

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

*Program and Management Improvement  
Recommendations*

# **The Orange Book**



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Inspector General**

**2001-02**

# **OFFICE OF INSPECTOR GENERAL**

<http://www.oig.hhs.gov>

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

## **Office of Audit Services**

The 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

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

Generally, these recommendations can be implemented by an administrative action, while some call for a change of legislation. Although these recommendations generally have a nonmonetary impact when implemented, 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.

We hope that this 2001-02 Orange Book will be an asset to decision-makers as they continue in their efforts to improve HHS program efficiency.

## HEALTH AND HUMAN SERVICES

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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 with four major agencies: the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration), the Public Health Service agencies, the Administration for Children and Families, and the Administration on Aging, 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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# **Centers for Medicare and Medicaid Services**

# Centers for Medicare and Medicaid Services

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## Overview

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

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

The Medicaid program provides grants to States for medical care for more than 40 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.



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## Related OIG Activities

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

**Centers for Medicare and Medicaid Services**

*-Ambulance-*

**Develop Prepayment Edit to Verify Medical Necessity of Ambulance Claims**

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

**Finding**

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

**Current Law**

The CMS 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 CMS work with the industry to establish a negotiated fee schedule for ambulance payments effective January 1, 2000.

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

In comments on our draft report, CMS concurred with the need for medical review of these types of ambulance claims. The CMS 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.

**Centers for Medicare and Medicaid Services**

*-Contractor Operations-*

**Strengthen CMS Regional Office Oversight of Medicare Contractors**

Report Number:	OAS-17-97-00097	Final Report:	04/1998
	OAS-17-98-00098		02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001

**Finding**

The CMS regional offices have oversight responsibility for Medicare contractors, which submit periodic financial reports used in preparing the CMS financial statements. Our audit of the FY 2000 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**

Guidance for the oversight effort is found in instructions issued by the Office of Financial Management.

**Recommendation**

**Legislative**

**Administrative**

**Material Weakness**

The CMS should (1) develop appropriate input/output controls for routinely reviewing and documenting financial reports received from Medicare contractors to timely identify unusual items and inconsistencies and to emphasize CMS's reliance on these reports; (2) develop procedures to ensure that an audit trail exists and that supervisors approve transaction entries at the Medicare contractors and the CMS central and regional offices; and (3) provide additional training for financial personnel at the central office, the regional offices, and the contractors to ensure that personnel understand the importance of posting entries correctly and performing account analyses and reconciliations.

**Status**

**Management Response**

The CMS has continued to improve financial management over the past several years and has developed a comprehensive plan for financial management to address OIG recommendations. Specifically, CMS has developed detailed procedures for performing quarterly trend analyses of Medicare contractors' financial reports. The trend analyses will help identify unusual items and inconsistencies in contractor reports. During FY 2001, CMS issued instructions to the Medicare contractors and regional and central offices related to the entire debt management process. The instructions detailed the requirements necessary to ensure adequate support (audit trails) for accounts receivable balances and required supervisory review of related reports. To ensure that financial management staffs are adequately trained, CMS developed an individual development plan. The CMS also began to develop an accounting manual that will assist in training new staff.

**Centers for Medicare and Medicaid Services**  
*-Contractor Operations-*

**Improve Evaluation of Fraud Unit Performance**

Report Number: OEI-03-97-00350 Final Report: 11/1998

**Finding**

Fiscal intermediary fraud units differed substantially in the number of complaints and cases handled. Some units produced few, if any, significant results. Despite CMS'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**

Fiscal intermediaries and carriers are companies under contract with CMS to administer a major part of the Medicare program. As of 1993, CMS 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, CMS 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, CMS, 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 CMS 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 CMS'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, CMS 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 CMS concurred with our recommendations. The CMS 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 site visits; (5) strengthening oversight of benefit integrity units; and (6) redesigning Fraud Investigation Database.

**Centers for Medicare and Medicaid Services**  
*-Contractor Operations-*

**Ensure Accuracy of Carrier Payment Dates**

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

**Finding**

According to CMS' National Claims History File data, it appears that Medicare paid over 80 percent of Part B claims prior to the 14-day floor requirement. However, according to CMS' Contractor Reporting of Operational and Workload Data (CROWD) system, payments for less than 1 percent of these Part B claims were made prior to the 14-day floor. Information from both CMS and carrier staff indicates that data from the National Claims History File may not accurately reflect carriers' actual date of payment.

