Department of Health and Human Services
Office of Inspector General

Program and Management Improvement Recommendations

The Orange Book

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OFFICE OF INSPECTOR GENERAL

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

Office of Audit Services

The OIG's 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 the Department.

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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. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, 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 administrative action, while some call for a change in legislation. Although these recommendations generally have a nonmonetary impact when implemented, the Department 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 requires that OIGs' semiannual reports to the 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 the Congress have in one document significant program and management improvement recommendations.

HEALTH AND HUMAN SERVICES

The Department 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 the elderly, disabled, and the poor. 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 Department operates within four agencies: Health Care Financing, Public Health, Children and Families, and Older Americans, as well as general departmental management. An overview of these agencies and related OIG findings and recommendations are highlighted in separate sections of this Orange Book.

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Health Care Financing

Overview

The Health Care Financing agency encompasses the Medicare and Medicaid programs, and the State Children's Health Insurance Program (SCHIP).

Introduction

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 were 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.

Related OIG Activities

The Office of Inspector General (OIG) activities that pertain to the health insurance programs administered by the Health Care Financing Administration (HCFA) 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.

Health Care Financing

Develop Prepayment Edit to Verify Medical Necessity of Ambulance Claims

Report Number: OEI-09-95-00412 Final Report: 11/98

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/Policy

The HCFA regulations state that ambulance services are covered only if other forms of transportation would endanger the beneficiary's health. The Balanced Budget Act of 1997 (BBA) mandates that HCFA work with the industry to establish a negotiated fee schedule for ambulance payments effective January 1, 2000.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA 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 HCFA and the industry can better address issues of medical necessity, including clear and consistent definitions.

Status

Management Response

In comments on our draft report, HCFA concurred with the need for medical review of these types of ambulance claims. The HCFA intends to issue a vulnerability report to all Medicare carriers so that where medical review workloads allow, each contractor could develop edits to assure appropriate ambulance payments.

Health Care Financing

Strengthen HCFA Regional Office Oversight of Medicare Contractors

Report Number:	OAS-17-97-00097	Final Report:	4/98
	OAS-17-98-00098		2/99
	OAS-17-00-00500		2/00

Finding

The HCFA regional offices have oversight responsibility for Medicare contractors, which submit periodic financial reports used in preparing HCFA's financial statements. Our audit of HCFA's FY 1999 financial statements identified continuing problems with the internal control procedures used by the regional offices to evaluate Medicare contractors' compliance with contracts, laws, and regulations. While we noted continued improvement in many regional office oversight procedures, certain procedures were not adequate or were not performed consistently in all regions to ensure that financial data provided by contractors were reliable, accurate, and complete.

Current Law/Policy

Guidance for the oversight effort is found in the Contractors Performance Evaluation (CPE) review process.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should (1) expand current assessment and onsite review procedures to provide the appropriate coverage of contractor operations; (2) enhance controls to ensure the appropriate tracking of contractor responses to CPE reports and the appropriate level of supervisory review related to CPEs; (3) provide additional guidance and training to communicate expectations and the procedures to be performed by regional offices to ensure that HCFA 750/751 and HCFA 1522 reports are submitted timely and are properly reconciled to accounting records; (4) develop a review protocol to directly evaluate the reliability of contractors' self-assessments of their internal controls; (5) ensure that Provider Overpayment Recovery and Physician Supplier Overpayment Recovery data are accurate, valid, and complete for all Medicare contractors; and (6) ensure that all regional offices use and document risk assessments in allocating resources to reviews.

Status

Management Response

The HCFA has developed a corrective action plan and has attempted to improve many of the Medicare oversight procedures performed by the regional offices.

Health Care Financing

Improve Evaluation of Fraud Unit Performance

Report Number: OEI-03-97-00350 Final Report: 11/98

Finding

Fiscal intermediary fraud units differed substantially in the number of complaints and cases handled. Some units produced few, if any, significant results. Despite HCFA's expectation that fraud units proactively identify fraud, half of the fraud units did not open any cases proactively. More than one-third of fraud units did not identify program vulnerabilities.

Current Law/Policy

Fiscal intermediaries and carriers are companies under contract with HCFA to administer a major part of the Medicare program. As of 1993, HCFA requires that fiscal intermediaries and carriers have distinct units to detect and deter fraud and abuse. From 1993 through 1997, funding was based mainly on the contractors' claim volume. However, in Fiscal Year 1998, HCFA changed the funding methodology to take into account the contractors' workload, risk, and performance. All fraud units must meet requirements outlined in the Medicare Intermediary Manual: identify program vulnerabilities; proactively identify fraud within their service area and take appropriate action; determine factual basis of complaints of fraud made by beneficiaries, providers, HCFA, Office of Inspector General and other sources; and initiate action to deny or suspend payments where there is reliable evidence of fraud.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (1) Improve the contractor performance evaluation system so that it not only encourages continuous improvement, but also holds contractors accountable for meeting specific objectives. (2) Require that all contractor performance evaluations list HCFA's national and regional objectives and address whether or not the fraud unit is meeting those objectives. (3) Establish a standard set of data that can be used to measure fraud units' performance in meeting established objectives and require that all contractor performance evaluation reports contain this data. (4) Establish clear definitions of key words and terms, disseminate these definitions and require that program integrity staff and fraud unit staff use the same definitions. In a future update of the Medicare Intermediary Manual, HCFA should revise sections so that these word are consistently used to mean the same thing. (5) Provide opportunities for fraud units to exchange ideas, compare methods, and highlight best practices relating to fraud and abuse detection.

Status

Management Response

The HCFA concurred with our recommendations. The HCFA has a number of initiatives underway related to (1) national contractor fraud unit training; (2) Medicare fraud information specialists; (3) contractor fraud unit teleconferences; (4) strengthening consistency for contractor performance evaluation; (5) program integrity oversight; and (6) redesigned fraud investigation data base.

Health Care Financing

Establish a National Medicaid Credit Balance Reporting Mechanism

Report Number: OAS-05-93-00107 Final Report: 5/95
OAS-04-92-01023 3/93

Finding

Previous OIG reports indicated that significant amounts of outstanding Medicaid credit balances exist nationwide. Currently, many State agencies' efforts are inadequate to ensure that, nationwide, the majority of Medicaid credit balances are being identified by providers and overpayments recovered in a timely manner.

Current Law/Policy

The HCFA 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

The HCFA should establish a national Medicaid credit balance reporting mechanism similar to the Medicare Part A credit balance reporting procedures. Also, HCFA should require its regional offices to actively monitor the reporting mechanism established.

Status

Management Response

The HCFA agreed to recover estimated outstanding credit balances and to perform an evaluation of State agencies' oversight activities. Initially, HCFA also agreed with the recommendation to establish a national Medicaid credit balance reporting mechanism similar to HCFA's Medicare Part A credit balance reporting mechanism. Upon reexamination, HCFA 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.

Health Care Financing

Strengthen Review and Accountability of Hospital Quality

Report Number: OEI-01-97-00050 Final Report: 7/99

Finding

The current system of hospital oversight has both significant strengths and major deficiencies. The HCFA does little to hold either the Joint Commission on Accreditation of Healthcare Organizations or State agencies accountable for their performance in overseeing hospitals.

Current Law/Policy

The 1965 Medicare Act required that hospitals meet certain minimum health and safety requirements to participate in the program, these requirements are called the conditions of participation. In addition to these requirements, Congress also provided that hospitals accredited by the Joint Commission were deemed to be in compliance with the conditions of participation. About 80 percent of the 6,200 hospitals that participate in Medicare are accredited by the Joint Commission. Hospitals that are not accredited by the Joint Commission are surveyed on average every 3.3 years, however, these surveys are a low priority for State agencies and the elapsed time between surveys is growing.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should hold the Joint Commission and State agencies more fully accountable to HCFA for their performance in reviewing hospitals by (1) Reassessing their approaches for obtaining information on Joint Commission and State agency performance. (2) Negotiate with the Joint Commission for changes such as (a) conduct more unannounced surveys; (b) more random selection of records as part of the survey process; (c) provide surveyors with more contextual information about the hospitals they survey; and (d) conduct more rigorous assessments of hospitals' internal quality improvement efforts. The HCFA should periodically assess the justification for the Joint Commission's deemed status authority. The HCFA should also determine the appropriate cycle for conducting certification surveys of nonaccredited hospitals.

Status

Management Response

The HCFA concurred with our report and included a detailed hospital quality oversight plan which incorporated many of our recommendations and presented a performance measurement strategy which will enable public reporting of comparative information on clinical performance among Medicare participating hospitals. The quality assurance plan initiative was carved out of the hospital regulations and revised and should be finalized in the new term.

Health Care Financing

Increase the Accountability of Dialysis Facilities for Quality of Services

Report Number: OEI-01-99-00050 Final Report: 6/99

Finding

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

Current Law/Policy

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 recommend that HCFA hold ESRD facilities more accountable through the following actions: revising the conditions of participation, using facility-specific performance measures, 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 recommend that HCFA 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

The HCFA generally concurs with our recommendations. The HCFA plans to publish revised conditions for coverage in the summer 2001, to request increased ESRD Network funding to support facility-specific performance measurements, and to request sufficient funding to increase the frequency of certification surveys to every 3 years.

Health Care Financing

Improve Comparative Information on Medicare+Choice HMO Extra Benefits

Report Number: OEI-02-99-00030 Final Report: 2/00

Finding

Three out of four recent HMO enrollees report that lower costs were one of the reasons they decided to join their health plan; half of them say it was the most important reason. Once enrolled in an HMO, Medicare beneficiaries value prescription drugs, regular physicals, and vision benefits the most. However, we also found that while most enrollees compare plans and extra benefits when joining an HMO, enrollees' understanding of their extra benefits is uneven. Further, while generally easy to understand, sample HMO marketing materials vary greatly.

Current Law/Policy

The Medicare managed care environment has recently undergone significant change. The 1997 Balanced Budget Act established Medicare+Choice provisions which set forth a number of different "coordinated care" options for beneficiaries to choose from. These new options mean that beneficiaries now need to make informed choices between the traditional fee-for-service health care program and a number of different types of managed care organizations. Many Medicare+Choice HMOs provide enrollees coverage that exceeds the required Medicare benefits for beneficiaries in the fee-for-service program.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA develop mechanisms to assure comparability of Medicare+Choice HMO plan costs and benefits.

Status

Management Response

The HCFA plans to implement the Plan Benefit Package as part of the 2001 Medicare managed care contract. The PBP will standardize the method whereby HCFA collects information from plans. Additionally, the PBP will be used to generate the standardized Summary of Benefits. The HCFA will provide the information in the standardized Summary of Benefits on the Medicare.gov web site. The HCFA is also requiring that remaining beneficiary notification (as opposed to advertising) materials (e.g. Evidence of Coverage, enrollment application forms, appeals-related materials) be standardized.

Health Care Financing

Improve Medicare Billing for Orthotic Devices

Report Number: OEI-02-99-00120 Final Report: 3/00

Finding

In a previous OIG inspection, we found that inappropriate Medicare reimbursement for orthotics continues at significant levels. Thirty percent of beneficiaries have one or more miscoded orthotic devices. We also found that qualifications of orthotic suppliers vary, with non-certified suppliers being most likely to provide inappropriate devices.

Current Law/Policy

Medicare pays for orthotic devices which are defined by regulation as leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition. Orthotic devices, which are mainly covered under Medicare Part B, must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve a malformed body member.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA take action to improve Medicare billing for orthotic devices. Options we suggest include (1) requiring suppliers to maintain a description of how custom fabricated and molded devices are made, (2) developing product classification lists for all major groups of orthotic devices, (3) educating the supplier community, and (4) working with the durable medical equipment regional carriers to strengthen the billing process for orthotics. In addition, we recommend that HCFA require standards for suppliers of custom molded and custom fabricated orthotic devices.

Status

Management Response

The HCFA generally concurred with the recommendations. The HCFA stated that it is currently working on a proposed rule that would establish training requirements for fitting and molding fabricated devices and intends to get standards for custom orthotics. Given the specialized training and skills necessary for fitting and creating custom molded and fabricated devices, we continue to believe in the importance of additional standards for suppliers providing custom devices. With regard to the second recommendation, HCFA has worked with the statistical analysis durable medical equipment regional carriers to create a product classification list for L0430 "Thoracic Lumbar-Sacral-Othosis."

Health Care Financing

Require Complete Documentation of Home Oxygen Therapy

Report Number: OEI-03-96-00090 Final Report: 8/99

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/Policy

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

The HCFA should delay payment for oxygen equipment claims until complete CMNs are submitted and 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. We recommend that oxygen equipment be targeted for focused medical review. Finally, the HCFA 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 HCFA concurs with the recommendations. The HCFA will make it clear to suppliers that file copy CMNs signed by physicians should contain all the information suppliers submit electronically. The HCFA will consider medical review, possibly focusing on portable oxygen systems. The HCFA is planning to issue service standards for home oxygen suppliers, and plans to continue physician education efforts.

Health Care Financing

Improve Review and Tracking of Managed Care Marketing Materials

Report Number: OEI-03-98-00270 Final Report: 2/00
OEI-03-98-00271 2/00

Finding

The goals of Medicare's National Marketing Guide for managed care -- which were to expedite the marketing material review process, reduce re-submissions 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 HCFA, were in full compliance with the National Marketing Guide. Also, nearly half the materials were not consumer-friendly.

Current Law/Policy

The HCFA 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 HCFA 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 HCFA regional offices, and outlines what information is required or prohibited in marketing materials.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA 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 non-complying health plans; and provide training for HCFA reviewers and managed care plans.

Status

Management Response

The HCFA is updating the National Marketing Guide, and adding checklists and model letters. As of contract year 2000, health plans contracting with HCFA must use a standardized Summary of Benefits. The agency is planning to use the Plan Benefit Package as a standardized way to collect descriptions of benefits from health plans and to review marketing materials. The HCFA has also established a quality control system in a pilot study and will require that all HCFA regional offices track receipt and approval of all marketing materials.

Health Care Financing

Prevent Payments for Services After Date of Death

Report Number: OEI-03-99-00200 Final Report: 3/00

Finding

Medicare paid $20.6 million in 1997 for services that started after a beneficiary's date of death. In many cases (totaling $12.6 million) Medicare had not yet received the date of death information at the time the claim was processed. In other cases (totaling $8 million), the date of death was posted in the Medicare system at the time Medicare paid for the service. We found that Medicare does not have uniform post-payment procedures to identify and recover payments for deceased beneficiaries.

Current Law/Policy

The HCFA's Common Working File (CWF), which is queried by contractors before payment is made, receives updated beneficiary information, including the date of death, from HCFA's Enrollment Database on a daily basis. The data contained in the Enrollment Database is received daily from the Social Security Administration and approximately three times a week from the Railroad Retirement Board.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should require Medicare contractors to conduct annual post-payment reviews to identify and recover payments for services after the date of death. In addition, HCFA should revise its CWF system edit to ensure that durable medical equipment payments are not made for deceased beneficiaries. Finally, HCFA should periodically reconcile date of death information between the Enrollment Database and the CWF system.

Status

Management Response

The HCFA concurred with the recommendations. The HCFA's analysis of the problem has been shared with all HCFA regional offices and Medicare contractors. During the FY 1999 benefit integrity conferences, all Medicare contractors were asked to perform similar analysis through their "proactive data analysis" efforts. Also, as an initial step to further study the problem, HCFA has funded pilot "deceased beneficiary" projects under Operation Restore Trust for a subset of the Medicare contractors. As appropriate, fraud referrals will be made to the OIG. To date, $4,913,505 in improper payments have been identified for recoupment, with $1,123,723 being recovered thus far. In addition, HCFA had initially planned to issue contractor instructions through its budget performance requirements for Fiscal Year 2001, requiring all Medicare contractors to perform these reviews. However, instructions will now be issued via a new program memorandum. The HCFA has also established the requirements for the system change necessary to revise CWF edits to prevent payment of durable medical equipment services billed after the beneficiary's date of death. The edits will be implemented in the January 2001 systems release.

Health Care Financing

Improve HCFA Management of Provider-Based Reimbursement to Hospitals

Report Number: OEI-04-97-00090 Final Report: 8/00

Finding

The HCFA regional offices use different processes and standards, and require varying levels of documentation for approving provider-based status for hospital owned entities. In addition, HCFA data systems are inadequate for furnishing any information regarding provider-based status. Hospitals often assume provider-based status for their off-site entities and bill Medicare without HCFA approval.

