FDA's adverse event reporting system for dietary supplements detects relatively few adverse events and has difficulty generating signals of possible public health concerns. FDA also lacks vital information to adequately assess signals of possible public health concerns generated by the adverse event reporting system. As a result, FDA rarely takes safety actions related to protecting the American consumer from certain dietary supplements.

Current Law

In 1993, FDA created a system to collect and review adverse event reports on supplements. Reporting adverse events associated with dietary supplements to FDA is strictly voluntary. FDA receives adverse event reports on dietary supplements from consumers, health professionals, and manufacturers through a variety of sources, including State health departments, Poison Control Centers, direct communication with individuals, and MedWatch, a computerized reporting system used to monitor a variety of FDA-regulated products. In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA) based on the premise that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary to promote wellness." Although DSHEA is grounded on the presumption that dietary supplements are safe, it provides FDA with the authority to take action against a dietary supplement or ingredient that "presents a significant or unreasonable risk of illness or injury."

Recommendation

Legislative **Administrative** **Material Weakness**

We recommended that FDA (1) facilitate greater detection of adverse events by requiring dietary supplement manufacturers to report serious events to FDA for some products; (2) obtain more information on adverse event reports by requiring dietary supplement manufacturers to register their companies and their products with the FDA; (3) notify manufacturers when FDA receives a serious adverse event report and develop a new computer database to track and analyze adverse event reports; (4) expedite the development and implementation of good manufacturing practices for dietary supplement manufacturers; and (5) disclose more useful information to the public about dietary supplement adverse events. We assessed FDA's regulations for dietary supplement labels, and the extent to which current dietary supplement labels reflect the key elements identified in our template, and presented FDA with a template of key label elements.

Status

Management Response

In response, the Center for Food Safety and Applied Nutrition (CFSAN) developed a new system for entering adverse events and consumer complaint reports involving foods, the CFSAN Adverse Event Reporting System (CAERS), which became partially operational in June 2003. The new system incorporates all existing adverse event reporting systems into one state-of-the-art reporting and monitoring system. CAERS staff work closely with program experts as well as external stakeholders. FDA intends to improve data links to the Center for Drug Evaluation and Research as funds become available. FDA also published proposed Good Manufacturing Practices regulations for dietary supplements in March 2003 and is now preparing the final regulation. In response to the requirement for food facility registration in the Public Health Security and Bioterrorism Preparedness Act of 2002, FDA now requires facilities that manufacture, process, pack, or hold dietary supplements to be registered with the FDA. FDA informs the public of new developments through its dietary supplements Web site.

Public Health Service Agencies
-Food and Drug Safety-

Improve Protection for Research Subjects in Foreign Clinical Trials

Report Number: OEI-01-00-00190 Final Report: 09/2001

Finding

FDA oversees significantly more foreign research than it did 10 years ago. It cannot assure the same level of human subject protections in foreign trials as in domestic ones. This is especially true in the case of research sites in countries that have limited experience in clinical trials. As a result, key entities overseeing or studying foreign research have raised concerns about some foreign institutional review boards (IRBs).

Current Law

In June 2000, the Office for Human Research Protections (OHRP) was established within the Office of the Secretary and took over many of the responsibilities of the former NIH Office for Protection from Research Risks. OHRP is charged with oversight of all research involving human subjects that is conducted or funded by HHS and conducts investigations at research institutions that have signed assurances. Under this new structure, NIH will continue its involvement in the funding and oversight of clinical trials and will coordinate with OHRP in activities related to the protection of 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.

Recommendation

Legislative

Administrative

Material Weakness

We directed our recommendations jointly to FDA and OHRP. We recommended that FDA examine ways to obtain more information about the performance of non-US IRBs and help those inexperienced IRBs build their capacities; encourage all non-US investigators participating in research to sign attestations upholding human subject protections; and develop a database to track the growth and location of foreign research. We recommended that OHRP exert leadership in developing strategies to ensure adequate human subject protections for non-US clinical trials funded by the Federal Government and those that contribute data to new drug applications.

Status

Management Response

OHRP concurred with our recommendations and emphasized that its new International Activities Program will serve as a focal point and coordinating center for HHS's efforts to improve human subject protection. In collaboration with the FDA and the Fogarty International Center, OHRP is working with a variety of national, regional, and international organizations with a goal of establishing effective education and review processes around the world. In 2004, OHRP sponsored capacity-building workshops for IRB members, gave presentations at international conferences, and began translating key guidance documents into foreign languages. FDA published a proposed rule in 2004, "Human Subject Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application" (21 CFR 312.120), to promote good clinical practice regardless of the location of the clinical trial. FDA and OHRP have contributed to efforts to strengthen research investigation and harmonize standards through collaboration with the World Health Organization, the Pan American Health Organization, the Council for International Organizations of Medical Sciences, and other organizations. FDA also contributed to the HHS/OHRP/NIH Working Group for Equivalent Protections in developing a HHS report and Federal Register Notice announcing proposed criteria for clinical trials conducted outside of the United States. In addition, FDA has assisted other countries with capacity-building activities for international GCP inspectorates, including Singapore and Australia. An ongoing FDA initiative to develop better communication with the European Medicines Agency will improve coordination between the respective European and FDA programs involving clinical trials. FDA has also provided staff as faculty to professional associations for outreach training programs, as well as creating a GCP Web site for current information about FDA clinical trial requirements.

Public Health Service Agencies
-Food and Drug Safety-

Improve FDA's Review Process for New Drug Applications

Report Number: OEI-01-01-00590 Final Report: 03/2003

Finding

Our evaluation found that the FDA drug application review process has several strengths, including collaboration with sponsors, responsiveness to time goals, and increased efforts to improve efficiency and consistency. FDA's use of expert scientific reviewers has increased both reviewers' and sponsors' level of confidence in FDA decisions. However, heavy workload pressures present challenges to the effectiveness of the review process. This is manifested in reviewer concerns about time pressures, staff turnover, decreased use of advisory committees, and less time for reviewers to participate in professional development and research activities.

Current Law

The Food and Drug Administration (FDA) reviews new drug applications (NDAs) to determine whether a drug can be marketed in the United States. The Prescription Drug User Fee Act (PDUFA), enacted in 1992, authorized FDA to collect user fees from sponsors to help expedite the review of NDAs, and at the same time, established time goals. PDUFA was reauthorized in 1997 and most recently, through the Public Health Security and Bioterrorism Preparedness Act of 2002. The current version of the law is commonly referred to as "PDUFA III."

Recommendation

Legislative **Administrative** **Material Weakness**

We recommended that FDA take full advantage of the opportunities presented in PDUFA III and take actions, such as retrospective examinations and evaluations of NDA reviews, staffing levels, and workload distribution. In addition, FDA should determine whether workload pressures justify exceptions to time goals to allow for more in-depth reviews, and applications that are incomplete or deficient should be rejected. FDA should also take advantage of its formidable data resources to conduct or support scientific research. Finally, the public should be provided a clear and timely explanation of NDA decisions.