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should conduct a review of the carriers' claims processing data to examine the scheduled date of payment entered on claims sent to the Common Working File. If there is no correlation between the claims payment date variable and the carriers' actual date of payment, we recommend that CMS (1) define what data should be entered into this field and how it should be calculated, and/or (2) revise the current variable definition to clarify for National Claims History data users that the schedule date of payment is not an accurate reflection of the actual claim payment date. The CMS should also review the carriers' claims processing data to determine the accuracy of the information contained in the CROWD system.

**Status**

**Management Response**

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

## Centers for Medicare and Medicaid Services

*-Contractor Operations-*

### Prevent Duplicate Payments for the Same Service by Multiple Carriers

Report Number: OEI-03-00-00090 Final Report: 03/2001

#### Finding

Although carriers and Common Working File (CWF) host sites have checks designed to detect duplicate billings, these measures are vulnerable to duplicate claims that are sent to different carriers. None of the medical records in our sample of likely duplicate claims justified billings to multiple carriers. For 222 services, provider documentation did not support the need for billing two separate carriers; therefore, half of these services (111) were improperly submitted to and paid by a Medicare carrier.

#### Current Law

After furnishing a service, providers submit a claim for reimbursement to the carrier with jurisdiction over this service. Under the CWF system, the carrier then sends the claims information to one of nine host sites for approval where the claim is screened for consistency, entitlement, and duplication of previously processed claims. Both the carriers and CWF host sites are required to review incoming claims for possible duplication using certain criteria and to deny ones that are potentially duplicate.

#### Recommendation

Legislative

Administrative

Material Weakness

The CMS should revise CWF edits to detect and deny duplicate billings to more than one carrier or increase post-payment reviews if such edits are determined not to be cost effective. Providers should be encouraged to conduct effective voluntary compliance activities to maintain optimum levels of integrity in their practices and clarify carrier jurisdiction questions by using carrier toll-free telephone lines.

#### Status

##### Management Response

The CMS concurred with our recommendations. It will reexamine existing criteria regarding duplicate editing in the CWF system to determine the cost effectiveness of including the carrier number in the match criteria. The CMS entered a contract to study duplicate billing. This contract will (1) conduct an analysis of current duplicate and near duplicate claim edits in the CWF, as well as in the standard and local systems; (2) conduct an analysis of why providers submit duplicate claims in the first place; (3) make recommendations to CMS on what edits CMS should put in CWF, the standard and local systems to detect duplicate and near duplicate claims; and (4) make recommendations to CMS on methodologies (e.g., provider education) that CMS can use to reduce duplicate claims submission.

## Centers for Medicare and Medicaid Services

*-Contractor Operations-*

### Prevent Duplicate Payments for the Same Service by an Individual Carrier

Report Number:

OEI-03-00-00091

Final Report:

06/2001

#### Finding

Carrier and Common Working File edits did not prevent potential duplicate payments. For 15 procedure codes that should never or rarely be billed more than once per day, individual carriers made potential payments involving 3,152 services in 1998, with questionable allowances of an estimated \$2.25 million. Individual carriers made an estimated \$2.2 million in potential duplicate payments for an additional 55 evaluation and management codes that should never or rarely be billed more than once per day. We also estimated that individual carriers made up to \$89 million in potential duplicate payments for 2,000 other procedures.

#### Current Law

After furnishing a service, providers submit a claim for reimbursement to the appropriate carrier. Under the Common Working File system, the carrier then sends the claims information to one of nine host sites for approval where the claim is screened for consistency, entitlement, and duplication of previously processed claims. Both the carriers and the Common Working File host sites are required to review incoming claims for possible duplication using certain criteria and to deny ones that are potentially duplicate.

#### Recommendation

Legislative



Administrative

Material Weakness

The CMS should revise Common Working File edits to detect and deny duplicate billings within a single carrier or increase post-payment reviews if such edits are determined not to be cost effective. The CMS should also investigate Medicare's claims processing systems to determine why potential duplicate services were not detected and recover payments for services determined to be inappropriate.

#### Status

##### Management Response

The CMS concurred with our recommendations. The CMS stated that it will continue to assess existing duplicate payment edits in the Common Working File as well as the Medicare Part B standard claims processing systems. This examination will include an assessment of those carriers in which a high number of duplicate payments were detected. The CMS entered a contract to study duplicate billing. The contract will (1) conduct an analysis of current duplicate and near duplicate claim edits in the Common Working File, as well as in the standard and local systems; (2) conduct an analysis of why providers submit duplicate claims in the first place; (3) make recommendations to CMS on what edits CMS should put in CWF, the standard and local systems to detect duplicate and near duplicate claims; and (4) make recommendations to CMS on methodologies (e.g., provider education) that CMS can use to reduce duplicate claims submission.