Current Law/Policy

Under Medicare, hospitals can account for medical entities they own as either free-standing or as part of the hospital, referred to as "provider-based." In order to claim provider-based status, hospital owned entities must request HCFA approval and meet criteria designed to ensure that the entity is actually part of the hospital.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

Because of concerns about the management and increased costs associated with the provider-based provision, as well as an absence of any significant benefit to Medicare or its beneficiaries, we recommend that HCFA eliminate the provider-based status as an accounting option for all types of hospital owned entities. If HCFA chooses not to eliminate the use of the provider-based option, it should (1) impose penalties when hospitals bill Medicare for unqualified medical entities they own; (2) revise and clarify its program policy and procedures for requesting, approving, tracking, and evaluating provider-based status; (3) develop reliable data systems for program management; and (4) require that all hospitals claiming provider-based status reapply for that status.

Status

Management Response

The HCFA did not concur with our recommendation to eliminate the provider-based program. Instead, HCFA has initiated various efforts to improve management of the program including: revising Form HCFA-855A to collect information about all hospital practice locations that will be billed as provider-based, revising regulations and procedures, implementing a new data management system which will furnish an indicator for any provider-based determination received by an enrolled or enrolling hospital, and provide training for staff responsible for administration and control. The HCFA plans to assess existing entities that currently claim provider-based status on a case-by-case basis. We continue to believe it is appropriate and well worth the additional administrative costs to require that all hospitals reapply for provider-based status for their off-site entities.

Health Care Financing

Consolidate Medicare Administrative Appeals

Report Number: OEI-04-97-00160 Final Report: 9/99

Finding

The number of appeals being heard by administrative law judges (ALJ) is increasing. The non-adversarial process, designed for beneficiaries, is now dominated by providers. Except for a small cadre of ALJs who specialize in Part B cases, judges spend most of their time on Social Security appeals, leading to minimal training and experience in Medicare rules.

Current Law/Policy

The Social Security Administration manages ALJs, who hear both Medicare and Social Security appeals.

Recommendation

☑ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should improve structural weaknesses in the appeals process by separating the beneficiary and provider appeal procedures, establishing an adversarial provider appeal process, improving contractor and ALJ training, developing regulations to guide Medicare appeals, and establishing a case precedent system for Departmental Appeals Board Rulings. The Department should consider consolidation of Medicare appeals either within HHS or through negotiation with Social Security for a dedicated Medicare ALJ corps.

Status

Management Response

The HCFA concurred with our recommendations. The HCFA plans to issue regulations for Parts A and B appeal processes, including regulations allowing contractors to be represented at hearings. The HCFA will evaluate the possibility of a precedent system. Finally, HCFA supports the creation of a dedicated Medicare corps of ALJs, and would support housing that activity within HCFA.

Health Care Financing

Improve DMERC Fraud Data

Report Number: OEI-04-97-00330 Final Report: 2/00

Finding

Overall, the durable medical equipment regional carriers (DMERCs) generally meet HCFA's objectives. However, one area of uncertainty is the effectiveness of their fraud units.

Current Law/Policy

On October 1, 1993, HCFA began using four DMERCs to process durable medical equipment, prosthetics, orthotics, and supplies claims for Medicare payment. The change to the four DMERCs was an effort by HCFA to improve ineffective and costly claims processing under the 34 carrier system.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA require the DMERCs to maintain needed data in their automated fraud information systems. This data should include complete and accurate documentation on the sources of opened cases and detailed financial information on fraud cases in overpayment status.

Status

Management Response

The HCFA concurred with our recommendation and is currently developing a Program Integrity Management Reporting System which will require Medicare contractors to report data on fraud and abuse overpayment status. The new system is scheduled for implementation spring 2001.

Health Care Financing

Improve Medicaid Mental Health Programs

Report Number: OEI-04-97-00340 Final Report: 1/00

Finding

Managed care allowed States to offer more specialized and creative out-patient services. States indicated that overall use of mental health services increased. Costs were reduced, although some concern was expressed that lower average length of stays and increased readmission rates may indicate that persons with serious mental illnesses are being released from in-patient care too quickly. Although costs were reduced, no State had working outcome measures in place; therefore, the overall effect on the health of persons with serious mental illness was not quantified. Savings were not always used to improve mental health services. Savings were sometimes used to expand services to non-Medicaid eligible persons and to help fund managed care administration, in some cases, even when some of the States did not have the appropriate Medicaid waiver to use operational savings in this manner.

Current Law/Policy

States are increasingly converting their Medicaid programs from traditional fee-for-service models to managed care models. Nearly every State has implemented, or is planning to implement, mandatory managed care for Medicaid beneficiaries who require mental health services.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should work with SAMHSA to develop and implement outcome measurement systems that can be used as a condition of waiver approval. The HCFA should encourage States to establish independent, third-party mental health systems for conducting beneficiary satisfaction surveys to promote more open and honest feedback from consumers. Lastly, before allowing the States to use savings that have resulted from managed care operations, HCFA should ensure that States obtain the required 1115 waiver to expand services to non-Medicaid populations.

Status

Management Response

The HCFA indicated that HHS, along with other Federal and State agencies and private sector researchers, is working to develop valid, reliable, and cost-effective outcome measurements. As soon as criteria is available, HCFA will work with States to ensure that appropriate measurements for mental health services are utilized. The HCFA indicated that the managed care regulations required by the Balanced Budget Act of 1997, once published, will strengthen the requirements for a grievance process and keep in place the statutory requirements for a State's fair hearing process. The HCFA agreed that States should be encouraged to improve their systems for measuring and promoting beneficiary satisfaction but failed to document specific action toward this end. The HCFA disagreed with the final recommendation indicating that the "recommendation was based on an incorrect understanding of the statute;" therefore, HCFA specified no action. The SAMHSA generally was not in agreement with the study methodology and, therefore, did not view the findings as very conclusive.

Health Care Financing

Improve Access to and Coordination of Children's Mental Health Services

Report Number: OEI-04-97-00344 Final Report: 1/00

Finding

Providing mental health services to children with serious emotional disturbances can present unique challenges not typically found when delivering services to adults. These challenges are generally systemic in nature and have existed for years under traditional fee-for-service care. Access to children's care is limited in three ways: (1) reduction of in-patient care for children was greater than for adults, (2) children's out-patient services lag behind those for adults, and (3) first year managed care contracts include limited provisions for children. Responsibility for care was fragmented with multiple agencies having responsibility. Concern was expressed about possible cost shifting. Lastly, States did attempt to improve coordination and access by negotiating interagency agreements. Reportedly, this resulted in improved coordination, but access to care by children is still limited.

Current Law/Policy

States are increasingly converting their Medicaid programs from traditional fee-for-service models to managed care models. Nearly every State has implemented, or is planning to implement mandatory managed care for Medicaid beneficiaries who require mental health services. These mandatory managed care contracts typically include services for both adults and children.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should specify services for children's mental health care in managed care contracts. This action would help ensure children receive the specialized care they require. The HCFA should also develop interagency agreements to promote coordination of children's mental health services. This action could result in reduced cost shifting concerns between agencies and better coordinated services.

Status

Management Response

The HCFA will emphasize to States the importance of managed care contracts defining clearly what mental health services must be provided to enrolled children. The HCFA has prepared draft Interim Review Criteria for Children with Special Needs and States who mandatorily enroll children in capitated plans will respond to these criteria as part of their waiver. In regards to the second recommendation, HCFA plans to highlight the importance of effective State-level coordination of all services to special needs populations in their imminent Report to Congress on the special needs of vulnerable populations enrolled in Medicaid managed care.

Health Care Financing

Identify and Monitor Hospital Ownership of Physician Practices

Report Number: OEI-05-98-00110 Final Report: 9/99

Finding

While hospitals are purchasing physician practices in significant numbers, HCFA is frequently unaware of hospital ownership of physician practices. Its lack of knowledge presents a fiscal vulnerability to the Medicare program and beneficiaries. The HCFA efforts to address the problem may not go far enough.

Current Law/Policy

The HCFA policy is that a hospital may choose to treat a hospital owned physician practice as either provider-based or free-standing. This decision will affect the amount of payment received by the hospital for physician services rendered in the practice. The decision to treat an acquired physician practice as provider-based increases costs to both the Medicare program and beneficiaries.

Recommendation

☑ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should change its policy and eliminate the provider-based designation for hospital owned physician practices and instead treat all purchased practices as free-standing entities. In addition, HCFA should require hospitals to report all purchases of physician practices and declare how costs associated with these entities are handled on the cost report. Finally, we recommend that HCFA seek legislation to be able to sanction hospitals for failure to report the ownership of physician practices.

Status

Management Response

The HCFA did not concur with our recommendation to eliminate the provider-based designation for hospital owned physician practices, but did concur with our other recommendations. The provider-based rules recently published by HCFA require that HCFA determine that an entity meets the criteria for establishing provider-based status.

Health Care Financing

Improve Enrollment in the Children's Health Insurance Program

Report Number: OEI-05-98-00310 Final Report: 5/99

Finding

Many States are experimenting with a variety of application and enrollment practices and processes in the State Children's Health Insurance Program (SCHIP) such as, application brevity, joint applications, multi-program applications, and written materials in other languages. People involved in the SCHIP application process stated that fear of being detected makes illegal aliens reluctant to complete an application, even for their children who meet citizenship requirements; Medicaid, SCHIP and other public benefit programs differ in their rules regarding verification of alien status, child support enforcement, and verification of income.

Current Law/Policy

The Balanced Budget Act of 1997 created Title XXI of the Social Security Act, the State Children's Health Insurance Program. Title XXI provides $39 billion over 10 years to develop health insurance programs for low-income children. States have the option to expand their existing Medicaid program, design a new children's health insurance program or develop a program that combines these strategies. Studies have shown that applications and enrollment procedures may be a barrier to families applying for Medicaid. Reducing the length and complexity of Medicaid and SCHIP applications may improve the uptake rate for eligible children. Researchers, advocacy groups, and HCFA are encouraging States to streamline Title XXI applications and the application process.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA work with States to improve the readability of SCHIP applications. We also recommend that HCFA continue to encourage States to simplify their applications and enrollment processes for SCHIP and Medicaid. We encourage HCFA to continue helping States investigate contracting with enrollment brokers, and eliminate some verification requirements.

Status

Management Response

The HCFA concurred with our recommendations. They highlighted their ongoing efforts in providing technical assistance to States on simplifying enrollment procedures. The HCFA is continuing to improve their outreach efforts by collaborating with HRSA and instituting a series of Technical Advisory Panels. The HCFA also worked with the Immigration and Naturalization Service to develop and release a policy guidance on the "public charge" issue.

Health Care Financing

Implement Medicaid Expansions for Prenatal Care

Report Number: OEI-06-90-00160 Final Report: 2/92

Finding

Significant problems prevent newly eligible women from receiving Medicaid-covered prenatal care: (1) client outreach is inadequate and (2) women are not completing the cumbersome application process.

Current Law/Policy

States are mandated to set income eligibility at 133 percent of the Federal Poverty Level; guarantee continuous eligibility until 60 days post partum; extend the presumptive eligibility period up to 60 days for States choosing this option; use special pregnancy-related application forms; use application sites other than where Aid to Families with Dependent Children applications are processed; and eliminate paternity establishment as a precondition to receive Medicaid-covered prenatal care.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (1) develop a comprehensive outreach strategy, and (2) simplify and streamline the application process.

Status

Management Response

The HCFA concurred and agreed to continue to work with PHS, ACF, and State Medicaid Directors.

Due to the new Welfare Reform and States opting to enroll Medicaid recipients into managed care programs, outreach strategies have increased. Many States have developed strategies targeted to provide continuous eligibility to pregnant women. States are also simplifying and streamlining application forms to alleviate administrative burdens and expedite the process.

Health Care Financing

(Continued 2)

Report Number: OEI-06-90-00160 Final Report: 2/92

Finding

In evaluating Medicaid expansions for prenatal care, the OIG found that: (1) States have difficulty recruiting prenatal care providers. There is a shortage of obstetricians to deliver adequate care. (2) States need more timely information and training from HCFA. (3) The HCFA and most States cannot measure the progress and impact of expansions due to lack of centralized data.

Current Law/Policy

States are mandated to set income eligibility at 133 percent of the Federal Poverty Level; guarantee continuous eligibility until 60 days post partum; extend the presumptive eligibility period up to 60 days for States choosing this option; use special pregnancy-related application forms; use application sites other than where Aid to Families with Dependent Children applications are processed; and eliminate paternity establishment as a precondition to receive Medicaid-covered prenatal care. Congressional concern about the health status of pregnant women has led to significant Federal and State Medicaid eligibility expansions.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (1) develop incentives to increase provider participation; (2) clarify policy and monitor implementation of Medicaid expansions for prenatal care; and (3) develop data collection systems and evaluation processes to measure progress of the eligibility expansions and future program effects.

Status

Management Response

The Balanced Budget Act of 1997 repealed Section 1926 of prior law, which contained requirements that States assure adequate Medicaid payment levels for obstetrical and pediatric services.

The HCFA works closely with State Medicaid Directors, informs States of legislative options and mandates and conducts local site visits on an ongoing basis. The Medicaid Maternal and Child Health Technical Assistance Group discusses areas where technical assistance is needed and plans for action to resolve those difficulties on a regular basis.

Health Care Financing

Identify Primary Health Insurance: Medicare Secondary Payer Auxiliary File

Report Number: OEI-07-98-00180 Final Report: 6/00

Finding

Only 0.43 percent of the beneficiaries in our sample who had primary health insurance coverage were not identified by Medicare. Based on improper payments made to these individuals, we estimated that the Medicare program inappropriately paid $56 million in 1997. These estimates only pertained to the 20 million Medicare beneficiaries in HCFA's Medicare secondary payer data system.

Current Law/Policy

Medicare provides health insurance coverage for eligible beneficiaries, but is not always the primary insurer. For example, Medicare is secondary for certain working-aged individuals and their spouses who have health insurance through their employer and certain working beneficiaries who qualify for Medicare based on disability and end-stage-renal disease. In addition, Medicare can be secondary to coverage under an automobile, no-fault, liability insurance, or workers' compensation plan.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should emphasize to providers the importance of reporting timely employment and health insurance information. In addition, HCFA should take steps to increase response rates for the initial enrollment questionnaire (IEQ).

Status

Management Response

The HCFA indicated that work has been initiated with the Coordination of Benefits contractor, which will emphasize to providers the requirement to obtain employment and health insurance information during each beneficiary visit. The HCFA agreed with the intent of the recommendation to increase the response rate for the IEQ but did not agree to any of the options outlined in the report.

Health Care Financing

Improve the Accuracy of Unique Physician Identification Number Data

Report Number: OEI-07-98-00410 Final Report: 9/99

Finding

While HCFA has implemented a number of enhancements which have improved unique physician identification number (UPIN) and provider identification number (PIN) data, some problems remain. Twenty-three percent of active UPINs and 39 percent of PINs have had no claims activity in the last year. Coding instructions create inconsistent entry of State license numbers, professional school codes, physician specialty, and board certification. A small subset of providers have more than 10 PINs associated with a single UPIN. Finally, some data fields are inconsistent between UPIN and PIN records for the same physician.

Current Law/Policy

The HCFA instructs carriers to deactivate the PIN after 12 consecutive months with no Medicare claims. The UPINs are deactivated when all associated PINs have been inactive for 12 months. State license numbers should be right justified and preceded with zeros.

Recommendation

☐ Legislative ☐ Administrative ☐ Material Weakness

The HCFA should ensure that carriers deactivate PINs and UPINs according to policy by including this activity in the Carrier Performance Evaluation review. State license numbers should be entered exactly as shown on State records, including characters, numbers, and spaces. The numbers should be left justified to enhance consistency. Individuals with large numbers of associated PINs should be a high review priority. The HCFA should reconcile identical data fields between UPIN and all associated PINs before implementing the national provider identification initiative.