Status

Management Response

FDA concurred with our recommendations and continues to progress toward full implementation. FDA's Center for Drug Evaluation and Research (CDER) completed a study examining various factors to determine the cause of delays in NDA reviews. CDER is also reviewing its workload and staff distribution and plans to hire a consultant to review the continuous marketing process. In accordance with the PDUFA III requirement, in 2002, CDER issued a Manual of Policies and Procedures on the filing process and as future long term goals are established, additional process guidelines will be added. In March 2005, the final guidance, "Good Review Management Practices and Principles for PDUFA Products," was published after the Agency incorporated comments received on the October 2003 draft guidance. FDA is in agreement with our recommendation that research projects be conducted or supported, and provides grants as part of its Regulatory Science and Review Enhancement Program. FDA agrees with our recommendation to provide clear and timely notification of approvals on our Web site but notes that FDA does not have authority to disclose information about disapproved applications. Final guidance for continuous marketing applications, Pilot 1 and 2, were published in October 2003, and the Agency hired a contractor to evaluate the programs. On July 16, 2004, FDA announced the establishment of a new cancer office and concomitant program, which will facilitate a more consistent approach to the review of drugs and therapeutic biologics to treat cancer. In February 2005, FDA created a new Drug Safety Oversight Board to assist in decisions on drug risk/benefit analyses and consumer safety.

Public Health Service Agencies
-Indian Health

Strengthen Hospital Systems for Credentialing, Privileging, and Suitability Reviews

Report Number:	OAS-06-04-00023	Final Report:	08/2004
	OAS-06-04-00024		11/2004
	OAS-06-04-00037		11/2004
	OAS-06-04-00038		12/2004

Finding

Four IHS operated hospitals reviewed—Northern Navajo Medical Center, Gallup Indian Medical Center, Lawton Indian Hospital, and Clinton Indian Hospital—did not routinely complete required credentialing, privileging, and/or personnel suitability reviews of their practitioners. The privileging lapses appeared in some cases to be a long-standing situation, with practitioners providing patient care without privileges for up to 4 years. The hospitals' management had not ensured that the credentialing, privileging, and personnel suitability review processes received the necessary level of priority in terms of management attention, adequate staffing, and availability of resources such as credentialing software. As a result, the hospitals' management could not assert full assurance that its practitioners had the appropriate qualifications, authorizations, and personnel history to provide patient care.

Current Law

Consistent with Joint Commission on Accreditation of Healthcare Organizations standards, IHS Circular 95-16 requires hospital management to follow a standardized process for a credentials review and the granting of clinical privileges. In addition, the Indian Child Protection and Family Violence Prevention Act (Public Law 101-630 § 408) requires IHS to obtain personnel suitability reviews through background investigations of its employees.

Recommendation

Legislative



Administrative



Material Weakness

We recommended that IHS ensure each hospital's management establishes a system to routinely perform credentialing, privileging, and suitability reviews. Specifically hospitals should (1) assign staff to perform the credentialing and privileging processes before practitioners provide patient care, (2) implement a computerized credentialing system to track and monitor the status of practitioners, and (3) initiate the required OPM background investigations of practitioners.

Status

Management Response

IHS concurred with our recommendations and indicated the hospitals have taken the corrective actions, including (1) increased staffing, (2) installed credentialing software, and (3) implemented a policy to initiate OPM background investigations on or before a practitioner's first day of duty, pursuant to IHS guidelines.

Public Health Service Agencies
-Health Resources and Services-

Improve Hospital Reporting to the National Practitioner Data Bank

Report Number: OEI-12-99-00250 Final Report: 07/1999

Finding

There are indications that hospitals may not be complying with the reporting requirements of the National Practitioner Data Bank. About two-thirds of hospitals have never reported an adverse action to the Data Bank.

Current Law

Section 423 of the Health Care Quality Improvement Act (42CFR U.S.C. 11133) requires that each hospital or health care entity which 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 Data Bank.

Recommendation

Legislative

Administrative

Material Weakness

To more fully encourage hospitals to follow the intent of Section 423 of the Health Care Quality Improvement Act, we recommended that HRSA propose legislation that would establish a civil money penalty of up to \$10,000 for each instance of a hospital's failure to report to the Data Bank.

Status

Management Response

HRSA fully supported the recommendations and awarded a contract to PricewaterhouseCoopers to look at the feasibility study for assessing compliance with the Data Bank 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 underlying their actions in the absence of clear legal authority requiring them to do so. The current 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.

Public Health Service Agencies
-Health Resources and Services-

Enhance Maternal and Child Health Training Grant Program

Report Number: OEI-04-98-00090 Final Report: 04/2000

Finding

The Interdisciplinary Leadership Education Excellence for Children with Neurodevelopmental and Related Disabilities (LEND) program benefits interdisciplinary treatment of children with disabilities by producing leaders, supporting university clinics serving special needs children, and reducing a shortage of adequately trained people who deliver services to special needs children. However, LEND grantees have mixed success demonstrating leadership and tracking graduates. Also, monitoring and evaluating grantees is minimal.

Current Law

The LEND program is a training grant program authorized under the Maternal and Child Health Services Block Grant as part of the “set-aside” for projects of regional and national significance. The LEND program seeks to achieve its mission through funding graduate level, interdisciplinary training which produces professionals to work with special needs children. The program was funded \$18.6 million in FY 2004.

Recommendation

Legislative **Administrative** **Material Weakness**

HRSA should (1) develop outcome measures for determining success of the LEND program; (2) work with grantees to develop more effective tracking of LEND graduates; and (3) use on-site visits to aid program oversight and to make funding decisions.

Status

Management Response

HRSA advised OIG that (1) performance measures for all Special Projects of Regional and National Significance, which includes training grants, have been developed and the data are now being collected which will allow HRSA to determine the success of the LEND program; (2) it is working with the Association of University Centers on Disabilities to develop better tracking mechanisms of former trainees; and (3) it is still on schedule to complete its goal of visiting 35 programs over the course of the grant project period. Approximately 28 of the 35 program visits have already been completed.

Public Health Service Agencies
-Health Resources and Services-

Faculty Loan Repayment Program - Making More Effective Use of Program Funds

Report Number: OEI-12-01-00510 Final Report: 01/2002

Finding

The Faculty Loan Repayment Program (FLRP) provides degree-trained health professionals from disadvantaged backgrounds with loan repayments of up to \$20,000 per year. In exchange, these individuals agree to serve as faculty members at medical or health-related institutions for at least 2 years. The academic institution is required by law to match the Federal Loan Repayment, unless they can demonstrate a financial hardship, in which case they can request a waiver. We found that waivers are routinely granted without an in-depth review of the institution's financial condition.

Current Law

The Faculty Loan Repayment Program was enacted as part of Public Law 101-527 Section 761 (November 6, 1990), the Disadvantaged Minority Health Improvement Act of 1990, and was codified in Section 738 (a) of the Public Health Service Act. The legislative history of the FLRP shows that Congress expected HRSA to apply certain criteria when making waiver decisions (House Report No. 101-804).

Recommendation

Legislative

Administrative

Material Weakness

HRSA should develop a policy for evaluating waiver requests. Such policy should include guidance on what documentation should be submitted by institutions seeking waivers.

Status

Management Response

HRSA agreed with our recommendation to consider developing policy guidance, and, as of February 2003, policy guidance providing criteria for defining a financial hardship was developed by HRSA. The members of the Federal Association of Schools of Health Professions, along with cognizant HRSA staff, provided assistance in developing this guidance.