## Centers for Medicare and Medicaid Services

*-Home Health-*

### Improve Physician's Role in Home Health Care

Report Number:

OEI-02-94-00170

Final Report:

06/1995

#### Finding

Agencies and physicians identify some obstacles and issues related to the physician role. Obstacles mentioned by respondents include: (1) 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

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 CMS 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 CMS should strengthen its efforts to educate both agencies and physicians about its policies regarding the physician's role in home health care.

#### Status

##### Management Response

The CMS has proposed revised conditions of participation for care planning and coordination of services. Specifically, the revisions would decrease the burden of home health agencies and would allow agency staff to develop care plans in coordination with the physician. The 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 2002. The CMS also plans to issue new billing instructions for carriers to install new edits and conduct provider education.

## Centers for Medicare and Medicaid Services

*-Hospices-*

### Strengthen Education of Contractual Relationships Between Hospices and Nursing Homes

Report Number:

OEI-05-95-00251

Final Report:

11/1997

#### 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

Hospice care is a treatment approach which recognizes that the impending death of an individual warrants a change focus from a curative to palliative care. The Medicare hospice benefit program began in 1983 and was expanded 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 CMS work with the hospice associations to educate the hospice and nursing home communities to help them avoid potentially fraudulent and abusive activities that might influence decisions on patient benefit choices and care.

#### Status

##### Management Response

The CMS concurred with our recommendation. The CMS 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 CMS will also continue to encourage the RHHIs to re-emphasize the potential fraudulent and abusive activities in their continuing educational efforts. The CMS is currently working on a notice of proposed rulemaking for the hospice conditions of participation.

**Centers for Medicare and Medicaid Services**  
*-Hospitals-*

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

Report Number:	OEI-01-98-00420	Final Report:	01/1999
	OEI-03-98-00560		12/1998
	OEI-03-98-00370		03/1999
	OEI-03-98-00490		04/1999

**Finding**

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

**Current Law**

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

**Recommendation**

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

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

## Centers for Medicare and Medicaid Services

-Hospitals-

### Improve External Quality Review of Psychiatric Hospitals

Report Number:

OEI-01-99-00160

Final Report:

05/2000

#### 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 CMS's contracted surveyors are held minimally accountable for their performance in overseeing psychiatric hospitals.

#### Current Law

Medicare requires psychiatric hospitals to meet two special conditions of participation — staff requirements and medical records — that apply only to psychiatric hospitals. The CMS 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 CMS should deploy its contracted surveyors more strategically, to take better advantage of their expertise and hold them more accountable. The CMS 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 CMS will provide a basic surveyor training of surveyors for psychiatric hospitals in March 2002. The intended audience will include State agency surveyors, regional office staff, and newly recruited psychiatric contracted surveyors for March 2002. In September 2001, CMS staff completed the revisions to the performance evaluation for psychiatric surveyors; a performance-based evaluation system to better assess the surveyors' current level of performance, to identify any areas requiring remediation, and to identify training needs. The evaluation of the contracted surveyors began in October 2001.

**Centers for Medicare and Medicaid Services**  
*-Hospitals-*

**Increase Oversight of the Emergency Medical Treatment and Labor Act**

Report Number: OEI-09-98-00221      Final Report: 01/2001

**Finding**

The enforcement process is compromised by long delays and inadequate feedback. Poor case tracking impedes oversight. The number of investigations and the proportion of confirmed violations varies widely between CMS regions, and peer review is not always obtained before CMS considers terminating a hospital for violations involving medical judgement.

**Current Law**

Section 1867 of the Social Security Act requires Medicare -participating hospitals to provide appropriate medical screening and stabilizing treatment to any individual who appears at the emergency department requesting examination and treatment. The CMS investigates alleged violations through survey and certification and refers cases to its peer review organizations. Confirmed violations are referred to OIG for possible sanction. The CMS may also terminate a hospital's Medicare certification.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should increase its oversight of regional offices, improve collection and access to data on complaints and investigations, ensure that peer review occurs before initiating termination from Medicare, and establish a technical advisory board.

**Status**

**Management Response**

The CMS has instituted a log system for tracking complaints and talks monthly with its regional staff. A new survey and certification system, the Quality Improvement and Evaluation System will further improve data collection and access. The CMS will revise its policy manual instructions to clarify the process of obtaining peer review, and will consider the best way to obtain stakeholder input.