Status

Management Response

The HCFA concurs with the report recommendations. Specifically, the HCFA agrees that Carrier Performance Evaluation should include deactivation of UPINs and PINs according to policy. The HCFA plans to release additional instructions for coding and data entry. The HCFA is implementing the Reassignment, Threshold Project, Physician Enrollment Chain and Ownership System, and address validation on the UPIN files, all of which address providers with multiple PINs. The HCFA plans to release additional instructions to carriers to deactivate the PINs within 6 consecutive months with no Medicare claims.

Health Care Financing

Improve Physician's Role in Home Health Care

Report Number: OEI-02-94-00170 Final Report: 6/95

Finding

Agencies and physicians identify some obstacles and issues related to the physician role. Obstacles mentioned by respondents include: (1) sixty-five 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 physician awareness and education in home health is inadequate and that they lack an understanding of the home health benefit.

Current Law/Policy

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 doctor is not required to see the patient.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should continue its efforts to change the plan of care to ensure it conveys critical information to caregivers and relieves unnecessary burden from physicians. The HCFA 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

The HCFA 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 NPRM was published on March 10, 1997. Public comments were received and revisions to the regulation are in progress. The final rule is targeted for publication by the end of Calendar Year 2000.

The HCFA also plans to issue new billing instructions for carriers to install new edits and conduct provider education.

Health Care Financing

Strengthen Education of Contractual Relationships Between Hospices and Nursing Homes

Report Number: OEI-05-95-00251 Final Report: 11/97

Finding

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

Current Law/Policy

Hospice care is a treatment approach which recognizes that the impeding death of an individual warrants a change focus from a curative to palliative care. The Medicare hospice benefit program began in 1983 and was expended 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 recommend that HCFA 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

The HCFA concurred with our recommendation. The HCFA staff, their contractors, and the regional home health intermediaries (RHHIs), are working together with the national and local hospice associations to educate them regarding potentially fraudulent and abusive activities. The RHHIs have been instructed to conduct educational seminars for providers, physicians, and/or consumers. The HCFA will also continue to encourage the RHHIs to re-emphasize the potential fraudulent and abusive activities in their continuing educational efforts. The HCFA is currently working on a notice of proposed rulemaking for the hospice conditions of participation.

Health Care Financing

Review HCFA's Investigation and Resolution of Patient Dumping Complaints

Report Number: OAS-06-93-00087 Final Report: 4/95

Finding

We assessed HCFA's effectiveness in investigating and resolving complaints involving potential violations of the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act. We found that HCFA regional offices were not always consistent in (1) conducting timely investigations of patient dumping complaints, (2) sending acknowledgements to complainants, (3) ensuring that provisions of the Act were addressed in substantiating violations, or (4) ensuring that violations were referred to the OIG for consideration of civil monetary penalties.

Current Law/Policy

Section 1867 of the Social Security Act, "Examination and Treatment for Emergency Medical Conditions and Women in Labor," prohibits patient dumping.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA amend its guidelines to the regional offices, conduct training on the requirements concerning patient dumping, ensure that all regional offices follow established procedures, and improve its process for referring cases to the OIG.

Status

Management Response

The HCFA concurred with our findings and recommendations.

Health Care Financing

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

Report Number:	OEI-01-98-00420	Final Report:	1/99
	OEI-03-98-00370		3/99
	OEI-03-98-00490		4/99
	OEI-03-98-00560		12/98

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 HCFA performs no such routine, ongoing analysis of hospital billing data to detect possible problems in DRG coding.

Current Law/Policy

Under Medicare's prospective payment system 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, HCFA has used two specialized contractors called Clinical Data Abstraction Centers to validate the DRGs on an annual national sample of over 20,000 claims billed to Medicare. This validation provides HCFA with an overall assessment of DRG coding.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

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

Status

Management Response

The HCFA concurred with our recommendation. The HCFA stated that peer review organization (PRO) contracts will conduct a Payment Error Prevention Program for inpatient hospital care. Under this approach, HCFA will conduct an independent ongoing surveillance of inpatient payment error rates, both nationally and on a State-by-State basis. The HCFA will also conduct analyses of discharge patterns and provide the results to the PROs. The PROs will conduct additional analyses of discharge patterns and take steps to reduce or eliminate erroneous billing. By Calendar Year 2000 end, HCFA anticipates having initial State-by-State surveillance data.

Health Care Financing

Improve External Quality Review of Psychiatric Hospitals

Report Number: OEI-01-99-00160 Final Report: 5/00

Finding

The current system of external review has some strengths that help protect patients but, it also has major deficiencies. We found that some psychiatric hospitals are rarely subjected to either a contracted or State agency review and that HCFA's contracted surveyors are held minimally accountable for their performance in overseeing psychiatric hospitals.

Current Law/Policy

Medicare requires psychiatric hospitals to meet two special conditions of participation — staff requirements and medical records — that apply only to psychiatric hospitals. The HCFA relies upon contracted psychiatric nurses and psychiatrists to assess compliance with these two special conditions. Additionally, like general hospitals, psychiatric hospitals are also subject to all Medicare conditions of participation (CoP) including the new "patients rights" CoP and can be deemed to meet them through either accreditation, usually by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or certification by State agencies.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should deploy its contracted surveyors more strategically, to take better advantage of their expertise and hold them more accountable. The HCFA should also establish a minimum cycle for contracted psychiatric surveys; negotiate with JCAHO to achieve a more patient-centered approach and a more rigorous assessment of discharge planning; and consider applying special Medicare CoP to both psychiatric hospitals and psychiatric units at acute care hospitals.

Status

Management Response

The HCFA is conducting observational performance reviews of its contracted surveyors and is in the process of designing a performance based evaluation system for them which they intend to put in place during FY 2001. As a result of new funding, HCFA anticipates reducing the interval between surveys to 3 years. The HCFA will continue to pursue additional funding for this function. The HCFA is currently negotiating with JCAHO to strengthen their standards and survey process in evaluating psychiatric services and assessing discharge planning. The HCFA intends to develop interpretive guidance for reviewers of psychiatric units in acute care hospitals to more rigorously implement existing requirements for exclusion from the prospective payment system that are found at 42 CFR 412.27. These requirements generally parallel the two special conditions of participation required for psychiatric hospitals. The HCFA also plans to use the contracted surveyors to supplement State agency reviewers.

Health Care Financing

Ensure That the Medicare Accounts Receivable Balance Is Fairly Presented

Report Number:	OAS-17-95-00096	Final Report:	7/97
	OAS-17-97-00097		4/98
	OAS-17-98-00098		2/99
	OAS-17-00-00500		2/00

Finding

Our audit of HCFA's FY 1999 financial statements found that significant financial management issues still affect HCFA's ability to accumulate and analyze Medicare accounts receivable, which had a $4.2 billion balance. During FY 1999, HCFA improved its accountability for accounts receivable; however, balances were not routinely analyzed or monitored other than on a very aggregate basis, so emerging trends could go undetected, and activities having a material impact could not be readily identified. Also, the reasonableness of the allowance for doubtful accounts was not ascertained, and contractor controls still need improvement.

Current Law/Policy

Guidance applicable to Medicare is in the Government Management Reform Act of 1994 and OMB Bulletin 98-08.

Recommendation

☐ Legislative ☑ Administrative ☑ Material Weakness

We recommend that HCFA (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 HCFA central office; (3) ensure that all Medicare contractors develop control procedures, including reconciliations with supporting documentation; (4) provide additional guidance and training to contractors; (5) develop input/output controls to routinely review and document contractor reports, to obtain detailed information by major type of receivable and contractor, and to investigate aberrant contractor items; (6) revise reporting requirements to obtain support for significant accounts, in auditable format, at each Medicare contractor; and (7) periodically reassess the reserve estimate for individual accounts receivable.

Status

Management Response

The HCFA hired consultants to help validate accounts receivable reported by Medicare contractors during FY 1999 and the first half of FY 2000. The contractors have developed subsidiary ledgers to provide detailed information supporting receivable balances. Also, the HCFA central office has implemented policies to write off uncollectable receivables and has provided training on accumulating and verifying accounts receivable balances. For the long term, HCFA is developing an agencywide integrated general ledger system as the cornerstone of its financial management controls for contractors and the central office. The President's FY 2001 budget also includes funding to establish financial management controls at the contractors and to hire contractor staff to implement the controls.

Health Care Financing

Improve Medicare EDP System Controls

Report Number: OAS-17-98-00098 Final Report: 2/99
OAS-17-00-00500 2/00

Finding

We found numerous electronic data processing (EDP) general control weaknesses at the HCFA central office and Medicare contractors and application control weaknesses at contractor shared systems. Such weaknesses do not effectively prevent (1) unauthorized access to sensitive personal information, (2) malicious changes that could interrupt data processing or destroy data files, (3) improper Medicare payments, or (4) disruption of critical operations. Further, weaknesses in HCFA's entity-wide security structure do not ensure that EDP controls are adequate and operating effectively. Although progress has been made, the EDP systems environment includes material weaknesses. For instance, the weakness previously noted related to the Fiscal Intermediary Shared System (FISS) remained unchanged in FY 1999; the Medicare data centers had access to the FISS source code and were able to implement local changes to FISS programs.

Current Law/Policy

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 the central office, HCFA should continue improvements to include (1) entity-wide security programs; (2) adequate, monitored, and enforceable general access controls to restrict access to sensitive data; (3) implementation of entity-wide, consistent change control procedures; (4) improved segregation of duties, including appropriate assignment of responsibilities; and (5) implementation of software to mitigate risks identified as a material control weakness in the production data base software access controls. For its Medicare contractors and system maintainers, HCFA should continue to implement (1) consistent adherence to OMB Circular A-130's 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; and (5) updated and documented service continuity procedures needed in the event of a system outage.

Status

Management Response

The HCFA generally concurred with the recommendations and has initiated comprehensive security initiatives for both its internal operations and those of its Medicare contractors and systems maintainers.

Health Care Financing

Consider Recommended Safeguards Over Medicaid Managed Care Programs

Report Number: OAS-03-93-00200 Final Report: 8/93

Finding

We found that there is a need for improved safeguards over Medicaid managed care programs to reduce the risk of insolvency and to protect Federal funds.

Current Law/Policy

Medicaid regulations allow States to impose solvency requirements on contracting managed care plans.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should consider several safeguards available to reduce the risk of insolvency and to ensure consistent and uniform State oversight. Specifically, we recommend that HCFA (1) use Medicare solvency guidelines, (2) establish minimum net worth standards, (3) develop a financial data base to measure the financial operations of managed care plans, (4) establish time frames in which to apply sanctions against poorly performing managed care plans, (5) mandate the use of a medical escrow account, (6) require that reinsurance plans be State approved and based on actuarial studies, (7) require State review of all third party transactions, (8) develop excess profit criteria, and (9) require State audits of managed care plans.

Status

Management Response

The HCFA concurred with recommendations 1 through 4. However, the Balanced Budget Act of 1997, Section 4706, requires managed care organizations to meet only the solvency standards established by the State for private health maintenance organizations. Recommendations 5 through 9 remain unresolved. The HCFA commented that the findings were of limited value because the report was based on examination of only two plans and that a broader analysis of managed care programs would be needed to identify shortcomings common to many Medicaid managed care plans and to make broad program recommendations. We disagree. The concerns raised in our report have also been expressed by Congress and the General Accounting Office. We do not believe HCFA should wait for a detailed study before taking a more aggressive role in protecting Federal and State funds. We are continuing our reviews of Medicaid managed care plans.

Health Care Financing

Retool Medicaid Agencies for Managed Care

Report Number: OEI-01-95-00260 Final Report: 8/97

Finding

We have identified five major organizational challenges faced by Medicaid agencies. The organizational challenges are (1) establishing core development teams; (2) acquiring necessary knowledge and skills; (3) instilling a new mission and culture; (4) redeploying fee-for-service staff; and (5) avoiding a fee-for-service meltdown.

Current Law/Policy

The movement to enroll Medicaid beneficiaries in managed care began in the early 1980s, as States experienced fiscal pressures due to rising Medicaid costs. Over the past 15 years, States have increasingly used managed care to provide medical services for Medicaid beneficiaries. States have primarily enrolled adults and children in low-income families into managed care, whereas aged for disabled beneficiaries remain under fee-for-service systems. By 1996, over 500 managed care organizations were providing services to 13 million Medicaid beneficiaries.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (1) provide forums to help State Medicaid managers take advantage of the opportunities managed care present for retooling their agencies and to minimize the associate dangers; (2) revise its review and monitoring protocols so that they devote greater attention to how State Medicaid agencies are handling the organizational challenges associated with expanded managed care; and (3) scrutinize possible adverse effects of managed care expansion on the performance of established fee-for-service functions.

Status

Management Response

The HCFA concurred with our recommendations. On an ongoing basis HCFA subsidizes the American Public Human Services Association meetings that address Medicaid managed care and the challenges it poses. However, HCFA reports that most efforts are currently focused on implementing provisions of BBA of 1997 rather than focus on how State Medicaid agencies are organized to address expanded managed care.

Health Care Financing

Use Beneficiary Surveys As A Protection Tool for Medicaid Managed Care

Report Number: OEI-01-95-00280 Final Report: 5/97

Finding

We found that (1) surveys provide little useful information about plan performance to Medicaid agencies;(2) the surveys have yet to provide beneficiaries with information to help them choose a plan; (3) both agencies and plans face basic hurdles in surveying the Medicaid population; (4) some agencies are beginning to use surveys in strategic ways, with potentially promising results; and (5) notwithstanding the limitations of beneficiary surveys, health plans still find them to be of some use in identifying and responding to enrollee concerns.

Current Law/Policy

Over the past 15 years, States have increasingly used managed care to provide medical services to Medicaid beneficiaries. States are allowed more flexibility in delivering managed care through the freedom-of-choice 1915b waiver or the 1115 waiver. The Health Care Financing Administration often requires Medicaid agencies implementing managed care waivers to conduct surveys.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should either establish a work group or technical advisory group on Medicaid beneficiary surveys or add to the agenda of an existing group. Either group should provide policy-level guidance on how to make cost-effective use of beneficiary surveys.

The HCFA should devote greater attention to how the Medicaid agencies are using beneficiary surveys. It should revise its written guides for reviewing and monitoring Medicaid managed care initiatives to call attention to the importance of using beneficiary surveys in more focused, strategic ways.

Status

Management Response

The HCFA partially concurred with recommendation one. The HCFA stated that its existing Medicaid Managed Care Technical Advisory Group has a work group currently working on consumer information and surveys. The HCFA is also collaborating with the Agency for Health Care Policy and Research, which is leading the Consumer Assessment of Health Plans study. The HCFA agreed with our assessment that agencies often conduct surveys for multiple purposes, but disagreed with our assessment that these were often of limited value.

The HCFA concurred with our second recommendation and plans to include a special session on survey development and use of survey data in its annual Managed Care College and will stress the importance of surveys in its technical assistance to HCFA regional offices and State Medicaid staff.

Health Care Financing

Coordinate Medicaid Managed Care Plans with HIV/AIDS Services

Report Number: OEI-05-97-00210 Final Report: 4/98

Finding

We found that (1) Medicaid managed care organizations (MCOs) that are paid an AIDS-enhanced rate appear to provide all needed medical services and drugs to AIDS patients. The MCOs that are not paid an enhanced rate report they cannot afford to continue providing these services and drugs without adequate financial compensation. (2) 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/Policy

Under Medicaid, States may choose to exercise any of several options to pay for care for 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

The HCFA should: (1) In consultation with HRSA, 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. (2) 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. The 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 the Ryan White programs.

Status

Management Response

(1) The HRSA and CDC have funded the development of sample purchasing specifications for use by purchasers of managed care products. The completed specifications provide options for language on contracting issues related to persons living with HIV/AIDS. The specifications can serve as a key technical assistance document for use by State Medicaid programs in developing appropriate services for beneficiaries living with HIV and AIDS. (2) The HRSA is working closely with HCFA to improve coordination and collaboration between Medicaid managed care organizations and Ryan White programs and will continue to do so in the future.