HRSA disagreed with the OIG conclusion that reducing the number of waivers has the potential for stretching Federal dollars to assist more disadvantaged faculty applicants.

Public Health Service Agencies
-Health Resources and Services-

Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

Report Number: OEI-02-01-00640 Final Report: 03/2004
OEI-02-01-00641 03/2004

Finding

Title I and Title II project officers are not adequately monitoring sampled grantees (e.g., progress reports were missing; monitoring visits were not conducted; 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; 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).

Current Law

The Ryan White Care Act (Public Law 101-381) was passed in 1990 and reauthorized in 1996. The legislation provides funding to States and other public and nonprofit entities to develop and operate health care services and provide support services to underserved individuals affected by HIV/AIDS. 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.

Recommendation

Legislative Administrative **Material Weakness**

HRSA should: (1) specify and enforce standards and policies for 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

Management Response

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.

Public Health Service Agencies
-PHS Administration-

Improve Managed Care Organizations Reporting to the National Practitioner Data Bank

Report Number: OEI-01-99-00690 Final Report: 05/2001

Finding

Managed care organizations rarely submit adverse action reports to the National Practitioner Data Bank (Data Bank). From September 1, 1990, to September 30, 1999, they reported only 715 adverse actions. Although under-reporting could be caused by misunderstanding of the reporting requirement, the two most likely explanations are (1) limited focus on clinical oversight and (2) reliance on “downstream” entities such as hospitals, physician group practices, and State licensure boards to conduct quality monitoring of practitioners.

Current Law

The Health Care Quality Improvement Act of 1986 requires that adverse actions taken by health care entities such as hospitals and managed care organizations be reported to a National Practitioner Data Bank. Reportable actions encompass all professional review determinations that affect a physician’s or dentist’s clinical privileges for more than 30 days.

Recommendation

Legislative

Administrative

Material Weakness

We encouraged the Agency for Healthcare Research and Quality (AHRQ), as part of its patient safety efforts, to devote attention to the kind of educational and remedial efforts that could be directed to practitioners who have been experiencing performance problems. We also noted that HRSA, which operates the Data Bank, could play a helpful role in determining how best to deal with unsafe practitioners. HRSA should consider working with State licensure boards to find ways to increase their capacity to address quality of care cases. In addition, to the extent that underreporting is being caused by misunderstandings, we suggested that HRSA conduct an outreach program to inform managed care organizations of their reporting responsibilities. We also suggested that CMS examine its practitioner monitoring systems.

Status

Management Response

On November 8 and 9, 2004, HRSA and AHRQ cosponsored an invitational conference entitled “Quality and Patient Safety in Managed Care Organizations: Whose Responsibility is it Anyway?” Since much of direct patient care is actually delivered by physician practice groups, the framework of this conference included not only managed care organizations, but physician practice groups that contract with managed care organizations to deliver patient care. The goal of the conference was to reach consensus on issues related to responsibility for quality and patient safety in managed care organizations and to make innovative recommendations that reflect the thinking of the participants. In order to meet these goals, 15 experts were convened for a one and one-half day conference. Formal conference proceedings and recommendations will be developed from the discussions and decisions reached by the experts. In addition, HRSA has conducted several outreach efforts to better explain reporting requirements to managed care organizations. These efforts include sending reporting guidance letters directly to managed care organizations registered with the NPDB and participation by Data Bank staff as faculty in National Committee for Quality Assurance (NCQA) training sessions for managed care organizations.

Public Health Service Agencies
-PHS Administration-

Improve HRSA's Administration of Travel and Certain Personnel Requirements

Report Number: OAS-03-01-00351 Final Report: 02/2002

Finding

While no substantive violations of ethics or travel policies were found, OIG found that improvements were needed in the timeliness and completeness of certain personnel forms, as well as in HRSA's policy on approving travel.

Current Law

The Ethics in Government Act of 1978 provides that senior governmental officials, including Executive Level and Senior Executive Service members, file annual public financial disclosure reports (SF-278). The Supplemental Standards of Ethical Conduct for Employees (5 Code of Federal Regulations, Chapter XLV) set forth the requirements for HRSA employees wishing to perform outside activities or engage in outside employment.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that HRSA (1) provide routine training to employees to emphasize the need to obtain approval before engaging in outside activities and to ensure that required forms are filled out correctly and completely and are filed and approved timely; (2) monitor the review function for approval of financial disclosure reports and outside activity requests; and (3) revise its policy to require that supervisors approve travel, and change travel approval chains in the automated travel management system so that only supervisors can approve subordinates' travel orders and vouchers.

Status

Management Response

HRSA concurred with the recommendations and indicated that it was taking corrective actions to address certain recommendations.

Children and Families

Children and Families

Overview

HHS's Administration for Children and Families provides Federal direction and funding for State, local, and private organizations as well as for State-administered programs designed to promote stability, economic security, responsibility and self-support for the Nation's families. It also oversees a variety of programs that provide social services to the Nation's children, youth, and families, persons with developmental disabilities and Native Americans.

Major types of family support payments to States include: Temporary Assistance for Needy Families (TANF), a cooperative program among Federal, State and local governments that gives States flexibility to design their own programs in ways that require work participation, promote self-sufficiency, and strengthen families; and the Child Support Enforcement (CSE) program, which provides grants to States to ensure that children are financially and emotionally supported by both parents, and to enforce obligations of absent parents by establishing and enforcing child support orders. The Head Start program provides comprehensive health, educational, nutritional, social and other services to preschool children and their families who are economically disadvantaged. The Foster Care and Adoption Assistance programs provide grants to States to assist with the cost of foster care and special needs adoptions, maintenance, administrative costs, and training for staff. Other programs include Community Services, Child Care and the State Legalization Impact Assistance Grants programs.



Introduction

Related OIG Activities

The Office of Inspector General continues to focus on oversight of Children and Families programs and activities, including reviews of the effectiveness of children and families social services and assistance programs. Particular emphasis is placed on child support enforcement and initiatives designed to enhance family self-sufficiency. We identify opportunities to improve the delivery of program services such as improving oversight and monitoring the implementation of TANF, child welfare and child care, as well as ensuring that Head Start program objectives are accomplished.

Administration for Children and Families
Child Support Enforcement-

Improve Access to Medical Insurance for Dependents Receiving Child Support

Report Number: OEI-07-97-00500 Final Report: 06/2000

Finding

Considerable progress has been made by child support agencies in the identification and enforcement of medical support. Ninety-three percent of child support orders in our study included a provision requiring medical coverage for dependent children compared to 24 percent in our 1998 study. Undetected available medical insurance declined from 48 to 30 percent. Projected losses to all States dropped from \$32 million to \$5.2 million. Nevertheless, weaknesses still exist in the detection of health insurance availability and enrollment.

Current Law

The Social Security Act requires that the Medicaid program pay for beneficiary medical services secondary to other health insurances which may exist for beneficiaries. In 1984, Congress passed child support enforcement (CSE) amendments (PL 98-378), adding Section 452(f) to the Act mandating the promulgation of regulations involving Medicaid-eligible children in the Aid to Families with Dependent Children program. In 1985 and 1988 Federal regulations were issued that require State CSE agencies to collect and submit medical support information to the State Medicaid agency for use in its recovery activities. More recently, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PL 104-193) requires that all child support orders specifically include a provision for health care coverage.