## Centers for Medicare and Medicaid Services

*-Information and Accounting Systems-*

### Ensure That the Medicare Accounts Receivable Balance is Fairly Presented

Report Number:	OAS-17-95-00096	Final Report:	07/1997
	OAS-17-97-00097		04/1998
	OAS-17-98-00098		02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001

### Finding

Our audit of the CMS FY 2000 financial statements found that significant financial management issues still affect CMS's ability to accumulate and analyze Medicare accounts receivable, which had a \$3.8 billion balance. During FY 2000, CMS improved its accountability for accounts receivable at the central office, primarily through trend analyses. However, controls at the Medicare contractors continue to need improvement. Also, the reasonableness of the allowance for doubtful accounts was not ascertained.

### Current Law

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 CMS (1) maintain internal controls to ensure that reported accounts receivable amounts and transactions are valid and documented; (2) establish an integrated financial management system for use by Medicare contractors and the CMS central office; (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 (arrayed by provider for the largest such accounts), and to investigate aberrant contractor items and implement monthly reviews at the central and regional offices; (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 CMS hired consultants to help validate accounts receivable reported by Medicare contractors during FY 1999 and the first half of FY 2000. The Medicare contractors have developed subsidiary ledgers to provide detailed information supporting receivable balances. Also, the CMS 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, CMS 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 included funding to establish financial management controls at the contractors and to hire contractor staff to implement the controls.

**Centers for Medicare and Medicaid Services**  
*-Information and Accounting Systems-*

**Improve Medicare EDP System Controls**

Report Number:	OAS-17-98-00098	Final Report:	02/1999
	OAS-17-00-00500		02/2000
	OAS-17-00-02001		02/2001

**Finding**

We found numerous electronic data processing (EDP) general control weaknesses, primarily at the Medicare contractors. With such weaknesses, controls 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. Also, weaknesses in the entity-wide security structure do not ensure that EDP controls are adequate and operating effectively. During FY 2000, the previously reported weakness related to the Medicare data centers' access to the source code of the Fiscal Intermediary Shared System (FISS) remained unchanged. This weakness has been expanded to include the Common Working File (CWF), since the design of the CWF software provides for programmer update access to CWF data files.

**Current Law**

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

**Recommendation**

Legislative



Administrative



Material Weakness

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

**Status**

**Management Response**

The CMS 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. Steps have been taken to track and control the changes that the Medicare data centers make to the FISS source code. The CMS has developed a policy that requires approval of all local changes. This policy also requires CMS to conduct annual audits to ensure that no unauthorized changes to the source code are made. The CMS is also in the process of collecting a comprehensive inventory of all existing source code changes. As of January 2001, CMS corrected the problem noted with the CWF source code.

## Centers for Medicare and Medicaid Services

*-Laboratories-*

### Ensure CLIA Regulation of Unestablished Laboratory Tests

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

#### Finding

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

#### Current Law

The Clinical Laboratory Improvement Amendments of 1988 require all laboratories which conduct testing on human specimens to be certified, with only a few, very specific exceptions.

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS concurred with our recommendations. The CMS has convened a work group to review OIG's recommendations, which were co-authored by CMS, and devise an action plan. In addition, CMS has initiated new efforts at educating the public and the laboratory community concerning CLIA procedures for evaluating unestablished laboratory testing, through posting of educational information on our web site and discussion of the issues at national forums and in trade publications.

**Centers for Medicare and Medicaid Services**  
*-Laboratories-*

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

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

**Finding**

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

**Current Law**

The Clinical Laboratory Improvement Amendments of 1988 provides for certificates of waiver for laboratories conducting only simple tests which are specifically designated by the FDA as waived. The statute requires these laboratories to follow manufacturers' instructions and to limit testing to waived tests.

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The CMS concurred with our recommendations. Since completion of a pilot survey protocol for improving CLIA enrollment and certification processing laboratories performing waived and provider-performed microscopy procedures (PPMP), all States will be required to survey a sample of waived and PPMP laboratories each year. In addition, CMS has added educational materials pertaining to self-assessment on its web site.