Health Care Financing

Improve Relationship Between Physician and Beneficiary When Ordering Medicare Equipment and Supplies

Report Number: OEI-02-97-00080 Final Report: 2/99
OEI-02-97-00081 2/99

Finding

We found that two-thirds of physicians are satisfied with the current process of ordering medical equipment and supplies. Physicians who are more informed about Medicare requirements for coverage and payment of medical equipment and supplies are more likely to be satisfied with the ordering process. Most medical equipment and supplies are prescribed by the treating physician, but in 6 percent of the cases the physician reported not knowing the patient and 13 percent of physicians who say they knew the patient did not order the equipment or supplies. Fourteen percent of sample medical equipment and supplies were either questionable or medically unnecessary, which represents $414 million in inappropriate Medicare payments.

Current Law/Policy

Medicare recognizes the physician as the key figure in determining the appropriate utilization of medical services. As one component of this process, Medicare requires that payment for certain non-physician services, such as home health agency, therapy and diagnostic services, as well as medical equipment and supplies, are conditional on the existence of a physician's order. According to Medicare regulation 42 CFR, Section 424, the provider of these services is generally responsible for obtaining the required physician certification and re-certification statements, and for keeping them on file for verification.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (1) strengthen its efforts to educate physicians regarding their ordering of medical equipment and supplies; and (2) ensure that the physician who orders the equipment or supplies is required to treat the patient prior to the order and a systematic process is developed to assure that the supplier submits a new CMN or order to the durable medical equipment regional carriers (DMERC) when the physician changes the equipment or supply, or the medical need for the equipment or supply changes; and that the referring physician's name and specialty and the patient's related diagnostic information are required on all claims for medical equipment and supplies.

Status

Management Response

The HCFA generally concurs with our recommendations. The HCFA believes there should be a relationship between the physician and beneficiary before a durable medical equipment (DME) item is ordered. The DMERCs are currently taking steps to educate all participating physicians with information about ordering medical supplies and equipment. The DMERCs are currently accomplishing this goal via a number of vehicles such as articles in carrier bulletins and presentations at carrier advisory committee meetings, national work groups, and consortia conferences. As part of this effort, the DMERC Summer 1999 Provider Bulletins contain information regarding ordering DME and the relationship between physicians and beneficiaries.

Health Care Financing

Ensure Appropriate Mental Health Services Delivered in Nursing Homes

Report Number: OEI-02-91-00860 Final Report: 5/96

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) lesser skilled individuals providing services.

Current Law/Policy

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

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

Status

Management Response

The HCFA concurs with the recommendation. The HCFA is taking steps to ensure appropriate services are delivered. The HCFA is developing a final rule for coverage of clinical psychological services. The Carriers Medical Directors workgroup developed and distributed a final model medical review policy to address Medicare coverage of psychiatry and psychology services. While the model policy is not HCFA's national policy, it is available to all carriers to use in developing their own local policies. A final rule for coverage of clinical psychological services is pending.

Health Care Financing

Improve Nursing Home Surveyor Staffing and Training

Report Number: OEI-02-98-00330 Final Report: 3/99

Finding

We found that nursing home surveyor staffing may be inadequate to conduct follow-up surveys and to respond to complaints. In addition, we found that while new surveyor training is consistent across our sample States, ongoing training for surveyors ranges from no training to 100 hours per year.

Current Law/Policy

Nursing home surveyors are required to complete mandatory standard surveys of each nursing home approximately annually. Surveyors are also responsible for surveying nursing homes when complaints are generated or when follow-up visits are required for nursing homes with deficiencies. Surveyors must complete HCFA-sponsored training and pass the required Standard Minimum Qualifications Test.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA: (1) Evaluate the surveyor staffing in each State to assure that adequate staffing is available to complete all standard surveys, follow up surveys, and respond to complaints. (2) Provide additional training to State surveyors.

Status

Management Response

In comments to the draft report, HCFA concurred with our recommendations. The HCFA indicated that it reviews State surveyor staffing as part of the survey and certification budget process. The HCFA will be examining these data more closely as part of the effort to determine whether States are complying with the requirements of the contractual agreement they enter into with HCFA to perform survey activities. The HCFA also indicated that the issue of training was being addressed by the new Federal Monitoring System and that feedback from the States on that system will guide training and coordination efforts.

Health Care Financing

Develop Nurse Staffing Standards for Nursing Homes

Report Number: OEI-02-98-00331 Final Report: 3/99

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/Policy

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 recommend that HCFA 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, HCFA has contracted for a study examining the relationship of staffing levels to the quality of care nursing home residents receive. The Phase I Report to Congress was delivered this summer, and it reported that the preferred minimum number of hours for Certified Nurse Assistant per resident is 2 and the preferred minimum number combined for Registered Nurse and Licensed Practical Nurse is 1 hour per day. Phase II of this study will verify the Phase I findings and will examine the costs of mandatory minimum staffing levels. An interim Phase II report will be issued in December, and all of Phase II will be completed in the fall of 2001.

Health Care Financing

Improve Medicaid Estate Recovery Programs

Report Number: OEI-07-92-00880 Final Report: 3/95

Finding

At the time of the survey (October 1993), 27 States had established estate recovery programs.

Current Law/Policy

The Omnibus Budget Reconciliation Act of 1993 required States to establish Medicaid estate recovery programs, effective October 1, 1993.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should develop performance indicators to track States' progress in implementing the OBRA '93 requirement. This would aid in identifying States with particular problems, establish expectations and a method for benchmarking progress, and yet allow States flexibility in finally choosing the mix of tools to achieve expected results.

Status

Management Response

The HCFA concurs. The HCFA drafted a national performance standard which was under review; however, they have abandoned their efforts.

Health Care Financing

(Continued 2)

Report Number: OEI-07-92-00880 Final Report: 3/95

Finding

Existing Medicaid estate recovery programs provide lessons on operational challenges. These operational challenges include: (a) Obtaining State enabling legislation. Forty of the 50 States require authorizing or confirming legislation to implement the OBRA '93 mandatory requirements. (b) Insufficient resources and limited staffing. Few States are able to budget for recovery program staff on a fulltime basis, most devote one-third to one-half of their time to estate recovery. (c) Reluctance to use lien recovery authority granted under TEFRA of 1982. Only 14 States file liens on property, six States utilize TEFRA liens. (d) Detecting out-of-State assets. States say they have limited capabilities to determine and verify the existence and amount of a Medicaid recipient's out-of-State assets. (e) Recovery from surviving spouse estates. Only 10 States pursue recoveries from the estate of the surviving spouse. States cite many difficulties in tracking the death of a surviving spouse.

Current Law/Policy

The Omnibus Budget Reconciliation Act (OBRA) of 1993 required States to establish Medicaid estate recovery programs, effective October 1, 1993. The programs may be developed in any manner that is approved by each State. The law permits a delayed compliance date for States requiring authorizing or conforming State legislation.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should (1) target mechanisms for recovery that have high dollar payoff and identify strategies to help make necessary information available to State agencies to pursue those mechanisms; and (2) closely monitor States' progress in obtaining enabling legislation and pursue legislative authority to impose sanctions or penalties if States do not act within a reasonable period of time to implement OBRA '93.

Status

Management Response

The HCFA concurs with our recommendations and has issued compliance letters to 12 States. A Technical Advisory Group on Third Party Liability is developing strategies for implementing this recommendation.

Health Care Financing

Assess Vulnerabilities in Medicaid Asset Verification

Report Number: OEI-07-92-00882 Final Report: 10/95

Finding

Most States rely only on readily available sources for asset verification. Nearly all States verify checking and savings accounts, paystubs and insurance policies, but States vary on requesting income tax returns and other types of financial information.

Efforts to identify and combat Medicaid fraud vary among States. Forty percent of States do not have Medicaid fraud hotlines and 24 percent of States do not have specific Medicaid long-term care fraud penalties for the non-reporting resources.

The HCFA has worked in partnership with State Medicaid agencies to improve asset verification.

Current Law/Policy

Eligibility for Medicaid long-term care coverage is based on an individual's income and assets. Individuals with substantial assets who need long-term care may be motivated to transfer their assets to other family members or friends. Such transfers create artificial poverty in order that individuals may finance their nursing home expenses through the Medicaid program. Each State has its own rules and provisions governing Medicaid long-term care eligibility.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should continue to work in partnership with States to promote:

- Comprehensive asset verification techniques
- Establishment of Medicaid fraud hotlines and penalties, an
- Identification and sharing of useful best practices among State

Status

Management Response

The HCFA concurs with our recommendations.

An Income Eligibility Verification Systems (IEVS) interagency workgroup was developed to oversee the State operation of IEVS. Prior to any future changes, the workgroup will need to consider the impact of welfare reform.

Health Care Financing

Improve Medicare's Oversight of Managed Care Plan Performance

Report Number: OEI-01-96-00190 Final Report: 4/98

Finding

Our inspection found that (1) HCFA's primary oversight approach--a site visit that relies on a rigid monitoring protocol--has fundamental limitations as a way of overseeing managed care plans' performance; (2) overall, HCFA is not taking widespread advantage of available data that could be used for ongoing, systematic oversight of plans; and (3) that HCFA is missing opportunities to capture additional data that could assist the agency in monitoring plans' performance.

Current Law/Policy

The HCFA is responsible for ensuring quality of and access to care provided to Medicare beneficiaries and for safeguarding the program from fraud and abuse. Medicare supports two primary types of managed care plans, fee-for-service and capitation plans.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should: (a) revise the processes that it uses to monitor the performance of managed care plans; and (b) take better advantage of data that are currently available to the agency as a way of monitoring plan performance on an ongoing basis.

Status

Management Response

The HCFA concurs with the intent of all the recommendations. The HCFA continues to work toward implementing data solutions. The Managed Care Information System was implemented in September 2000. This system will allow regional offices to input findings from monitoring reviews while conducting on-site reviews. All of the monitoring data will be housed in a mainframe in central office, thus allowing national data analysis of findings. We have also begun analysis of the Health Plan Employers Data and Information Set with the goal of incorporating this information into ongoing monitoring of Medicare managed care contractors.

Health Care Financing

Ensure Expertise in HCFA Staff for Managed Care Oversight

Report Number: OEI-01-96-00191 Final Report: 4/98

Finding

We found that HCFA regional offices made a strong commitment to increase staffing for managed care oversight. However, the vast majority of the new staff lack experience with managed care. We also found that managed care units in many regional offices lack staff with specialized backgrounds that could enhance oversight of managed care plans.

Current Law/Policy

The HCFA is responsible for ensuring quality of and access to care provided to Medicare beneficiaries and for safeguarding the program from fraud and abuse. Medicare supports two primary types of managed care plans, fee-for-service and capitation plans.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

(1) The HCFA should develop, coordinate, and provide a comprehensive training program for regional office staff with responsibility for oversight of managed care plans. (2) As HCFA increases staff in its managed care operations in regional offices, we recommend that the agency seek out people with experience in managed care, data analysis, and clinical expertise. (3) We also recommend that HCFA develop a pilot program to provide opportunities for staff development and staff sharing with managed care plans and beneficiary advocacy groups.

Status

Management Response

The HCFA continues to develop methods for staff training. The training team conducted three major efforts this year. There was a week-long subject matter training course for more experienced staff conducted in March 2000. The training team also developed and has begun implementing basic orientation and mentoring programs for new staff. Training in these programs was conducted for all regional offices via videoconferencing. The training team also organized a 3-day face-to-face conference for all managed care staff in August 2000.

Individual regional offices have worked with the central office to conduct subject matter training for managed care organizations. Several regional offices have conducted training in the Medicare requirements for beneficiary appeals and quality improvement activities.

The HCFA has also conducted outpatient encounter training for the Medicare+Choice organizations.

Health Care Financing

Assess Beneficiaries' Experiences with and Satisfaction with Medicare Services

Report Number: OEI-04-97-00030 Final Report: 6/98

Finding

(1) As in 1995, beneficiaries report positive experience with the Medicare program. (2) Beneficiary awareness of one service improved from 1995 to 1997. (3) Beneficiary awareness of some services declined. (4) Some services needed improvement in 1995, and still do in 1997. (5) Beneficiary awareness of some services not reported on in 1995 was found to be lacking in 1997.

Current Law/Policy

Medicare is a Federal health insurance program for individuals age 65 and older, and for certain categories of disabled people. The HCFA has responsibility for the Medicare program. However, other organizations share program administration. The Social Security Administration establishes eligibility, enrolls beneficiaries in the program, and collects Medicare premiums. Private health insurance companies contract with the Federal Government to service claims for Medicare payment.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HCFA develop a plan for improving beneficiary satisfaction and understanding in the trouble areas mentioned in this report. We suggest that in planning corrective actions, HCFA set numerical goals that can be tracked for program improvement.

Status

Management Response

The HCFA concurred with our recommendation. The HCFA has initiated a National Medicare Education Program that will use multidimensional strategies to assist beneficiaries in making informed health care decisions. Further, HCFA will provide access to program information via the Internet and an updated Medicare Handbook.

Health Care Financing

Improve Controls to Monitor Chiropractic Care

Report Number: OEI-04-97-00490 Final Report: 9/98

Finding

We found that Medicare, Medicaid, and private insurers rely on utilization caps, x-rays, physician referrals, co-payments, and pre and post payment 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/Policy

In 1972, Section 273 of the Social Security Amendment (P.L. 92-603) expanded the definition of physician under Part B of Medicare 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 Balance Budget Act of 1997 required HCFA to establish new utilization guidelines for Medicare chiropractic care by January 1, 2000. It also eliminated the x-ray requirement.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA 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

The HCFA intends to issue a vulnerability report to all Medicare carriers, so the carriers can, where possible, implement systems edits to detect and prevent unauthorized payments for chiropractic maintenance treatment.

Health Care Financing

Ensure Children in Medicaid Managed Care Receive Timely EPSDT Services

Report Number: OEI-05-93-00290 Final Report: 5/97

Finding

During our inspection we found that: (1) fewer than one in three Medicaid children enrolled in managed care plans receive timely early and periodic screening, diagnosis, and treatment (EPSDT) services. Six of 10 receive none at all; and (2) children receive significantly more EPSDT services from Medicaid managed care plans when States inform the managed care plans which children are due for EPSDT.

Current Law/Policy

Under EPSDT, State Medicaid agencies must provide eligible children services that include comprehensive, periodic health assessments beginning at birth and continuing through age 20. All medically appropriate immunizations are required. Age appropriate assessments must be provided at intervals following defined periodicity schedules. State Medicaid agencies have turned to managed care to rein in escalating health care costs, difficult to in a fee-for-service environment, while ensuring health care access for Medicaid enrollees.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should (1) revise its EPSDT reporting requirements and data collection to emphasize the number of children who receive all of their EPSDT screens in a timely fashion; (2) encourage States to actively notify managed care plans of enrollees due for EPSDT exams and to follow up if EPSDT services are not rendered shortly thereafter; (3) work with States to ensure timely managed care EPSDT reporting; and (4) emphasize to States the need to define and clarify EPSDT requirements in its Medicaid contracts with managed care plans.

Status

Management Response

The HCFA concurred with our recommendations. The HCFA has developed a work group comprised of representatives from the public and private sectors to assess and recommend changes to the current EPSDT reporting and data collection tool. The HCFA will continue to encourage States through its review and approval of new and existing waivers to include specific EPSDT programmatic requirements in their contracts with managed care programs.

Health Care Financing

Improve Oversight of the Rural Health Clinics

Report Number: OEI-05-94-00040 Final Report: 7/96

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/Policy

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

The HCFA, along with the Health Resources and Services Administration, should modify the certification process to increase State involvement and ensure more strategic placement of rural health clinics.

The HCFA should expedite the issuance of the regulations now under development.

The HCFA 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

The HCFA concurs with the intent of our recommendations. The Balanced Budget Act of 1997 refines the requirements for rural health clinic designations, and provider-based reimbursement. The HCFA developed a program memorandum consolidating and clarifying the policy regarding provider-based and free-standing designation decisions. The HCFA issued proposed regulations on rural health clinics on February 28, 2000, and is now in the process of developing final regulations with the expectation to issue this rule in early 2001.

Health Care Financing

Improve Oversight of the Medicare Risk HMO Program

Report Number: OEI-06-95-00430 Final Report: 3/98

Finding

We found that, overall, beneficiaries in Medicare risk health maintenance organizations (HMOs) gave a favorable report of good service access in 1996. Some problems we reported in 1993 have substantially improved. Some reported problems continued in 1996, however, and some new ones have surfaced. The more vulnerable Medicare beneficiaries in HMOs--the functionally limited, disabled, and chronically ill--experienced more service access problems.