Recommendation

Legislative

Administrative

Material Weakness

ACF should ensure compliance with regulations for enforcing medical support. In addition, as managed care has become a more common means of health care delivery, ACF, in conjunction with CMS, should examine alternatives to recover the costs of managed care premiums from the noncustodial parents.

Status

Management Response

The President's FY 2005 and FY 2006 budgets proposed legislation to improve medical support enforcement by requiring States to consider health care coverage available to both the noncustodial and custodial parent when establishing a medical support order and requiring that the IV-D agency receive a copy of any COBRA notice for IV-D children covered pursuant to a medical support order. ACF is working with CMS to develop a report from the Secretary of HHS to the Congress recommending legislation to support increased medical coverage for children. Also, ACF is sponsoring five regional meetings for State Medicaid, SCHIP and CSE directors to collaborate on new approaches for securing medical insurance for dependents and explore cost savings. In 2004, OCSE awarded Special Improvement Project grants to New Jersey, Montana, and Vermont and also awarded in 2004 a Section 1115 grant to Georgia to support State innovations in medical child support enforcement. In the continuing effort to secure medical insurance for dependents, OCSE and the Department of Labor have updated the National Medical Support Notice and reissued it based on comments from the public during the Paperwork Reduction Act process.

Administration for Children and Families
-Family Assistance

Improve Child Support Issues Related to Children on TANF

Report Number: OEI-05-99-00392 Final Report: 02/2002

Finding

We found that States pay some families less in Temporary Assistance for Needy Families (TANF) cash assistance than they collect in child support on their behalf. We also found that after leaving TANF, 8 percent of custodial parents in our 5 case study States experienced delays in receiving their child support payments and 3 percent were underpaid. Eleven States reported that they were not always able to accurately distribute child support. Additionally, in our case study States, there is no systematic oversight of the child support distribution process.

Current Law

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996, (P.L. 104-193), created the TANF program. Under TANF, Federal law requires families to assign their rights to child support payments to the State and cooperate with child support enforcement efforts. According to a departmental report to Congress, one in four families leaving TANF have child support collected on their behalf while they are on TANF. By law, the “assignment” of child support to the State must end upon a family’s exit from TANF.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF’s Office of Child Support Enforcement (OCSE) and the Office of Family Assistance (OFA) provide technical assistance to the State child support and TANF agencies to (1) improve automated system interfaces’ capacity to accurately and efficiently share caseload information and automatically redistribute collected child support, (2) ensure timely disbursement of collected support by emphasizing custodial parent address verification in the TANF discontinuation notice and the Child Support Enforcement continuing services notice, (3) implement policies and procedures for handling excess child support, and (4) improve accountability through a State self-assessment process that addresses the outcome of collections and distributions for families leaving TANF.

Status

Management Response

OCSE and OFA continue to work together to provide technical assistance to State child support and TANF agencies. These activities include: a IV-A/IV-D data exchange workgroup which met May 2004, several Urban Initiative meetings in 2004 which addressed this issue, and follow-up training in Los Angeles, CA, and Philadelphia, PA, both in August 2004. In addition OCSE is working with OFA to enable State IV-D agencies to obtain data from the National Directory of New Hires (NDNH) to assist the States in identifying potential fraud and under reporting of income.

A “Dear Colleague Letter,” DCL-03-28, was issued to State IV-A and IV-D agencies to encourage the agencies to work together to serve families. The letter asked State directors to jointly examine whether the links between the programs were adequate to assure: improved transfers of information between IV-A and IV-D workers achieved through mutual redesign of automated systems; full, accurate and prompt child support payments as families exit TANF; timely and accurate referrals from IV-A to IV-D so that court orders for child support can be promptly obtained; and TANF clients better educated on services they can expect from the Child Support Office, and on the importance of updating their addresses to assure timely payment of child support.

Administration for Children and Families
-Family Assistance

Improve Methods of Recruiting Foster Parents

Report Number: OEI-07-00-00600 Final Report: 05/2002

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.

Current Law

ACF has regulatory oversight of the Title IV-E Foster Care program. The Title IV-E Foster Care program is 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.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

ACF concurred with our findings and recommendations, stating that the information presented in this report will be useful to them in its continued efforts to meet the needs of children in need of care. ACF's comments emphasize its continued focus on the importance of children's issues. In addition, ACF provided important contextual information in which, for example, ACF notes that States can use some Federal funds for child care and respite care services and that 64 percent of foster children adopted in 1999 were adopted by foster parents.

Administration for Children and Families
-Family Assistance

Improve State Strategies for Working with Hard-to-Employ TANF Recipients

Report Number: OEI-02-00-00630 Final Report: 07/2002

Finding

We found that States rely on the following strategies to identify each of the eight significant barriers to employment for TANF recipients: using standardized tools (e.g., brief screening instruments; comprehensive needs assessments administered face-to face or as written questionnaires); developing partnerships with other agencies and organizations to serve recipients; and referring recipients to receive appropriate services. States have also structured their TANF policies to provide additional flexibility for recipients with barriers. However, States report that challenges to help recipients with multiple barriers and to effectively track and evaluate how well these populations are being served remain.

Current Law

The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA, P.L. 104-193) of 1996 replaced the Aid to Families with Dependent Children Federal entitlement program with the Temporary Assistance for Needy Families block grant program. The legislation imposes strict work requirements, limits Federal assistance to 5 years, and establishes minimum work participation rates. Within these limits, States have broad flexibility to design their own programs to promote work and self-sufficiency.

Recommendation

Legislative

Administrative

Material Weakness

This inspection suggested several opportunities to improve the TANF program to better serve the hard-to-employ recipients. Based on our findings, ACF could encourage States (1) to create and expand innovative programs to better serve recipients with barriers, particularly facing multiple barriers, and (2) to expand States' capacity to track recipients who have barriers to employment to increase capacity to evaluate their initiatives that address these populations and the effects of their sanction policies.

Status

Management Response

ACF is in general agreement with the background, findings, and "next steps" identified in this inspection. We concurred with ACF that the Administration's proposed reauthorization legislation (as of May 7, 2002) is consistent with our findings and next steps. We further recognized that ACF's past and on-going technical assistance efforts continue to assist States in implementing initiatives to better serve hard-to-employ populations. However, we urged ACF to consider more targeted efforts regarding the next steps that we outlined.

Administration for Children and Families
-Children, Youth and Family Services-

Improve Efforts to Increase the Qualifications of Head Start Teachers

Report Number: OEI-07-01-00560 Final Report: 01/2004

Finding

According to the Administration for Children and Families (ACF), 51 percent of Head Start teachers held appropriate degrees in enrollment year 2002, effectively meeting the Community Opportunities, Accountability, and Training and Educational Services (COATS) Act mandate. OIG found that several factors have contributed to Head Start's progress in increasing teachers' qualifications. Disparities exist in individual programs' progress in meeting ACF's self-imposed goal that all programs strive to achieve 50 percent degreed teaching staff. The lack of attainment of ACF's self-imposed goal was particularly acute in 15, mostly southern, States. Also noted were 72 counties with multiple Head Start programs, where at least 1 program met ACF's self-imposed goal and at least 1 had not.