Current Law/Policy

The HCFA has oversight responsibility for Medicare risk contracts with HMOs. Under a risk contract, Medicare pays the HMO a predetermined monthly amount per enrolled beneficiary. Once enrolled, beneficiaries are usually required to use HMO physicians and hospitals, and obtain prior approval from their primary care physicians for other primary care.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We continue to believe HCFA needs to improve its oversight of the Medicare risk HMO program in six persistent areas: (1) assuring HMOs properly inform beneficiaries about their appeal and grievance rights; (2) improving beneficiaries' understanding of HMO procedures and restrictions for obtaining services; (3) preventing inappropriate screening of beneficiaries' health status at application; identifying and carefully monitoring service access problems encountered by functionally limited, disabled, and chronically ill beneficiaries; (4) systematically collecting and tracking over time HMO-specified beneficiary-reported data on access to medical services and reasons for disenrollment; and (5) distinguishing between administrative and non-administrative disenrollments, if HMO disenrollment rates are to be used as a performance indicator.

Status

Management Response

The HCFA concurs with the recommendations. The HCFA is striving to improve beneficiary outreach and education to make them aware of their appeal and grievance rights. The HCFA has developed a Medicare managed care data base to assist in improving beneficiaries' understanding of procedures and restrictions within managed care plans. In addition, HCFA's Quality Improvement System for Managed Care and the Health of Seniors component of the Health Plan Employer Data and Information Set will help assess whether Medicare beneficiaries believe they receive adequate access to health care services.

The HCFA continues to work on the areas identified in this report. Additional questions regarding the administration of appeal and grievance rights and procedures have been added to the consumer assessment of health plans survey and the disenrollment survey.

Health Care Financing

Address Problems Identified by Beneficiaries in Medicare Risk HMOs

Report Number: OEI-06-95-00434 Final Report: 8/98

Finding

We found significant differences between these vulnerable beneficiaries and their healthier counterparts regarding their experiences with enrollment, access to services, care from their primary doctors, and difficulty of obtaining health maintenance organization (HMO) care. Specifically, functionally limited, comorbid and disabled beneficiaries experienced more problems in accessing services than healthier beneficiaries, particularly specialized services; vulnerable beneficiaries found it hard to obtain care through their HMO; while able to obtain timely appointments when they were very ill, vulnerable beneficiaries were more critical of the care received from their primary physicians; and a sizable proportion of vulnerable enrollees said that while their health improved, about one-fifth of vulnerable disenrollees were more likely than less impaired groups to have been inappropriately asked about their health problems when applying to their HMO.

Current Law/Policy

Medicare beneficiaries may join a risk HMO or remain in the fee-for-service program. When enrolling beneficiaries, the HMO may not deny or discourage enrollment based on a beneficiary's health status except for end-stage renal disease or hospice care. The HMO must also adequately inform beneficiaries about lock-in to the HMO and appeal and grievance procedures. Once enrolled, beneficiaries are usually required to use HMO physicians and hospitals and to obtain prior approval from their primary care physicians for other primary care.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The HCFA should address the problems identified by vulnerable beneficiaries in Medicare risk HMOs and we suggest these options: (1) In developing the health status capitation risk adjusters required by the Balanced Budget Act of 1997, HCFA should take into account the following considerations: (a) servicing access problems encountered by vulnerable populations in HMOs should continue to be monitored and (b) contractual requirements could be used by HCFA to encourage or require plans to designate specialists as primary physicians in appropriate cases or to provide standing referrals for ongoing specialty care needs. (2) The HCFA could also use contractual requirements to assure that referral and utilization criteria are available on request to providers and to beneficiaries for use in accessing care and appealing any denials of service.

Status

Management Response

The HCFA issued a new monitoring guide in December 1999. This guide, used by HCFA since January 2000, addressed many of the issues raised through the implementation of new policy guidance in many areas. These areas include enrollee rights, availability and access, and continuity and coordination of care. There will be an effort to review the effectiveness of the new standards in the Year 2001.

Health Care Financing

Extend PRO Review of Physician Office Surgery

Report Number: OEI-07-91-00680 Final Report: 6/93

Finding

One-fifth of medical records reviewed did not document reasonable quality of care for surgeries in a physician's office.

Thirteen percent of the medical records did not document an indication for surgery.

The physician's office was not an appropriate setting for a small number of surgeries.

In 16 percent of our sample cases, procedure codes did not match the surgeries performed.

Current Law/Policy

Section 1154(a)(4)(A) of the Social Security Act required that "Each peer review organization (PRO) shall provide that ....a reasonable allocation of such [quality review] activities is made among the different cases and settings" except that PRO review in physician offices could not begin before January 1, 1989. The PROs' reviews generally do not extend to services performed in physician offices.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The PROs should extend their review to surgery performed in physicians' offices.

Status

Management Response

Under the PRO 6th Scope of Work, PROs will examine several kinds of services in the office setting (immunizations, breast cancer screening, and diabetic care). In addition, a regulation now approaching final publication will complete the regulatory basis for obtaining physician office records. Also, HCFA has issued policy guidance and manual instructions to explicitly state that PROs have the responsibility to review all care in physicians' offices when a beneficiary complains.

Health Care Financing

Collect Overpayments for Routine Prenatal and Postpartum Care for Undocumented Aliens

Report Number: OEI-07-96-00310 Final Report: 5/98

Finding

Six States have claimed Federal funds for routine prenatal and postpartum care for undocumented alien women. Three still do. Survey respondents in 31 States and territories indicated they were not aware of HCFA's guideline on this subject. Two HCFA regional offices did not send guidance to States. A Federal court has ordered continuation of benefits in New York.

Current Law/Policy

The Omnibus Budget Reconciliation Act of 1986 amended the Social Security Act to limit Federal payment for emergency medical services under the Medicaid program to undocumented aliens except in certain cases. The amendment explains that an emergency medical condition occurs when the patient's health would be in serious jeopardy caused by serious impairment to bodily functions, or serious dysfunction of any bodily organ or part without immediate medical attention. This includes labor and delivery but does not include routine prenatal and postpartum care.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

In an earlier inspection, we found two States were improperly claiming Federal funds for routine postpartum medical care for undocumented alien women. Since misinterpretation or misunderstanding of the law on this matter continues to exist in some States, we recommend that HCFA: identify and recover Federal funds that Minnesota, Nebraska, Oklahoma, Vermont, and West Virginia inappropriately claimed; assure States and territories are aware of and implement policy and provisions applicable to claiming Federal funds; and continue to monitor and support the Department of Justice's efforts to resolve the legal issues involving New York.

Status

Management Response

The HCFA concurs with the recommendations. The HCFA will ask the regional offices to follow up with the States cited to recover the potential overpayments, and remind States and territories of the policy provisions. The HCFA will continue to actively support the Department of Justice in resolving the issues raised in the lawsuit.

Health Care Financing

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

Report Number: OAS-06-91-00092 Final Report: 11/92

Finding

Although manufacturers' best price determinations were acceptable, calculations of average manufacturer price (AMP) were inconsistent. The variations occurred because HCFA had not provided sufficiently detailed instructions to manufacturers 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 HCFA.

Current Law/Policy

Section 1927 of the Social Security Act requires drug manufacturers to enter into and comply with rebate agreements with the Secretary in order for States to receive Federal financial participation 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 HCFA 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

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

Status

Management Response

The HCFA did not concur, stating that the drug rebate law and the rebate agreements already established a methodology for computing AMP. We disagree. The rebate law and agreement defined AMP but did not provide specific written methodology for computing AMP.

Health Care Financing

Implement Proper Accountability Over Billing and Collection of Medicaid Drug Rebates

Report Number: OAS-06-92-00029 Final Report: 5/93

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 using their best efforts to collect the billings or resolve disputes with manufacturers. Also, there was virtually no system of internal controls in place in these States for drug rebate program funds.

Current Law/Policy

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 identify adequately 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

The HCFA 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 HCFA with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program.

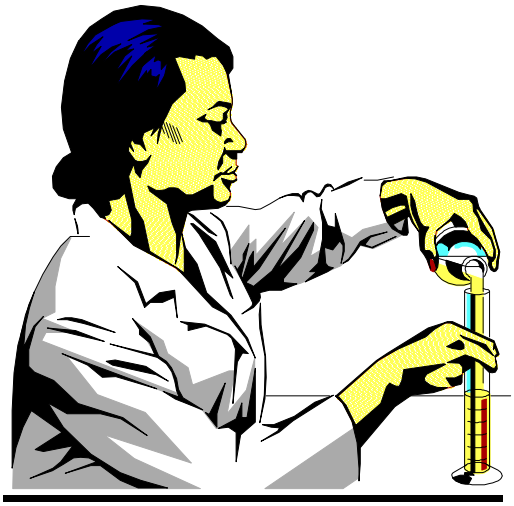
Status

Management Response

The HCFA concurred with the recommendation. States will now be required to maintain detailed supporting records of all rebate amounts invoiced to drug companies using a formal accounts receivable system. The HCFA issued interim regulations in FY 1996.

Public Health

Overview



Introduction

The activities of the Department'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) provides a system of health surveillance to monitor and prevent disease outbreaks, supports research into disease and injury prevention; and partners with States and others to help guard against international disease transmission, maintain national health statistics, and provide immunization services. (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. (8) The Substance Abuse and Mental Health Services Administration (SAMHSA) provides leadership in mental health and substance abuse treatment and prevention.

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. The 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 which are awarded contract and grant funding by the Department. 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

Improve Administration of the NIH Small Business Innovation Research Program

Report Number: OAS-15-98-00031 Final Report: 11/99

Finding

The NIH does not ensure that all Small Business Innovation Research (SBIR) program grantees comply with requirements for disclosure of inventions and patents to the funding agencies. Also, NIH does not evaluate the success of its SBIR grantees in commercializing the results of their research projects.

Current Law/Policy

The Bayh-Dole Act and its implementing regulation require grantees to disclose inventions and patents to the funding agencies. The Small Business Innovation Development Act of 1982 and the Small Business Research and Development Enhancement Act of 1992 link the importance of private sector commercialization to the success of the SBIR program.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that NIH (1) incorporate specific invention reporting requirements in the SBIR solicitation, including actions and time limits placed by law and consequences for not meeting invention reporting requirements; (2) continue efforts to link NIH's extramural invention data base with the Patent and Trademark Office (PTO) patent data base to identify patents that were supported with NIH funds; (3) contact all NIH SBIR award recipients and urge them to adhere to all invention reporting requirements; (4) develop a system to evaluate the performance of the SBIR program that will include measuring the success of award recipients in commercializing products resulting from their research; (5) use NIH's extramural invention data base to track the commercialization success of SBIR award recipients; and (6) revise peer review evaluation criteria for SBIR proposals to emphasize the potential of the proposed research for commercial application.

Status

Management Response

The NIH generally concurred with our recommendations. The agency indicated that it had improved its notification to grantees of their invention reporting responsibilities and expressed an interest in entering into discussions with PTO regarding ways to identify patents supported with NIH funds. Also, NIH is developing a methodology to evaluate the SBIR program and has revised its review criteria to emphasize the potential of the proposed research for commercial use.

Public Health

Maintain an Accurate Data Base to Monitor NIH's National Research Service Award Recipients

Report Number: OAS-15-99-80002 Final Report: 1/00

Finding

The NIH has not maintained a complete and accurate payback data base to adequately monitor the current payback status of over 4,100 National Research Service Award (NRSA) recipients or the financial debts they potentially owe the Government. Problems occurred because NIH components did not always follow established policies and procedures for maintaining the data base and because the automated system did not always perform the functions needed to update the data base when new information was entered. Additionally, several NIH components share the responsibility for maintaining the data base.

Current Law/Policy

The NRSA legislation requires some recipients of support to pay back the Federal Government by engaging in health-related biomedical or behavioral research, teaching, or a combination of these activities. These recipients must undertake such service continuously within 2 years after termination of the support. If a recipient fails to perform the service, the U.S. Government is entitled to recover financial debts from the recipient. The recipient is required to complete financial payback within 3 years of the date the debt is due to the Government.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The NIH should (1) review all NRSA recipients that have new, open, or delinquent payback records to determine whether their status is properly and consistently recorded in the payback data base; (2) review a sample of recipients that have closed payback records to determine whether their status is accurately recorded in the data base and, if the sample discloses significant problems, expand such testing; (3) establish computer records within the data base for all recipients obligated for service or financial payback; (4) update the data base in a timely manner to reflect recipients' current payback status; (5) verify periodically that the computer records within the data base are consistent with paper files; (6) reconcile periodically the recipients obligated for financial payback to the Office of Financial Management's accounts receivable; (7) use available monthly NRSA Payback Reports to ensure the data base is accurately maintained; (8) review the automated information system to determine what improvements are needed to properly update the data base when information is entered; and (9) consider centralizing the data base maintenance function.

Status

Management Response

The NIH concurred with all recommendations. The NIH has taken steps to establish procedures for maintaining and processing records on NRSA recipients and is planning to centralize under a single unit the responsibility for ensuring that recipients fulfill their payback requirements.

Public Health

Protect Human Research Subjects by Strengthening Institutional Review Boards (IRBs)

Report Number: OEI-01-97-00193 Final Report: 6/98
OEI-01-97-00197 4/00

Finding

The effectiveness of IRBs is in jeopardy. They face major changes in the research environment, review too much too quickly and with too little expertise, conduct minimal continuing reviews of approved research, face conflicts that threaten their independence, and provide little training for investigators and board members. Neither the IRBs nor HHS devotes much attention to evaluating IRB effectiveness.

Current Law/Policy

Initially, the Office for Protection from Research Risks (OPRR) and FDA shared responsibility for IRB oversight. In June 2000, the human subjects protection functions of OPRR moved from NIH to the Office of the Secretary and are now housed in the new Office for Human Research Protections (OHRP). The OHRP will provide leadership for all 17 Federal agencies that carry out federally-funded research under the Common Rule. The OHRP will also work with NIH and the FDA to carry out new patient protection initiatives for research involving human subjects. Under the new OHRP structure, FDA retains its enforcement authority to ensure that researchers carry out FDA-authorized drug and medical device clinical trials are complying with HHS patient protection and consent requirements.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

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

Status

Management Response

While our recommendations have not been fully implemented, many intermediate actions have been taken and the Department has made a commitment to implement them. The number of investigations conducted of research institutions by OPRR and of IRBs by FDA has significantly increased. The NIH now requires data and safety monitoring boards to share summary information with IRBs. The NIH also implemented the requirement for monitoring plans for phase I and II trials. Both NIH and FDA have ongoing initiatives in educational outreach and programs. In June 2000, the NIH issued an announcement requiring key personnel of projects that involved human subjects to be educated in the protection of human subjects. Investigators must comply with this requirement prior to funding. The FDA hosted a national conference addressing human subject protections and has had numerous workgroups. The DHHS, in collaboration with NIH, FDA, and CDC, sponsored a national conference of financial conflict of interest. The NIH constructed a web site containing bioethics resources.

Public Health

Improve Recruiting Practices for Human Research Subjects

Report Number: OEI-01-97-00195 Final Report: 6/00
OEI-01-97-00196 6/00

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 including offering incentives, targeting their own patient bases, seeking additional patient bases, and advertising and promoting their research (many of which raise concerns). Oversight of these recruitment methods is limited.

Current Law/Policy

As of June 2000, the Office for Human Research Protections (OHRP) in the Office of the Secretary was established taking on much of the responsibility that was formerly housed within the NIH Office for Protection from Research Risks. The OHRP will oversee all research involving human subjects that is conducted or funded by HHS and will have responsibility for conducting 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 activities related to the protection of human subjects with OHRP. The FDA retains its enforcement authority to ensure that researchers carrying out FDA-authorized drug and medical device clinical trials are complying with FDA patient protection and consent requirements.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We directed our recommendations jointly to FDA, NIH and the Assistant Secretary for Health. We recommend 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 the Department's response to our report, which is focused on industry-sponsored trials, it expressed concern that some contemporary recruiting practices put potential subjects at unnecessary risk, noting that such risk could be reduced to minimal levels if IRBs were uniformly diligent in exercising their oversight authorities. The Department noted its responsibility to provide IRBs appropriate guidance to meet this challenge. It committed OHRP (which came into existence 1 month after the Department commented on this report) to quickly assess current guidance related to IRB oversight of recruitment practices and augment it as appropriate. The OHRP, FDA, and NIH will work with professional societies to develop guidelines on appropriate recruiting practices. The Department will institute new requirements for continuing education regarding the protection of human subjects for investigators, IRB members and staff, and officials involved in compliance. The FDA is developing a plan to register IRBs in collaboration with OHRP as a first step toward fostering an accreditation process for institutional systems designed to protect human research subjects. The FDA has increased its on-site inspections of IRBs significantly and will expand this inspection system as resources allow.

Public Health

Stengthen FDA Oversight of Clinical Investigators

Report Number: OEI-05-99-00350 Final Report: 6/00

Finding

We found that in general, oversight of clinical investigators by sponsors, institutional review boards (IRB), and the 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/Policy

The 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. The 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

The 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

The FDA commented specifically on this report and the Department more generally as part of its comments on our other work on IRB oversight and protecting human research subjects. The FDA notes that the current system of retrospective monitoring to ensure data integrity and informed consent which occurs primarily in a sample of studies is designed to assess record consistency and completeness to evaluate study quality. However, in the Department's response to our other work on IRBs and protecting human research subjects it notes that FDA (1) has increased its on-site inspection process; (2) is developing a plan to register IRBs which will be implemented as resources allow; (3) is working with NIH and OPRR to improve education on human subject protections for investigators, IRB members and staff, and officials involved in regulatory compliance; (4) in concert with NIH and OHRP is working to assess current guidance on the consent process/recruiting human subjects and augment it as appropriate; and (5) in concert with NIH and OHRP is working with professional societies and others to identify exemplary recruitment practices and incorporate them into a guidance document.

Public Health

Improve CDC's Controls Over the Accounting for Direct and Indirect Costs

Report Number: OAS-04-98-04226 Final Report: 5/99

Finding

The CDC does not have adequate internal controls in place to ensure that direct costs charged at the program activity level are based on the actual efforts of personnel and the actual use of other resources. In addition, controls over indirect costs are inadequate to ensure that costs from all organizational levels are properly identified and consistently allocated among various programs and activities. These basic control deficiencies were identified in our review of the Chronic Fatigue Syndrome (CFS) program, which found that some program funds were actually spent on other programs and activities and that CDC failed to document the relevance of other costs charged to the CFS program.

Current Law/Policy

Under a broad framework of Federal laws, regulations, and other guidance, agencies must maintain accountability for the financial results of actions taken, control over financial resources, and protection of assets. As stated in the Office of Management and Budget Circular A-127, agencies are required to maintain financial management systems and related internal and management controls that "provide complete, reliable, consistent, timely and useful financial management information on Federal Government operations to enable central management agencies, individual operating agencies, divisions, bureaus, and other subunits to carry our their fiduciary responsibilities; deter fraud, waste, and abuse of Federal Government resources; and facilitate efficient and effective delivery of programs. . . ."

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that CDC (1) implement a training and certification program for managers and staff responsible for budget and accounting functions within all organizational components to ensure they are aware of requirements on the use of Federal funds and understand how to properly use CDC's accounting system; (2) establish an internal quality assurance capacity within CDC's Financial Management Office to carry out regular assessments of CDC's policies, procedures, and controls related to budget and accounting functions; and (3) continue developing systems to properly identify and allocate indirect costs at the CDC level and begin developing similar systems to identify and allocate indirect costs at the organizational component level based on the relative benefits provided.

Status

Management Response

The CDC generally concurred with our finding that some amounts budgeted for CFS research were actually used for other programs and activities. The CDC cited actions it had taken to implement our recommendations and committed to share a comprehensive CFS spending plan with the national CFS advisory committee, the Congress, and nonprofit organizations providing support to CFS patients. Also notable is CDC's commitment to restore all diverted funding to its CFS research program.

Public Health

Improve the Process by Which Blood Establishments Notify FDA of Errors and Accidents Affecting Blood

Report Number: OAS-03-93-00352 Final Report: 5/95

Finding

Error and accident reports were not submitted timely by blood establishments, and there was no assurance that unlicensed establishments were voluntarily submitting the reports.

Current Law/Policy

The Public Health Service Act (Title 42, U.S.C. 262) and the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. 331) place the responsibility for the oversight of blood establishments with FDA.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The FDA should (1) expedite the development and issuance of revisions to Federal regulations on error and accident reporting (21 CFR 600.14(a)) to be more specific concerning the time frame in which reports are required to be submitted; (2) expedite the development and issuance of regulations to require unlicensed blood establishments to submit error and accident reports; and (3) expand the Center for Biologics Evaluation and Research's (CBER) use of information in its current error and accident data base to identify blood establishments that regularly fail to submit error and accident reports in a timely manner and provide additional trend analysis reports to FDA field offices and blood establishments.

Status

Management Response

The FDA is pursuing final revisions to Title 21, CFR 600.14, Reporting of Errors and Accidents, to require that unlicensed blood establishments submit reports and to be more specific concerning the timeframe for reporting.

Public Health

Improve FDA's Handling of Adverse Drug Reaction Reports

Report Number: OAS-15-98-50001 Final Report: 12/99

Finding

The FDA's postmarket surveillance system includes the use of reports of adverse drug reactions (ADR) to obtain information on rare, latent, or long-term effects not identified during a drug's premarket clinical studies. Based on the incidences of ADRs estimated in the medical literature, FDA receives a low percentage of ADR reports. We found that FDA needs to increase the number and quality of ADR reports it receives, and we identified a number of procedural and oversight deficiencies in FDA's management of reported ADRs.

Current Law/Policy

The initial reporting of ADRs by hospitals, health professionals, and consumers to the manufacturer and/or FDA is strictly voluntary. Manufacturers that receive ADR reports are required by regulation to report them to FDA.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The FDA should (1) develop procedures for more effective coordination between its postmarket drug risk assessors and review divisions to better ensure that prompt and appropriate regulatory action is taken when necessary; (2) implement a quality control system to ensure that signals of serious, yet unrecognized adverse reactions that might indicate a public health problem are not overlooked; (3) quantify the extent and scope of the ADR problem with the goal of reducing the occurrences of serious preventable ADRs; (4) encourage greater interactive reporting of serious ADRs and product problems by health professionals directly to FDA by telephone; (5) coordinate with HCFA to require hospitals to report all serious, unexpected ADRs directly to FDA as a condition for participation in Medicare and Medicaid; (6) explore proactive methods to obtain ADR data to supplement the agency's passive postmarketing monitoring system; and (7) evaluate the adequacy of postmarketing surveillance staffing levels needed to effectively monitor the safety of the increasing number of marketed drugs and, as necessary, identify funding sources for additional staff.

Status

Management Response

The FDA generally concurred with the recommendations.

Public Health

Enforce State Pharmacy Boards' Oversight of Patient Counseling Laws

Report Number: OEI-01-97-00040 Final Report: 8/97

Finding

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

Current Law/Policy

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

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

Status

Management Response

The FDA offered no comments.

The HCFA concurred with our recommendation to facilitate State efforts to enforce the Medicaid patient counseling mandate. The HCFA will assist States by amending the Drug Utilization Review Annual Report instructions to collect specific information regarding the compliance, monitoring, and effectiveness of these efforts. In addition, HCFA will gather best practices from the States and distribute this information to all pharmacy boards.

Public Health

Strengthen FDA Oversight of State Food Firm Inspections

Report Number: OEI-01-98-00400 Final Report: 6/00

Finding

The 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/Policy

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 the partnership agreements. In particular, we emphasize 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 longer term objective, we recommend that FDA work with the States to achieve basic equivalency in food safety standards, laws, and inspection practices as a basis for future work with States.

Status

Management Response

The FDA developed and drafted the following documents; Contract Audit Form, Guidance for Contract Audit, and Field Management Directive (FMD) 76. Currently, the documents are being reevaluated and will be redesigned. As a result of the reevaluation and redesign of these documents, the State Contract Audit Course will be delayed to a later date. The FDA posted a number of audit inspections for Fiscal Year 1999 on both the Internet and Intranet.

Public Health

Evaluate Comprehensive Hemophilia Treatment Centers' Utilization of the 340B Drug Pricing Program

Report Number: OAS-01-98-01505 Final Report: 12/99

Finding

Improvements in the 340B drug pricing program are needed to ensure that all State Medicaid agencies obtain the full advantages available under the program. Officials at 6 of the 23 comprehensive hemophilia treatment centers contacted stated that their entities purchase outpatient drugs at the 340B discount prices, but not for their Medicaid beneficiaries. For one selected center, we determined that the State could achieve annual savings ranging from $18,395 to $27,170 per person if it reimbursed the center at the 340B discount prices instead of the Medicaid rate.

Current Law/Policy

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid Drug Rebate program and required drug manufacturers to provide State Medicaid agencies with statutory rebates for covered outpatient drugs. This act established the foundation for the Veterans Health Care Act of 1992, which authorized section 340B of the Public Health Service Act to establish price controls to effectively limit the cost of drugs to certain Federal grantees (covered entities). The HRSA implemented this statutory mandate by establishing the 340B program. Covered entity participation in this program is voluntary.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HRSA and HCFA work together to achieve a fair and equitable resolution of the issues involving the economical purchasing, and subsequent Medicaid billing, of covered drugs by entities participating in the 340B program.

Status

Management Response

Both HRSA and HCFA concurred with the recommendation. According to HRSA, the HRSA and HCFA work group, chaired by the Deputy Administrators of the two agencies, plans to meet quarterly to discuss the clarification of earlier guidance to remedy any potential confusion regarding the duplication of the discount mechanism.

Public Health

Improve the Administration of HRSA's Health Professions Student Loan Program

Report Number: OAS-05-99-00017 Final Report: 3/00

Finding

We found that 8 of the 10 educational institutions audited were carrying uncorrectible loans in their accounting records. These schools did not assess the collectibility of their Health Professions Student Loans on a regular basis, and 5 of them did not have a mechanism to identify loans that were about to exceed the 10-year repayment period. In addition, several of the allopathic medicine programs maintained large cash balances which may exceed the needs of the schools.

Current Law/Policy

The HRSA's Health Professions Student Loan program regulations require participating schools to assess the collectibility of any loan that is more than 3 years past due. If a school determines that a loan is uncorrectible, or if the 10-year repayment period has expired, the school should either request HRSA's permission to write off the loan within 30 days or reimburse HRSA the full amount of the principal, interest, and penalty charges that remain uncorrectible. The regulations also require schools to estimate their collections and expenditures for the year at all allopathic schools and return to HRSA any cash determined to be excess to their needs.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that HRSA (1) reemphasize program regulations requiring schools to submit to HRSA their uncollectible loans for write-off or to reimburse HRSA for the uncollected loan balances; (2) reemphasize the importance of having a mechanism in place to identify loans that are about to exceed the 10-year repayment period; and (3) review the appropriateness of the estimated expenditures and collections associated with excess cash determinations at all allopathic schools and, if necessary, revise the methodology for computing excess cash.

Status

Management Response

The HRSA concurred and stated that it had resolved or is in the process of resolving each of the recommendations.

Public Health

Enhance Maternal and Child Health Training Grant Program

Report Number: OEI-04-98-00090 Final Report: 4/00

Finding

The Interdisciplinary Leadership Education Excellence in Caring 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 in demonstrating leadership and tracking graduates. Also, monitoring and evaluation of grantees is minimal.

Current Law/Policy

The LEND program is a training grant program authorized under the Maternal and Child Health Services Block Grant as a 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 at almost $18 million in FY 1998.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

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

Status

Management Response

The HRSA concurred with all recommendations. Performance measures are being developed and expect to be submitted to the Office of Management and Budget. The HRSA is also working with the American Association of University Affiliated Programs to develop instruments to assist in data collection and tracking activities. The agency completed site visits to more than 30 percent of LEND grantees during FY 2000 and expects completion of 25 percent in FY 2001.

Public Health

Improve Hospital Reporting to the National Practitioner Data Bank

Report Number: OEI-12-99-00250 Final Report: 7/99

Finding

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

Current Law/Policy

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 National Practitioner 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

The HRSA agreed with the recommendation. The legislative proposal is currently under review within the Department.

Public Health

Ensure That Indian Tribes Appropriately Use the 340B Drug Pricing Program

Report Number: OAS-01-99-01502 Final Report: 8/00

Finding

An Indian tribe with a self-determination contract with IHS (1) improperly extended eligibility for federally discounted drugs to non-Indian employees without making the required determination that reasonable alternative services were not available to these employees and (2) did not follow Federal guidelines pertaining to the 340B drug pricing program.

Current Law/Policy

Indian tribes are eligible for discounted drugs based on their contractual or compact agreements with IHS. Federal law and HRSA guidelines provide additional criteria on the eligible recipients of 340B drugs. Specifically, the Public Health Service Act, Section 340B(a)(5) (B), provides that only individuals considered to be patients (further defined by HRSA in an October 24, 1996, Federal Register notice) of the covered entity may receive discounted drugs. Also, the Indian Health Care Improvement Act requires tribes to demonstrate that reasonable alternative services do not exist before procuring discounted drugs for otherwise ineligible individuals.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that IHS and HRSA work cooperatively to instruct all federally recognized tribal entities on the proper use of the 340B program to obtain prescription drugs. Such instruction should include direction on eligible recipients/patients and requirements for participation.

We also recommend that IHS (1) notify all tribes that the eligibility determination regarding the availability of reasonable alternatives must be made before procuring discounted drugs for otherwise ineligible individuals and (2) review all existing tribal self-determination contracts/compacts and associated annual funding agreements to determine whether they contain language inferring that tribes that may use Federal discount drug programs to procure drugs on behalf of ineligible individuals. Where such language exists, it should be eliminated in the next negotiation process.

Status

Management Response

In response to a draft of this report, both IHS and HRSA agreed with the recommendations.

Public Health

Improve Management of the Office of Program Integrity and Ethics

Report Number: OEI-04-97-00060 Final Report: 11/98

Finding

We found that the mission, policies and procedures for the Office of Program Integrity and Ethics are not clear. In addition, organizational structure obscures visibility and prominence; and organizational placement fragments responsibility for personnel security. Also, staffing may be inadequate.

Current Law/Policy

The IHS Director asked the Office of Inspector General to evaluate, for effectiveness, the operation of its program integrity and ethics functions. The Office of Program Integrity and Ethics investigates complaints about IHS and tribal employees, performs ethics activities, and coordinates personnel suitability investigations.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that the IHS should: (1) Finalize its policies and procedures manuals and distribute it to all offices as soon as possible. The manual should delineate the integrity and ethics responsibilities of all IHS components, and procedures for components to follow. (2) Evaluate the adequacy of staffing.

Status

Management Response

The IHS concurs with our recommendations. The IHS is in the process of finalizing its policies and procedures manual which will delineate the integrity and ethics responsibility of all IHS components. In addition, the Office of Program Integrity and Ethics currently maintains a listing of "Area Ethics Contacts," for all IHS area offices. This listing is utilized as the master contact points for all IHS ethics issues.

Public Health

Improve the Indian Health Service EEO Complaint Process

Report Number: OEI-05-99-00290 Final Report: 7/00

Finding

The Indian Health Service (IHS) operates under four conditions which complicate the equal employment opportunity (EEO) complaint process: Indian preference, commissioned corp employees, tribal contracting/compacting, and downsizing. Inconsistencies in the EEO system result in unequal treatment of complaints. Employee distrust of EEO is widespread throughout IHS and undermines the effectiveness of the EEO process.

Current Law/Policy

Operating division EEO offices are responsible for establishing and maintaining EEO programs. In addition, 29 CFR 1614.102(a)(1) requires each agency to provide sufficient resources to its EEO program to ensure efficient and successful operation.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The IHS should address specific issues pertaining to Indian preference, commissioned corp employees, tribal compacting/contracting, and downsizing; should standardize the handling of EEO complaints; improve counselor performance and supervision; standardize complaint reporting, recording, and file retention; eliminate conflicts of interest and the potential for complaints of interest; and improve communication and expand EEO training and educational opportunities to all IHS employees, EEO staff, and counselors.

Status

Management Response

The IHS concurred with the majority of our recommendations. The IHS has developed an EEO web site, a fact sheet explaining the differences between Indian preference and Title VII discrimination, and new EEO posters. In addition, IHS has numerous plans to further address the recommendations in FY 2001.