Current Law

The Community Opportunities, Accountability, and Training and Educational Services Act (P.L. 105-285) of 1998 reauthorized the Head Start program through FY 2003 and amended the Head Start Act to require more specific education performance standards and increased teacher qualifications. The COATS Act specifically mandates that by September 30, 2003, at least 50 percent of Head Start teachers nationwide in center-based programs must have an associate, baccalaureate, or advanced degree in early childhood education, or a degree in a field related to early childhood education, with experience teaching preschool children.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF, in conjunction with its regional offices, provide targeted assistance to those programs where the level of degreed teaching staff is below 50 percent. The first priority should be to assist programs that are having the most difficulty. Special attention also must be focused on Alaska Native/Native American, migrant, and Early Head Start programs that experience special challenges.

Status

Management Response

ACF concurred with our recommendation. The Head Start Bureau has recently completed implementation of a new Training and Technical Assistance System (T/TA). Under this system, T/TA staff specialists are assigned to local grantees to assist in the identification and delivery of T/TA. They will work with those grantees with low percentages of degreed staff to find ways to increase staff qualifications. Head Start plans to continue to explore ways to work with local or State organizations on innovative ways to assist grantees in increasing their number of degreed teachers. They also plan to increase their State Collaboration Offices, where appropriate, to explore ways to increase staff credentials. Finally, once Head Start is reauthorized, they will develop strategies to implement any new requirements that may be included in the reauthorization.

Administration for Children and Families
-ACF Administration-

Improve Employment Programs for Persons with Developmental Disabilities

Report Number: OEI-07-98-00260 Final Report: 08/1999

Finding

While State Developmental Disabilities Councils do not obtain direct employment for persons with developmental disabilities, they are instrumental in facilitating job opportunities for them. A number of positive initiatives are being undertaken by State Councils. However, identifying performance data is difficult.

Current Law

The Developmental Disabilities Assistance and Bill of Rights Act established Developmental Disabilities Councils in each State. Councils receive approximately \$65 million annually from ACF.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF establish core data requirements to evaluate job initiatives and work with State councils to share promising and innovative practices.

Status

Management Response

ACF's Administration for Developmental Disabilities has established several data reporting requirements to evaluate employment initiatives. For example, all Developmental Disabilities Councils now report annually on the number of adults with developmental disabilities that secure jobs.

Administration for Children and Families
-ACF Administration-

Improve TANF Client Sanction Notices

Report Number: OEI-09-98-00292 Final Report: 10/1999

Finding

Comprehensive and understandable notices can improve the sanction process. Sanction notices are deficient in some respects. Although most notices adequately explain some sanction details, many lack instructions on how to resolve sanctions. Confusing wording on notices impedes client understanding, an effect heightened by language barriers.

Current Law

Public Law 104-193 directs States to sanction Temporary Assistance for Needy Families clients for failure to participate in work activities and noncooperation with child support enforcement efforts.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF encourage States to issue comprehensive and understandable sanction notices.

Status

Management Response

ACF concurred with our recommendation. CMS conducted Medicaid/TANF access reviews and identified concerns about the clarity of TANF notices. As a result, a number of States have been working on improving their notices.

Administration for Children and Families
-ACF Administration-

Strengthen State Licensing of Residential Foster Care

Report Number: OEI-02-98-00570 Final Report: 05/2000

Finding

While States are meeting Federal requirements to establish standards and license facilities, some standards and licensing procedures differ among States. For example, of the nine States in our sample, one State prohibited the use of restraints and one State did not have policies on their use. The other seven States either address the use of restraints in their standards or require facilities to develop their own policies. Six of the nine States regulate the use of isolation.

Current Law

Title IV-E of the Social Security Act states that in order for a residential facility to receive Federal foster care payments the institution must “be licensed by the State in which it is situated or have been approved, by the agency of such State responsible for licensing or approval of institutions of this type...”

Recommendation

Legislative

Administrative

Material Weakness

As an opportunity for improvement, ACF should take a leadership role by working with States to provide technical assistance and facilitate information sharing.

Status

Management Response

No corrective action plan has been submitted to date. ACF agreed that variability in licensing standards is of concern. ACF indicated that they are taking an outcome-based approach to monitoring States.

Administration for Children and Families
-ACF Administration-

Strengthen Adoption and Foster Care Analysis and Reporting System (AFCARS)

Report Number: OEI-07-01-00660 Final Report: 03/2003

Finding

We found that ACF's Child Welfare Outcomes Reports, which include AFCARS data, were not being published timely and published data were incomplete and inconsistent. In addition, States experienced difficulties accessing technical assistance and were concerned about penalties associated with AFCARS reporting.

Current Law

Federal regulations require all States to report child-specific foster care and adoption data to ACF through AFCARS. The final rule, published in the Federal Register on December 22, 1993, requires States to collect and report specific information (66 data elements) about all children in foster care for whom the State has responsibility for placement, care, or supervision. The regulations also require information (37 data elements) about each child under State jurisdiction who was adopted or for whom the State agency is providing adoption assistance.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF should work to make AFCARS data more useful, increase the accessibility of technical assistance resources, and develop incentives to help ensure State compliance with AFCARS regulations.

Status

Management Response

ACF supported our recommendations and indicated that it is assessing internal agency processes for analyzing data and meeting required reporting time frames; however, a corrective action plan has not been submitted.

Administration for Children and Families

-ACF Administration-

Improve Foster Care Children's Use of Medicaid Services in New Jersey

Report Number: OEI-02-00-00360 Final Report: 07/2003

Finding

OIG found that 2 years of Medicaid claims for 50 foster children in New Jersey show that few of these children are receiving Medicaid services, particularly Early and Periodic Screening Diagnosis and Treatment (EPSDT) services, although all the children have coverage. In addition, the interviews with the caseworkers and caregivers reveal that they are not informed about the Medicaid program, and they have received very little training in Medicaid services. Also, we found that most caseworkers and caregivers did not receive their foster child's medical information and report difficulty finding Medicaid providers.

Current Law

The Medicaid program provides health care to low-income persons and long term care to the disabled and low-income elderly. 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 states that children in foster care who are covered under Title IV-E of the Social Security 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 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.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that ACF work with the State of New Jersey to provide more training to caseworkers and caregivers on the Medicaid program, EPSDT, and managed care. In addition, we recommended that ACF and CMS work with New Jersey to address the concerns of caseworkers and caregivers regarding the lack of access to Medicaid providers and to promote communication.

Status

Management Response

Both ACF and CMS agreed with our recommendations. ACF indicated that each year States are required to review and update a comprehensive 5-year Child and Family Services Plan to address newly identified areas needing improvement. Giving the findings of our report, ACF will involve the State of New Jersey in discussions about its need to provide training to caregivers and caseworkers for the purpose of ensuring a greater level of services for foster children in need of medical and mental health services from Medicaid providers. The Child and Family Service Reviews are designed to identify both strengths and weaknesses in States' child welfare programs. New Jersey was reviewed in 2004. ACF also looks forward to coordinating with CMS regarding access to Medicaid providers and the communication between New Jersey Medicaid and the Division of Youth and Family Services.