Public Health

Establish an FDA Performance Measurement System in Compliance with the Prompt Payment Act

Report Number: OAS-15-96-40002 Final Report: 5/97

Finding

The FDA has not established a systematic, agencywide performance measurement system to assess its payment system.

Current Law/Policy

The OMB Circular A-125 requires agencies to establish a systematic performance measurement system throughout each agency to estimate payment performance, provide managers with information on problems, and assist in targeting corrective action.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The FDA should assess its payment process at headquarters to include (1) assessments of transactions processed using standard payment procedures; (2) comparisons and analyses of payment system data with original purchase orders, invoices, and receiving reports for selected transactions; and (3) adjustments made when compiling data reported by field offices.

Status

Management Response

The FDA is working to establish a performance measurement system for assessing the performance and reporting of headquarters' payments to vendors, and a policy requiring implementation of the system is under development. Individuals independent of the FDA Accounting Operations Branch will make the periodic assessments, which will be scheduled depending on the availability of resources.

Public Health

Improve FDA's Cost Management of Construction Projects

Report Number: OAS-15-98-50002 Final Report: 9/99

Finding

Construction of the Arkansas Regional Laboratory exceeded the budget estimate by $10.4 million because of $3.4 million in costs that were not included in FDA's original budget; a $2.1 million increase in the architecture and engineering (A&E) firm's revised estimate; and $4.9 million in costs attributable to a variety of factors, such as inflation and the A&E firm's cursory assessment of market conditions.

Current Law/Policy

The OMB Circular A-11, Appendix 300A, specifies principles of budgeting for capital asset acquisitions.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

To ensure that the Arkansas Laboratory and future construction projects are implemented within anticipated cost ranges, FDA should (1) ensure that all applicable costs are included when preparing the initial cost estimate, (2) obtain a construction management estimate of the cost of construction, (3) ensure that construction project estimates are updated for inflation and changing market conditions if the contract is not bid within 3 months of the date of the estimate, and (4) notify the Congress of potential cost overruns at the earliest possible date.

Status

Management Response

The FDA generally concurred with the recommendations.

Public Health

Develop Plan to Address Youth Use of Cigars

Report Number: OEI-06-98-00020 Final Report: 2/99

Finding

Cigars have not faced the same degree of Federal regulation and oversight as other tobacco products, such as cigarettes and spit tobacco. State enforcement of laws and regulations prohibiting the sale to, and use of cigars by, minors is currently severely limited. Lack of resources and a low enforcement priority are seen as the most significant barriers to effective control of cigar use by minors.

Current Law/Policy

The Synar Amendment to the Public Health Service Act requires States to have in place a law that prohibits the sale or distribution of any tobacco product to individuals under the age of 18 (minors) through any sales or distribution outlet and to reduce the rate of sale of cigarettes to minors according to a plan agreed to with SAMHSA. States face the loss of significant amounts of the Substance Abuse and Treatment block grant if they do not show progress in reducing the sales of cigarettes to minors on a yearly basis. Synar is not currently enforced for cigars.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that the Department, under the leadership of the Assistant Secretary for Health, develop an action plan to address the public health risks posed by cigars, particularly access by youth. As a first step, we recommend an initiative to inform the public of the health risks through public education that is appropriate for cigars. As a second step, the Department should address the need for additional research on cigars.

Status

Management Response

On June 26, 2000 the Department joined with the Federal Trade Commission (FTC) and announced an agreement that will result in the first comprehensive health warning system for cigar packaging and cigar advertising. At the Surgeon General's request, senior staff from the National Cancer Institute and the Centers for Disease Control and Prevention reviewed the labels originally under consideration by the FTC to assure that they were consistent with the most current science. This represents the first time a tobacco product has included a warning about environmental tobacco smoke. The new health warnings will insure that nearly all cigars sold in the United States will contain labels based on the latest scientific evidence. In addition, the Centers for Disease Control and Prevention has accelerated its cigar related education and surveillance activities through development of an innovative internet strategy and the national dissemination of television and radio counter-advertisements through the Office on Smoking and Health's Media Campaign Resource Center.

Public Health

Expand Dissemination of Treatment Improvement Protocols

Report Number: OEI-07-96-00130 Final Report: 3/98

Finding

Thirty-two percent of SAMHSA funded grantees reported that they were aware of at least one of five treatment improvement protocols (TIPS) referenced in our survey. Eighty-six percent of FDA narcotics/methadone treatment providers responded that they were aware of at least one of the five TIPS while 32 percent of community heath centers reported they were aware of at least one of the five TIPS.

Current Law/Policy

The TIPS are consensus-based "best practices" guidelines developed for SAMHSA for use in the treatment of individuals with alcohol or drug problems. Since 1993, 23 TIPS have been developed and issued at a cost of about $300,000 each.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The SAMHSA should (1) take a more proactive approach to advertising the availability of all past and future TIPs, and (2) consider expanding their "target audience."

Status

Management Response

The SAMHSA conducted a major, 1-year retrospective study to assess the effectiveness of the TIPS effort and completed a two-wave, cross-sectional analysis of the study. The total sample consisted of 4,257 treatment providers, randomly selected from the Uniform Facility Data Base, with an 80 percent response rate. The findings, which reflected the OIG's conclusions, indicated the need to better disseminate TIPS to clinical supervisors and program counselors, rather than stopping at the single State agency or facility director level.

The SAMHSA, through its Center for Substance Abuse Treatment (CSAT), has implemented these recommendations which include distribution of TIPS to all treatment providers (over 17,000 copies), use of searchable CD ROMs, quick reference guides, and user-friendly fact sheets to enhance the usability and value of TIPS. Implementation of these new dissemination strategies, along with the development of a culturally specific expert panel to recommend TIPS to wider and more culturally and ethnically diverse populations should ensure that the recommendations are completely addressed. The retrospective study also contains an evaluation component which will be continued to further ensure a saturation of the treatment market with these important CSAT-sponsored publications and products.

Public Health

Develop Performance Measures for Detoxification Services for Medicaid Beneficiaries

Report Number: OEI-07-97-00270 Final Report: 11/98

Finding

Fifteen States have a formal process for providing transition from substance abuse detoxification to treatment; 32 of the 35 remaining have informal processes. We also found that States tailor substance abuse programs to complement their own service delivery systems; have limited data on detoxification and treatment activity outcomes; one-third of States conduct performance monitoring of substance abuse programs and; seldom use outpatient settings for detoxification services.

Current Law/Policy

Detoxification and substance abuse treatment are funded federally by HCFA and SAMHSA. Annually, SAMHSA spends over $1.5 billion on substance abuse prevention and treatment services. In addition, HCFA covers substance abuse detoxification and treatment in most State Medicaid programs.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The SAMHSA and HCFA should work with States to develop appropriate performance measures.

Status

Management Response

The SAMHSA's Center for Substance Abuse Treatment (CSAT), in collaboration with the National Association of State Alcohol and Drug Abuse Directors (NASADAD), successfully negotiated an agreement with State substance abuse agencies to provide voluntary reporting of treatment outcome data as part of the annual Substance Abuse Prevention and Treatment Block Grant application. Analysis of this data is ongoing. Additionally, CSAT used the Washington Circle Group (WCG), a group of State, academic, and treatment representatives with expertise in alcohol and other substance abuse (AOSA) disorders, managed care and performance management, to improve the quality and effectiveness of AOSA prevention and treatment services through the use of performance measures. This activity focused on development of performance measures to track the activities of public and private health plans to prevent, recognize, and treat AOSA disorders.

Through collaboration and dialogue with others in the AOSA and mental health fields, including NASADAD, WCG is building upon existing performance monitoring systems and data sets to ensure more efficient measurement of AOSA services. Seven core process measures related to adult treatment outcomes have been identified and are being pilot tested. A report on the pilot test findings is expected by March 2001.

Working in collaboration with HCFA, SAMHSA, through its CSAT, has convened a conference of State Medicaid, Substance Abuse, and Mental Health Directors to discuss performance measures issues. In addition, CSAT is continuing to work with the National Committee for Quality Assurance to implement the same measures both in the public and private sectors.

Children and Families

Overview

The Department's Children and Families agency 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.

Introduction

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 and 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 program.

Related OIG Activities

The Office of Inspector General (OIG) 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 Head Start program objectives are accomplished.

Children and Families

Enhance Implementation of the Interstate Compact for Placement of Children

Report Number: OEI-02-95-00044 Final Report: 3/99

Finding

The Compact facilitates interstate placements and States are fulfilling their obligations under the Compact. However, some weaknesses are acknowledged, including lack of awareness of the Compact by key stakeholders such as judges, lawyers, and caseworkers; placements in violation of the compact; the lengthy process; and differing adoption laws among States that may hinder placements.

Current Law/Policy

The Interstate Compact on the Placement of Children is a contract among the States intended to ensure that children placed across State lines receive adequate protection and services.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

As an opportunity for improvement, ACF should support efforts to increase information dissemination about the Compact's purpose, importance, and process.

Status

Management Response

An Adoption Opportunities grant was awarded to the American Public Human Services Association, Grant Number 90CO0898, to develop and deliver training to State agencies regarding the functioning of the Interstate Compact for the Placement of Children. The training manual was completed February 2000 and a pilot training for trainers was delivered in March 2000. In April 2000, training for all new Association of Administrators of the Interstate Compact for the Placement of Children (AAICPC) members was delivered at the annual AAICPC conference. The training was developed for new ICPC Administrators/liaisons, ICPC trainers, public and private child welfare agencies, residential treatment facilities, judiciary, and attorneys. There are trainers available to the States to provide the training if requested.

Children and Families

Strengthen State Licensing of Residential Foster Care

Report Number: OEI-02-98-00570 Final Report: 5/00

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/Policy

Title 4-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

The ACF agreed that variability in licensing standards is of concern. They indicated that they are taking an outcome-based approach to monitoring States.

Improve Client Cooperation with Child Support Enforcement: Strategies, Public Assistance Agencies, and Use of Good Cause Exception

Report Number:	OEI-06-98-00041	Final Report:	3/00
	OEI-06-98-00042		3/00
	OEI-06-98-00043		3/00

Finding

Local public assistance and child support staff report they give clients multiple opportunities to cooperate with child support enforcement, and that most provide enough useful information to pursue support. Local offices try to educate clients; however, some clients may not cooperate fully until penalties are threatened or imposed. States attempt to encourage cooperation by improving procedures, but public assistance and child support agencies sometimes have difficulty communicating and sharing case information.

It appears local staff received few requests for good cause exceptions to client cooperation requirements, and received virtually no fraudulent claims. Staff believe clients at risk of domestic violence may not request a good cause exception because they find it easier to claim they have no information, wish to avoid intervention from the State, fear retaliation, or do not fully understand the process of claiming an exception. Some efforts are made to preserve client safety and confidentiality, but these efforts are often modest and not fully implemented.

Current Law/Policy

The Personal Responsibility and Work Opportunity Act of 1996 required TANF clients to name and provide information about the absent parent of their children, and otherwise cooperate as determined by the State. The TANF clients can be exempted from this requirement through a good cause exception if their circumstances meet that criteria. Child Support Enforcement agencies are required to determine a client's cooperation status. Public assistance agencies must impose penalties against uncooperative clients. If State public assistance agencies fail to do so, Federal law allows for the State to be penalized up to 5 percent of their TANF funds.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that ACF encourage States to evaluate policies which require redundant client interviews, create disincentives to cooperation, and provide benefits prior to cooperation. We also recommend encouraging proper imposition of penalties for non-cooperation, further local staff training, and greater interaction between public assistance and child support agencies. The ACF should encourage States to develop strategies that allow TANF clients at risk of violence to safely pursue child support, enhance staff training on domestic violence and the use of good cause exceptions, and evaluate their practices for protecting client confidentiality.

Status

Management Response

We are awaiting agency comments on our reports.

Children and Families

Promote State Activities Which Effectively Address Workplace Violence

Report Number: OEI-06-98-00044 Final Report: 3/00

Finding

Workplace violence appears to be a concern for many managers in State and local child support and public assistance offices. Many managers fear for the safety of their staff and, while actual reported violence is rare, some incidents of violence have occurred in local offices. A variety of stresses and circumstances were discussed which may lead to concerns about potential violence. Some local offices have employed a variety of security measures to reduce or prevent workplace violence.

Current Law/Policy

On March 5, 1997, Secretary Shalala issued a memorandum to the heads of all Department operating divisions and staff divisions regarding the issue of violence in the workplace. While the Secretary's memorandum focuses on improving workplace safety in HHS agency offices, States and local jurisdictions also administer social service agencies and local offices where employees may encounter workplace violence. The data collected during our inspection provides information that may be useful to program officials for better understanding the potential for violence in local public assistance and child support offices.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

No recommendations were made. While local office safety is primarily the responsibility of States, based on our findings, we suggest that ACF may wish to discuss the extent and severity of workplace violence with its State partners with a view to promoting the development and sharing of strategies which effectively address this issue.

Status

Management Response

The OCSE has provided local managers and staff with various tools to raise security awareness and to provide a safer workplace for all employees. These tools include production and distribution of a video which discusses how protecting data and ensuring the physical safety of child support staff are essential to the continuation of services. The OCSE has also developed a 6-hour "Training of Trainers" course which focuses on raising security awareness and the need to make security a priority. A second training course for managers is being developed which will focus on security from the managers perspective. A manager's self-assessment checklist is being developed to help managers assess the security levels in their own offices and offers suggestions to begin implementation of a security plan. Flash Bulletins will be issued to identify security problems or best practices that States may implement. The OCSE is planning to add all of the above information to its Web site. All of these tools are adaptable for use by local public assistance management and staff.

Children and Families

Improve Medicaid-Only Clients Cooperation with Child Support Enforcement

Report Number: OEI-06-98-00045 Final Report: 4/00

Finding

Workers in some child support and public assistance offices observed that the proportion of clients in their caseload who only receive Medicaid is increasing. A number of workers, as well as clients, do not understand that Medicaid clients must cooperate with Child Support Enforcement (CSE). It appears that sanctions often are not applied when Medicaid-only clients do not cooperate. Local child support managers and workers expressed concern that being held accountable for large numbers of unresolved Medicaid cases could have an adverse effect on their performance measures and budgets.

Current Law/Policy

Federal law continues to require that custodial parents must cooperate with the CSE agency as a condition of eligibility for Medicaid. Medicaid clients who fail to cooperate with CSE, unless exempted for good cause, can be penalized through the loss of eligibility for Medicaid coverage, although Medicaid coverage of dependent children and women who are pregnant must continue even when clients do not cooperate.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

While no recommendations were made, as an opportunity for improvement, further study is warranted before developing specific corrective action, but our limited research led us to some potential solutions. The ACF in cooperation with HCFA could provide additional technical assistance and encouragement to State and local partners to provide additional training to ensure that agency workers and clients understand their responsibilities and expectations under existing policy. The HCFA and ACF may want to continue to develop new policy or refine and issue promising pending rules encouraging collaboration between CSE and those agencies responsible for cash and medical assistance. The ACF may consider further evaluation of staff and program performance structures and revision of Medicaid-only case closure criteria.

Status

Management Response

The ACF staff have been meeting with HCFA staff to discuss policy and procedural issues between CSE and Medicaid and State Children's Health Insurance Program agencies. The HCFA has drafted a letter to State Medicaid Directors clarifying the cooperation requirement for individuals. The HCFA and ACF will continue to provide technical assistance and policy and procedural clarifications in response to requests from State and local staff.

The ACF has developed proposed regulations for the Child Support Performance and Incentive Act. A final rule is expected in the Fall. The regulations will address the creation of the National Medical Support Notice as a means of enforcing medical support provisions in child support orders.

It is anticipated that the Administration will submit a performance indicator to measure the effectiveness of IV-D agencies to Congress in a report by June 2001. In regard to case closure criteria, ACF will provide technical assistance to States to clarify the existing case closure rules for Medicaid-only cases.