Administration for Children and Families
-ACF Administration-

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

Report Number: OEI-07-00-00640 Final Report: 08/2003

Finding

OIG determined that all children in foster care in Kansas are eligible for Medicaid health care services, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services. The report verified that all 50 children in the sample had received Medicaid health care services since entering foster care. It also verified that all 50 sampled children had received mental health services. However, we found that foster care providers experienced difficulty locating dentists willing to accept new Medicaid patients, and 20 of the 46 foster care providers interviewed never received a medical history for the child in their care.

Current Law

The Medicaid program provides health care to low-income persons and long term care to the disabled and low-income elderly. 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 states that children in foster care who are covered under Title IV-E of the Social Security 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 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.

Recommendation

Legislative

Administrative

Material Weakness

OIG recommended that ACF work with the Kansas Department of Social and Rehabilitation Services (SRS) to promote the importance of obtaining medical histories for children in foster care and providing available health care information to foster parents. CMS should work with Kansas SRS to increase the number of Medicaid health care providers willing to provide services to children in foster care and develop lists of Kansas' health care providers participating in the Medicaid program willing to treat these children.

Status

Management Response

Both ACF and CMS concurred with our recommendations. ACF is actively working with the Kansas Department of Social and Rehabilitation Services on the recommendations to promote the importance of obtaining medical histories for children in foster care and providing this information to foster parents. Specific actions are included in the Program Improvement Plan developed in response to a Child and Family Services Review in Kansas. The ACF regional office will be monitoring the progress of this plan quarterly.

Administration for Children and Families
-ACF Administration-

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

Report Number: OEI-07-00-00642 Final Report: 03/2004

Finding

OIG determined that all 50 sampled children in the Illinois foster care program are receiving Medicaid services, and nearly all children received their most recent required Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) medical and dental examinations and initial health examination upon entry into foster care. In contrast, less than half of the sampled children received a comprehensive health care evaluation and mental health screening. We also found less than half of case files contained a copy of the medical history, which is required by State and Federal regulations designed to ensure that children are provided with needed health care services. As a result, several children received duplicate services.

Current Law

The Medicaid program provides health care to low-income persons and long term care to the disabled and low-income elderly. 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 states that children in foster care who are covered under Title IV-E of the Social Security 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 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.

Recommendation

Legislative

Administrative

Material Weakness

OIG recommended that ACF work with the Illinois Department of Children and Family Services (DCFS) to ensure that Comprehensive Health Evaluations and Mental Health Screens are conducted within required timeframes and that Health Passports are (1) updated on an ongoing basis, (2) reviewed for accuracy and completeness during the Administrative Case Review, (3) copied each time the health information is updated, and (4) maintained in the case file, with the original provided to the foster care provider. CMS should work with the Illinois Department of Public Aid to prevent potentially unnecessary costs to the Medicaid program resulting from duplicate services.

Status

Management Response

ACF is actively working with the Illinois DCFS to improve the provision of health and mental health services to children in foster care. These services will be addressed in Illinois' Program Improvement Plan in response to a Child and Family Services Review. CMS agrees in part with our recommendation, recognizing the concern about the potential for Federal and State funds being unnecessarily expended for duplicate Medicaid services; however, CMS believes DCFS should work to better inform foster care parents and providers of the availability of services and the State requirements under the Healthworks and Passport program.

Administration for Children and Families
-ACF Administration-

Improve Foster Care Children's Use of Medicaid Services in Oregon

Report Number: OEI-02-00-00363 Final Report: 06/2004

Finding

OIG found that the foster care children in the sample have Medicaid coverage and access to services. Targeted case management is the most common and most costly Medicaid claim for children in our sample. Yet we found that recipients do not receive any extra, or even ordinary, health care as a result of targeted case management. Twenty of the fifty sampled foster care children did not have preventive care claims during the study period. This lack of preventive care may be due, in part, to the belief of some Oregon officials that Oregon is not bound by any Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) requirements. In fact, Oregon is bound by EPSDT requirements and is relieved only from its obligation to pay for services required to treat a condition identified during an EPSDT screening that are beyond the scope of the benefits package available to an individual receiving Medicaid. For some foster care children in the sample, caregivers have difficulty obtaining medical records and accessing dental and mental health services. We also found that sampled children placed out-of-State experience problems obtaining medical coverage.

Current Law

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 states that children in foster care who are covered under Title IV-E of the Social Security 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 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.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that CMS review the use of targeted case management for foster care children in Oregon to ensure that it is consistent with State plan provisions and current CMS requirements. CMS should work with Oregon to clarify the intent of the EPSDT portion of Oregon's 1115 waiver and the State obligations under EPSDT. The Administration for Children and Families should work with Oregon to promote preventive health care consistent with EPSDT guidelines. Finally, ACF should address the health care needs of foster care children placed across State lines.

Status

Management Response

Both CMS and ACF concurred with our recommendations. CMS is willing to work with the State of Oregon on the EPSDT issues identified in this report.

Administration for Children and Families
-ACF Administration-

Improve Children's Use of Health Care Services While in Foster Care: North Dakota

Report Number: OEI-07-00-00643 Final Report: 08/2004

Finding

OIG found that all 50 of the children in our sample had Medicaid coverage and Medicaid claims for health care services. Thirty-five of the fifty sampled children received their most recent required Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) examination, and 30 of 38 sampled children required to receive EPSDT dental services had received their most recent EPSDT dental service. Some sampled children waited months after entering foster care to receive an initial comprehensive medical examination recommended by the State. We also found that mental health needs were not documented for 12 of the 34 sampled children who received mental health services as Federal law requires. Such documentation is important to ensure that children receive appropriate and necessary services timely. Finally, Federal law and State policy require that foster care providers (i.e., foster parents or residential care facility staff) receive medical information about the child in their care, yet 9 of the 48 foster care providers interviewed reported never receiving this information.

Current Law

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 states that children in foster care who are covered under Title IV-E of the Social Security 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 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.

Recommendation

Legislative **Administrative** **Material Weakness**

ACF should work with the North Dakota Division of Children and Family Services to examine how initial comprehensive medical examinations for children entering foster care are being provided; ensure that case plans reflect required mental health needs; and promote the importance of caseworkers obtaining medical information for children in foster care and giving the medical information to foster care providers, in accordance with Federal requirements. CMS should work with the North Dakota Division of Medical Services to develop a method for notifying foster care providers of when required EPSDT services are due; and to increase the number of dental providers accepting Medicaid in North Dakota. ACF and CMS should work with the North Dakota Department of Human Services to coordinate State agency efforts to educate caseworkers and foster care providers regarding the importance and availability of EPSDT medical examinations; to ensure caseworkers and foster care providers understand the difference between comprehensive EPSDT examinations and medical examinations for specific health conditions; and to educate caseworkers and foster care providers regarding State EPSDT frequency schedules for dental services.

Status

Management Response

ACF 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. Many of these issues are being addressed in the Program Improvement Plan developed in response to a Child and Family Services Review. CMS generally concurred with our recommendations but clarified that they should be carried out by joint action of the North Dakota Divisions of Medical Services and Children and Family Services. CMS stated that their regional office staff is available to provide technical assistance to both Divisions, as appropriate.

Older Americans

Older Americans

Overview

The Administration on Aging (AoA) aims at improving older American's quality of life through nutrition and service programs which help senior citizens remain independent for as long as possible.

Over 40 million people are 60 years of age or older. While most older Americans are active members of their families and communities, others are at risk of losing their independence. These include 4 million Americans aged 85 and older living alone without a care giver.

AoA is dedicated exclusively to policy development, planning, and the delivery of supportive home and community-based services to our Nation's diverse population of older Americans and their caregivers. AoA also provides critical information and assistance and programs that protect the rights of vulnerable, at-risk older persons through the Older Americans Act of 1965.



Introduction

Working in close partnership with its sister agencies in HHS and throughout the executive branch of Government, AoA leads a national aging network which includes AoA's central and regional offices; 57 State units on aging; 655 area agencies on aging; 223 tribal organizations, representing 300 tribes; and thousands of service providers, senior centers, care givers, and volunteers.

Related OIG Activities

The Office of Inspector General continues to focus on oversight of older Americans programs and activities. Particular emphasis is on improving nutrition for the elderly, providing transportation, developing guidelines for ombudsman programs, and helping end the abuse, exploitation, and neglect of older people.

Administration on Aging
-Nutrition and Services-

Improve Safeguards for Long Term Care Residents

Report Number: OAS-12-97-00003 Final Report: 09/1998

Finding

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, but those that do believe the checks 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.

Current Law

Under CMS statute and regulations, residents of nursing homes and other long term care 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.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that (1) CMS and AoA work collaboratively with the States to improve the safety of long term care 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

Management Response

CMS and AoA agreed with our recommendations and have planned or taken some actions to improve safeguards for long term care residents in nursing homes. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) established the framework for a program to evaluate national and State background checks on direct patient access employees of long term care facilities or providers. The program, which may include up to 10 States, will identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks.

Administration on Aging

-AoA Administration-

Improve Long Term Care Ombudsman Program

Report Number:

OEI-02-98-00351

Final Report:

03/1999

Finding

The Ombudsman program's overall capacity to monitor and promote nursing home care is limited. First, the program is limited by staffing constraints, leading to limited regular nursing home visits by ombudsmen. The program is further constrained by the lack of a common standard for complaint response and resolution, inconsistent advocacy efforts, a lack of support, and limited collaboration with surveyors.

Current Law

The Ombudsman program is authorized by Title VII of the Older Americans Act. State ombudsmen programs have multiple functions which are mandated by law, many of which are closely tied to ensuring quality care for long term care residents. They include: (1) identifying, investigating, and resolving complaints; (2) protecting the legal rights of patients; (3) advocating for systemic change; (4) providing information and consultation to residents and their families; and (5) publicizing issues of importance to residents.

Recommendation

Legislative



Administrative

Material Weakness

We recommended that AoA work with States to strengthen the Ombudsman program. In particular, AoA should (1) develop guidelines for a minimum level of program visibility; (2) further highlight strategies for recruiting, training, and supervising more volunteers; (3) develop guidelines for complaint and resolution times; (4) continue to strengthen the program's data reporting system; and (5) work with CMS to enhance collaboration with the survey and certification agency.

Status

Management Response

Recommendations are implemented through annual national, State and regional ombudsman training conferences, frequent ombudsman teleconferences, and an array of materials. These include the following comprehensive documents developed by AoA during 2003-04: (1) a self-evaluation tool covering all aspects of ombudsman work, developed with input from all State ombudsmen; (2) development of a training curriculum for teaching basic ombudsman skills and knowledge, utilizing adult education methodology (the first of four modules has been completed); and (3) an update to the Ombudsman Desk Reference and the Ombudsman Guide to the Omnibus Budget Reconciliation Act, which address all aspects of ombudsman work in nursing homes.

In addition to providing training on volunteer recruitment and management at ombudsman conferences, two 1.5 hour national teleconferences were held in 2004 for State and local volunteer coordinators, with an average of 75 people on each call. Also in 2004, AoA conducted an extensive training program to improve the uniformity and consistency in reporting ombudsman case and complaint data, training about 1260 State and local ombudsmen through 7 on-site trainings and 42 teleconferences. Additional required training is being conducted by every State ombudsman program.

AoA developed materials, including a training curriculum, to assist State and local ombudsman programs in helping residents, families, and consumers understand the CMS Nursing Home Quality Initiative. AoA also provided conference calls and other forums to enhance collaboration between the State ombudsmen and the Quality Improvement Organizations on several initiatives, including the CMS Nursing Home Quality Improvement Initiative, the Home Health Quality Initiative, and the Quality Improvement Organization Medicare Beneficiary Mediation Option.

Administration on Aging

-AoA Administration-

Improve the Consistency of Reporting the National Ombudsman Reporting System Data and Continue to Clarify and Refine the Process

Report Number: OEI-09-02-00160 Final Report: 03/2003

Finding

Nationally, from 1996 to 2000, the number of nursing home complaints reported to State ombudsmen increased, but the types of complaints did not change significantly. We also found from our sampled States, that local ombudsmen do not uniformly report complaints into National Ombudsman Reporting System (NORS).

Current Law

To protect the interest of nursing home residents, Congress established the State Long Term Care Ombudsman Program in a 1978 amendment to the Older Americans Act. The Older Americans Act requires States to collect ombudsman complaint data and for the State ombudsman to report aggregate data to the Administration on Aging (AoA). In 1995, AoA implemented NORS.

Recommendation

Legislative

Administrative

Material Weakness

We recommended that AoA improve the consistency of reporting NORS data, share this report with State ombudsmen, and continue to clarify and refine the NORS process.

Status

Management Response

AoA agreed with our recommendations. It plans to conduct regional and State training on the use of complaint codes.

General Department Management

General Department Management

Overview

The Office of Inspector General's (OIG) departmental management and governmentwide oversight role includes reviews of payroll activities, accounting transactions, implementation of the Federal Manager's Financial Integrity Act and the Prompt Pay Act, financial management audits under the Chief Financial Officer's Act, grants and contracts, HHS's Working Capital Fund, conflict resolution, and adherence to employee standards of conduct. OIG also participates in interagency efforts through the President's Council on Integrity and Efficiency to prevent losses to and abuses of Federal programs.

In addition, OIG has oversight responsibility for audits conducted of certain Government grantees by non-Federal auditors, principally public accounting firms and State audit organizations. The Office of Management and Budget (OMB) Circular A-133 designates HHS as the cognizant agency for most States and major research organizations. In addition, the OIG is responsible for auditing HHS's financial statements.

The general Department management includes overall direction for departmental activities and common services such as personnel, accounting, and payroll to departmental operating divisions.



Introduction

Related OIG Activities

The OIG's work in departmental management and governmentwide oversight focuses principally on financial statement audits, financial management and manager's accountability for resources entrusted, standards of conduct and ethics, and governmentwide audit oversight, including recommending necessary revisions to OMB guidance. OIG also reviews the adequacy of States' systems to control the growth of administrative/indirect costs claimed for Federal financial participation.

General Department Management
-Financial Management

Update Cost Principles for Federally Sponsored Research Activities

Report Number: OAS-01-92-01528 Final Report: 05/1993

Finding

HHS's hospital cost principles for federally sponsored research activities contained in 45 CFR, Part 74, Appendix E (known as OASC-3) are not up to date and do not always provide clear guidance for determining what types of costs should be allowed and how costs should be allocated.