Children and Families

Improve Paternity Establishment: Use of Alternative Sites for Voluntary Paternity Acknowledgment

Report Number: OEI-06-98-00052 Final Report: 7/99

Finding

Half of the States offer acknowledgment services through some of their public assistance offices. Few States have expanded services to other sites. State efforts to encourage participation have met reluctance by some entities due to time demands on limited staff and lack of financial incentives. Typical services offered through alternative sites include distribution of public outreach materials explaining voluntary acknowledgment and, to a lesser degree, personal assistance to parents in completing paternity acknowledgments. Many State child support agencies have not developed adequate methods of monitoring and evaluating alternative sites.

Current Law/Policy

The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996 requires State child support agencies to provide voluntary paternity acknowledgment services through in-hospital acknowledgment programs and through the State agency responsible for maintaining birth records. To further expand services to unmarried parents, the Act allows but does not require States to offer acknowledgment services through "other entities." If States use this added flexibility to expand acknowledgment services, the law requires State child support agencies to administer alternative sites in the same manner as in-hospital programs.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The ACF should (1) focus technical assistance on the most promising alternative sites, (2) minimize complexity for participating entities, (3) encourage full-service participation, (4) consider developing incentives for alternative site participation, and (5) encourage State agencies to more closely monitor these sites.

Status

Management Response

The ACF notes that OCSE has committed to State development of alternative sites by allowing States to pay up to $20 for each voluntary paternity acknowledgment obtained by hospitals, State birth record agencies, and other entities designated by the State and participating in the State's voluntary paternity establishment program for each voluntary acknowledgment obtained pursuant to an agreement with the child support agency. In addition, ACF anticipates that in an effort to increase paternity establishment ratios to the levels PRWORA requires, States will work closely with and monitor the progress of paternity acknowledgment in alternative sites.

Children and Families

Improve Employment Programs for Persons with Developmental Disabilities

Report Number: OEI-07-98-00260 Final Report: 8/99

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/Policy

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

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that ACF (1) establish core data requirements to evaluate job initiatives and (2) work with State Councils to share promising and innovative practices.

Status

Management Response

The 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.

Children and Families

Improve TANF Client Sanction Notices

Report Number: OEI-09-98-00292 Final Report: 10/99

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/Policy

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

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

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

Status

Management Response

The ACF concurred with the recommendation and indicated it will provide States with examples of understandable and comprehensive sanction notices and facilitate networking among States interested in improving these notices.

Children and Families

Improve Child Support Enforcement Annual Report to Congress

Report Number: OEI-02-98-00070 Final Report: 10/98

Finding

We found that, overall, users are satisfied with and rely on the Office of Child Support Enforcement's Annual Report to Congress. They view it as a valuable and unique source of child support program information. Users cite the report's lack of a clearly defined story line, program performance data, timelines, and data integrity as its main weaknesses.

Current Law/Policy

The Child Support Enforcement (CSE) program was established in 1975 under Title IV-D of the Social Security Act. It is administered at the State level and overseen federally by the Office of Child Support Enforcement (OCSE). In establishing the CSE program, Congress requires OCSE to submit an annual report to them no later than 3 months after the end of each fiscal year. While the legislation mandates the reporting of certain data, it does not define many of the data elements.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

(1) We recommend that ACF focus primarily on performance in the Report to Congress. Specifically, the report should (a) highlight program successes, strengths, and weaknesses; (b) emphasize performance data which demonstrates how well the program is meeting its goals, and; (c) adequately describe program accomplishments that, when used to compare different program strategies, may be valuable to Federal policy makers and State programs. (2) We recommend that ACF review the report's production and distribution processes and identify specific actions to improve its timeliness.

Status

Management Response

The ACF concurred with our recommendations. According to ACF, as of Fiscal Year 1999, the annual report reflects the Personal Responsibility and Work Opportunity Act of 1996 changes in the way data is gathered and reported. The ACF also anticipates that fundamental changes in the Child Support Enforcement program such as performance-based financial incentives for States, that require new forms and standards definitions, will change the way data is presented in the annual report. The ACF is working to streamline production and distribution of the annual report and plan to publish a preliminary data report for States and individuals.

Children and Families

Improve Access to Medical Insurance for Dependents Receiving Child Support

Report Number: OEI-07-97-00500 Final Report: 6/00

Finding

Considerable progress has been made by the 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 the 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/Policy

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 AFDC program. In 1985 and 1988 Federal regulations were issued that requires 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

The 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 HCFA, should examine alternatives to recover the costs of managed care premiums from the noncustodial parents.

Status

Management Response

The ACF expressed its commitment to working with HCFA and other State partners to improve access to medical coverage for children. The ACF noted medical support as being one of its top priorities. In addition, ACF is planning to disseminate to all State child support agencies the OIG report and a summary of present regulations as they apply to medical support. In addition, the Child Support Performance and Incentive Act of 1998 directed the Secretary of HHS and the Secretary of Labor to establish a Medical Child Support Working Group. The Working Group has issued recommendations to improve medical support and coordination between CSE agencies and Medicaid.

Children and Families

Provide Guidance to Tribal Child Care Programs

Report Number: OEI-05-98-00010 Final Report: 11/98

Finding

We found that the Child Care Development Fund (CCDF) grants provide Indian children greater access to child care. However, lack of State and Tribal coordination impacts costs, wastes resources, and opens up the potential for duplicate payments. We also found that impediments exist in the coordination of Head Start and CCDF programs and that Tribal child care plans, payment systems, and reporting are flawed.

Current Law/Policy

The Child Care Development Block Grant Act of 1996 (CCDBG), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, now permits Tribal grantees to directly administer child care funds, in addition to operating CCDBG programs. The amended CCDBG Act also permits Tribal grantees to use funds for construction and renovation purposes. Indian children can access child care from their own Tribes, other Tribes or from a consortium. Tribal CCDF programs serve Indians living in self-defined service areas.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

We recommend that ACF (1) encourage Tribes and States to develop reciprocal agreements, share systems and establish single points of enrollment; (2) compile and disseminate information about model Head Start/child care collaborative initiatives; and (3) provide model timesheets, model accounting practices and on-site assistance to Tribes.

Status

Management Response

The ACF concurred with our recommendations and many are being addressed by the Child Care Bureau's technical assistance contract for a Tribal Child Care Technical Assistance Center (TriTAC). Under this contract, the Child Care Bureau continues to provide technical assistance at the regional office meetings, on-site visits, cluster training, and at the Child Care Bureau's annual national American Indian/Alaska Native Child Care Conference. In direct response to OIG recommendations, a number of workshops were held at the May 2000 American Indian/Alaska Native Child Care conference that addressed the recommendations.

The Child Care Bureau plans to establish a Listserv specifically for tribal CCDF grantees. The Listserv will be a valuable tool for grantees to provide "peer to peer" technical assistance on a variety of topics, including State-Tribal agreements, collaborations with other programs such as Head Start, TANF and Child Welfare, and administrative and fiscal issues.

Older Americans

Overview

The Older Americans agency aims at improving older Americans' 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.

One Federal agency - the Administration on Aging (AoA) in the Department of Health and Human Services (HHS) - 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 care givers. The 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 (OIG) 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.

Older Americans

Improve Long-Term Care Ombudsman Program

Report Number: OEI-02-98-00351 Final Report: 3/99

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 compliant response and resolution, inconsistent advocacy efforts, a lack of support, and limited collaboration with surveyors.

Current Law/Policy

The Ombudsman program is authorized by Title VII of the Older Americans Act. State Ombudsman 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 recommend 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 HCFA to enhance collaboration with the survey and certification agency.

Status

Management Response

The AoA has developed program visibility guidelines which will be sent to the field for review. The AoA has produced two papers for circulation to all State ombudsmen that highlight and promote strategies for recruiting, training, and supervising volunteers. The AoA has developed a guideline for complaint investigation and resolution time which will also be sent to the field for comment. Finally, in order to ensure that all State ombudsmen understand and use the definitions in the data reporting system, AoA staff explained the definitions at State ombudsmen training sessions held in the spring of 1999 and 2000. Following receipt of comments from the field, AoA has indicated that it will send the OIG the final guidelines for program visibility and complaint investigation.

Older Americans

Improve Safeguards for Long-Term-Care Residents

Report Number: OAS-12-97-00003 Final Report: 9/98

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 on-board 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 screens more effective, none of the nursing homes surveyed in six States was aware of this data base or its availability on the Internet.

Current Law/Policy

Under HCFA statute and regulations, residents of nursing homes and other long-term-care facilities have the right to reside in a safe and secure environment, 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 recommend that (1) HCFA 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) HCFA consider establishing Federal requirements and criteria for performing criminal checks, and (3) HCFA consider developing a national abuse registry or expanding the current State registries to include all workers in facilities receiving Federal reimbursement.

Status

Management Response

The HCFA and AoA verbally agreed with our recommendations.

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 Managers' Financial Integrity Act and the Prompt Pay Act, financial management audits under the Chief Financial Officers Act, grants and contracts, the Department's Working Capital Fund, conflict resolution, and adherence to employee standards of conduct. The OIG also participates in interagency efforts through the President's Council on Integrity and Efficiency to prevent losses to and abuses of Federal programs.

Introduction

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 audit agency for most States and major research organizations. In addition, the OIG is responsible for auditing the Department'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.

Related OIG Activities

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

General Department Management

Update Cost Principles for Federally Sponsored Research Activities

Report Number: OAS-01-92-01528 Final Report: 5/93

Finding

The Department's hospital cost principles for federally sponsored research activities contained in CFR, Title 45, 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/Policy

The OASC-3 was published over 25 years ago when the research environment and Federal funding rules were less complex. The OASC-3 does not always provide clear guidance for determining what types of costs should be allowed and how costs should be allocated.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

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

Status

Management Response

The Department circulated a draft of the hospital cost principles to the National Institutes of Health, and the grants management community submitted comments in August 2000. The Department hopes to issue the cost principles by December 1, 2000.

General Department Management

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

Report Number: OAS-01-93-04000 Final Report: 6/93

Finding

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

Current Law/Policy

Currently, the Office of Management and Budget (OMB) Circulars A-21 and A-122, "Cost Principles for Educational Institutions" and "Cost Principles for Nonprofit Organizations," do not state whether the accrued portion of PRB 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 PRB costs.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The Assistant Secretary for Management and Budget (ASMB) should (1) work with OMB to revise applicable cost principles to address the impact of FASB 106 on PRB costs and (2) advise negotiators for the Division of Cost Allocation to pay special attention to PRB costs when reviewing fringe benefit rates for schools and nonprofit organizations.

Status

Management Response

The OMB has revised OMB Circular A-87 to limit PRB costs to the amount funded. While OMB agreed that similar provisions should be incorporated into Circulars A-21 and A-122, revisions made to these circulars in May and June 1998 did not address PRB costs. In the interim, ASMB has issued instructions to negotiators that PRB costs claimed under Circulars A-21 and A-122 should be treated in the same manner as the provisions of Circular A-87.

General Department Management

Improve Recharge Centers' Financial Accounting Systems

Report Number: OAS-09-92-04020 Final Report: 1/94

Finding

Recharge centers of 11 of 12 universities reviewed did not maintain adequate accounting systems and records to allow for the development of billing rates based on actual costs or the identification of surplus or deficit fund balances. As a result, some recharge centers (1) accumulated surplus and deficit fund balances that were not adjusted in subsequent billing rates, (2) included duplicate or unallowable costs in billing rates, (3) included recharge center costs in the calculation of indirect cost rates, (4) used recharge center funds for unrelated purposes, and/or (5) billed some users at reduced rates. These practices overstated billing rates, resulting in overcharges of $3.2 million to the Federal Government.

Current Law/Policy

The OMB Circular A-21, "Cost Principles for Educational Institutions," requires billing rates for recharge centers to be based on actual costs, designed to recover the aggregate cost of a good or service, and reviewed periodically.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

The ASMB should require universities to (1) develop and implement policies and procedures for operating recharge centers consistent with OMB Circular A-21, (2) establish and maintain adequate accounting and record keeping procedures for recharge centers, and (3) analyze and adjust billing rates to eliminate deficit and surplus funds.

In addition, ASMB should work with OMB in revising Circular A-21 to ensure that criteria related to the financial operation of recharge centers are clear.

Status

Management Response

The ASMB asked OMB to clarify Circular A-21 regarding recharge centers, stating that recharge centers should be evaluated as part of an institution's A-133 audit. The ASMB role would then be to resolve reported A-133 deficiencies.

General Department Management

Improve Financial Reporting Processes

Report Number:	OAS-17-98-00001	Final Report:	4/98
	OAS-17-98-00015		2/99
	OAS-17-99-00002		2/00

Finding

The Department and its operating divisions do not have fully integrated accounting systems capable of producing financial statements in a timely and efficient manner. Instead, HHS and many of its operating divisions use manual processes to summarize accounting data, 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.

Current Law/Policy

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements and establish time frames for submitting audited statements. The OMB Bulletin 97-01 requires that financial statements be the culmination of a systematic accounting process, and OMB Bulletin 93-06, Audit Requirements for Federal Financial Statements, provides OIGs with guidance to audit and report on the statements.

Recommendation

☐ Legislative ☑ Administrative ☑ Material Weakness

We recommend that ASMB work toward establishing a more formal, structured process capable of producing complete and reliable financial statements in a timely manner. Recommended steps include, in part, assessing HHS staffing levels to ensure that sufficient resources are available to prepare annual statements without hampering day-to-day accounting operations and automating and standardizing manually intensive processes used to prepare financial statements.

Status

Management Response

The HHS is taking steps to ensure that departmentwide and operating division financial statements are prepared timely and are auditable.

General Department Management

(Continued 2)

Report Number:	OAS-17-98-00001	Final Report:	4/98
	OAS-17-98-00015		2/99
	OAS-17-99-00002		2/00

Finding

At a number of operating divisions, there were significant delays in providing documentation supporting financial statement balances during the FY 1999 financial statement audits. We also noted numerous instances in which general ledger balances had not been periodically reconciled to supporting documentation. Reconciliation is an effective internal control for detecting and correcting duplicate postings, omitted entries, or incorrect transfer of data--all of which could result in material misstatements.

Current Law/Policy

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. The OMB Bulletin 93-06, Audit Requirements for Federal Financial Statements, provides OIGs with guidance to audit and report on the statements.

Recommendation

☐ Legislative ☑ Administrative ☑ Material Weakness

We recommend that ASMB oversee operating divisions' efforts to develop auditable documentation for financial statement amounts, ensure that accounting records are reconciled, and ensure that corrective actions continue on other accounting and control issues identified during audits of the HHS operating divisions.

Status

Management Response

The ASMB and operating divisions concurred and are taking steps to ensure that accounting records supporting financial statements are complete and accurate.

General Department Management

Improve Accounting for Property, Plant, and Equipment at NIH and FDA

Report Number:	OAS-17-98-00001	Final Report:	4/98
	OAS-17-98-00015		2/99
	OAS-17-99-00011		2/00

Finding

Although NIH and FDA have improved their accounting for property, plant, and equipment, management must make a commitment to sustain this progress. For example, during FY 1999, NIH's accumulated depreciation was understated by $8.4 million for 68 buildings and was overstated by $5.6 million for 19 buildings. Previous efforts will be lost unless NIH develops formal procedures to ensure proper accountability of assets and the monthly reconciliation of general ledger balances with personal property records.

During FY 1998, FDA completed a physical inventory of accountable personal property and reconciled its subsidiary ledger to the general ledger. Further policies and procedures were put in place for annual complete inventories and quarterly reconciliations of accounting records. However, we continued to find some differences between the property listing and property on hand and, for FY 1999, noted problems in tracking property transfers and maintaining documentation. Although these problems did not have a material impact on FDA's financial statements, the cause of these types of discrepancies, if not correctly identified and promptly resolved, could undermine the progress FDA has made.

Current Law/Policy

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 Federal entities to develop, maintain, and test the adequacy of their internal controls and financial management systems and to report on any material weaknesses and planned corrective actions.

Recommendation

☐ Legislative ☑ Administrative ☐ Material Weakness

Specific recommendations for corrective actions were made to the operating divisions. We also recommend that ASMB oversee the implementation of these corrective actions.

Status

Management Response

The ASMB and operating divisions concurred with the recommendations and are taking corrective actions.

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 Managers' 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 Follow-up
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 Follow-up 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 ACCESSIBLE

To access the 2000 Orange Book and various other Office of Inspector General materials on the Internet, use the following address:

http://www.os.dhhs.gov/oig