Current Law

The OASC-3 was published over 25 years ago when the research environment and Federal funding rules were less complex.

Recommendation

Legislative

Administrative

Material Weakness

The Assistant Secretary for Budget, Technology, and Finance (ASBTF) should modernize and strengthen the cost principles applicable to hospitals by either (1) revising OASC-3, where applicable, for consistency with OMB Circular A-21, or (2) working with OMB to extend Circular A-21 coverage to all hospitals.

Status

Management Response

ASBTF is working with various offices at HHS and OMB to address concerns related to the draft updated Hospital Cost Principles document which has been circulated through the HHS for review and comment. When the updated Hospital Cost Principles are finalized, the related guidance will be updated.

General Department Management
-Financial Management

Incorporate Provisions for Implementing FASB 106 in Guidelines To Reimburse Educational Institutions and Nonprofit Organizations

Report Number: OAS-01-93-04000 Final Report: 06/1993

Finding

The Financial Accounting Standards Board Statement Number 106 (FASB 106) affects postretirement benefit costs claimed for reimbursement by schools and nonprofit organizations conducting federally sponsored research. The FASB 106 changed the treatment of these costs from the cash basis to the accrual basis of accounting.

Current Law

Currently, OMB Circulars A-21, “Cost Principles for Educational Institutions,” and A-122, “Cost Principles for Nonprofit Organizations,” do not state whether the accrued portion of postretirement benefit expenses should be recognized as a reimbursable cost. Without guidance on whether accrued expenses should be charged, scarce Federal research funds may be used to reimburse unfunded postretirement benefit costs.

Recommendation

Legislative

Administrative

Material Weakness

ASBTF should (1) work with OMB to revise applicable cost principles to address the impact of FASB 106 on postretirement benefit costs, and (2) advise negotiators for the Division of Cost Allocation to pay special attention to such costs when reviewing fringe benefit rates for schools and nonprofit organizations.

Status

Management Response

ASBTF views the requirements of FASB 106 as sound accounting policy that will more accurately disclose the affected entities’ liabilities. However, from the perspective of good public policy regarding cost reimbursement under Federal grants, neither ASBTF nor OMB believes that Federal funds should be paid to grantees when they have not actually funded these costs. This policy is consistent with HHS’s policy concerning accrued leave costs. OMB has advised that it will formalize this policy in Circulars A-122 and A-21 when they are next revised.

General Department Management
-Financial Management

Improve Financial Analysis and Reporting Processes

Report Number:	OAS-17-98-00001	Final Report:	04/1998
	OAS-17-98-00015		02/1999
	OAS-17-99-00002		02/2000
	OAS-17-00-00014		02/2001
	OAS-17-01-00001		02/2002
	OAS-17-02-00001		01/2003
	OAS-17-04-00001		12/2004

Finding

The FY 2004 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. Substantial manual processes are used to summarize accounting data, perform reconciliations, make adjustments and prepare financial statements. These manual processes increase the risk that financial statements may be materially misstated and contribute to delays in preparing statements in a timely manner. Many operating divisions did not follow HHS policies or conduct all required financial oversight, analyses, and reconciliations throughout the year. Had the required analysis been performed timely, many anomalies would have been detected earlier. Analysis and reconciliation are effective internal controls for detecting and correcting duplicate postings, omitted entries, or incorrect transfer of data—all of which could result in material misstatements.

Current Law

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. Government Auditing Standards and OMB Bulletin 01-02, Audit Requirements for Federal Financial Statements, provide auditors with guidance to audit and report on the Federal financial statements.

Recommendation

Legislative Administrative Material Weakness

Pending installation of the new systems under development, routinely meeting accelerated reporting deadlines will require changes in processes. Some of the auditors recommendations were that HHS operating divisions (1) implement corrective actions to mitigate system deficiencies that impair the capability to support and report accurate financial information; (2) develop formal procedures to conduct periodic, detailed reviews and analyses of transactions within the subsidiary ledgers; (3) establish controls to identify, research, and resolve significant accounting anomalies in a timely manner; (4) allocate adequate resources to perform required account reconciliations and analyses monthly; and (5) ensure, as required by OMB Bulletin 01-09, Form and Content of Agency Financial Statements, the preparation of future years' interim financial statements supported by reconciliations and account analyses to ensure such reporting is accurate for decisionmaking. Furthermore, ASBTF should oversee CMS's corrective actions to provide a mechanism for central and regional office monitoring of contractors' activities and enforcement of compliance with CMS financial management procedures.

Status

Management Response

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 within HHS with a Unified Financial Management System (UFMS). HHS noted it was well on its way to implementing this new system. 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 2006. HHS plans to implement the UFMS departmentwide by 2007.

General Department Management
-Crosscutting Issues-

Strengthen State Protections for Persons With Disabilities in Residential Settings

Report Number: OAS-01-00-02502 Final Report: 05/2001

Finding

Up to 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 where 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.

Current Law

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.

Recommendation

Legislative

Administrative

Material Weakness

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

Management Response

OIG received positive feedback from the responsible operating divisions and detailed actions they planned or are taking to improve safeguards. For example, SAMHSA has a grant program, begun in FY 2001, to identify effective alternative practices, including training efforts, to reduce restraint and seclusion practices, and will promote the application of the findings from these grants.

Statutory and Administrative Responsibilities

Effective April 1989, statutory authority for the Office of Inspector General was transferred from Public Law 94-505 to 95-452, as amended. Other statutory and administrative reporting and enforcement responsibilities include:

AUDIT AND MANAGEMENT REVIEW RESPONSIBILITIES AND OFFICE OF MANAGEMENT AND BUDGET CIRCULARS

P.L. 96-304	Supplemental Appropriations and Rescissions Act of 1980
P.L. 96-510	Comprehensive Environmental Response, Compensation and Liability Act
P.L. 97-255	Federal Manager's Financial Integrity Act
P.L. 97-365	Debt Collection Act of 1982
P.L. 98-502	Single Audit Act of 1984
P.L. 99-499	Superfund Amendments and Reauthorization Act of 1986
P.L. 100-504	Inspector General Act Amendments of 1988
P.L. 101-121	Governmentwide Restrictions on Lobbying
P.L. 101-576	Chief Financial Officers Act of 1990
P.L. 102-486	Energy Policy Act of 1992
A-21	Cost Principles for Educational Institutions
A-25	User charges
A-50	Audit Followup
A-70	Policies and Guidelines for Federal Credit Programs
A-73	Audit of Federal Operations and Programs
A-76	Performance of Commercial Activities
A-87	Cost Principles for State, Local, and Indian Tribal Governments
A-88	Indirect Cost Rates, Audit, and Audit Followup at Educational Institutions
A-102	Cooperative Agreements with State Grants and Local Governments
A-110	Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations
A-122	Cost Principles for Nonprofit Organizations
A-123	Management Accountability and Control
A-127	Financial Management Systems
A-128	Audits of State and Local Governments
A-129	Policies for Federal Credit Programs and Non-Tax Receivables
A-133	Audits of States, Local Governments and Other Nonprofit Organizations
GAO	Government Auditing Standards

INTERNET ACCESS

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