**Centers for Medicare and Medicaid Services**  
*-Managed Care-*

**Consider Recommended Safeguards Over Medicaid Managed Care Programs**

Report Number: OAS-03-93-00200 Final Report: 08/1993

**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**

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

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should consider several safeguards available to reduce the risk of insolvency and to ensure consistent and uniform State oversight. Specifically, we recommend that CMS (1) use Medicare solvency guidelines, (2) establish minimum net worth standards, (3) develop a financial database 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**

Although CMS initially concurred with recommendations 1 through 4, the agency believes that section 4706 of the Balanced Budget Act of 1997 sets forth congressional expectations on this issue in specifically requiring managed care organizations to meet the solvency standards established by the State for private health maintenance organizations. The CMS expected to publish regulations implementing the solvency standards in the spring of 2002. Recommendations 5 through 9 remain unresolved. The CMS 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 the Congress and the General Accounting Office. We do not believe that CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Managed Care-*

**Ensure Children in Medicaid Managed Care Receive Timely EPSDT Services**

Report Number: OEI-05-93-00290 Final Report: 05/1997

**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**

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 accomplish in a fee-for-service environment, while ensuring health care access for Medicaid enrollees.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS 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 CMS concurred with our recommendations. The CMS, in consultation with public and private sector representatives, developed a revised EPSDT report and a data-collection tool. This revised tool has been used since April 2000 when States reported its FY 1999 EPSDT data. The CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Managed Care-*

**Use Beneficiary Surveys As A Protection Tool for Medicaid Managed Care**

Report Number: OEI-01-95-00280      Final Report: 05/1997

**Finding**

We found that (1) surveys provide little useful information about plan performance to Medicaid agencies; (2) 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**

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 CMS often requires Medicaid agencies implementing managed care waivers to conduct surveys.

**Recommendation**

**Legislative**

**Administrative**

**Material Weakness**

The CMS should either establish a work group or technical advisory group on Medicaid beneficiary surveys or add it 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 CMS should devote greater attention to how 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 CMS partially concurred with recommendation one. It has developed a protocol for States to use when conducting beneficiary surveys of its satisfaction with the health care services it receives and another for validating results of surveys conducted by managed care organizations. These protocols set out a methodologically sound set of activities and steps that States should undertake to ensure that the surveys will yield accurate and reliable results. In addition, CMS continues to provide training to regional office and State staff on survey development.

**Centers for Medicare and Medicaid Services**  
*-Managed Care-*

**Retool Medicaid Agencies for Managed Care**

Report Number: OEI-01-95-00260 Final Report: 08/1997

**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**

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 or 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 CMS 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 associated 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 CMS concurred with our recommendations. On an ongoing basis CMS subsidizes the American Public Human Services Association meetings that address Medicaid managed care and the challenges it poses. However, CMS 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.

## Centers for Medicare and Medicaid Services

*-Managed Care-*

### Coordinate Medicaid Managed Care Plans with HIV/AIDS Services

Report Number:

OEI-05-97-00210

Final Report:

04/1998

#### Finding

We found that (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

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 CMS 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 CMS to improve coordination and collaboration between Medicaid managed care organizations and Ryan White programs and will continue to do so in the future.

## Centers for Medicare and Medicaid Services

*-Medical Equipment and Supplies-*

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

Report Number: OEI-02-97-00080      Final Report: 02/1999  
OEI-02-97-00081      02/1999

#### 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

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 CMS 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 CMS generally concurs with our recommendations. The CMS 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.

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

**Prevent Inappropriate Payments for Blood Glucose Test Strips**

Report Number: OEI-03-98-00230 Final Report: 06/2000

**Finding**

Medicare allowed \$79 million for blood glucose test strip claims with missing or flawed documentation. Orders for 25 percent of the sampled claims failed to establish beneficiaries' eligibility for the supplies. These claims represented \$33 million in allowances. An additional \$46 million in test strip claims had incomplete orders or no supplier delivery records. We found that suppliers submit claims for test strips at irregular intervals. This can make it difficult to identify overlapping claims, claims without correct supporting documentation, and claims for excessive numbers of test strips.

**Current Law**

Medicare covers home blood glucose monitors and test strips for beneficiaries who must periodically test their blood sugar levels as part of their diabetes management, regardless of insulin usage. Prior to July 1, 1998, Medicare coverage was restricted to beneficiaries with insulin-treated diabetes.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should take several steps to promote compliance with Medicare guidelines for blood glucose test strips (1) alert suppliers of the importance of properly completed documentation to support their claims for test strips; (2) require suppliers to indicate actual and accurate "start" and "end" dates on claim forms; (3) promote supplier concurrence and cooperation with OIG's recently issued document entitled, "Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry;" and (4) advise beneficiaries, as part of its outreach service, to report any instances of fraudulent or abusive practices (such as receiving excessive or unrequested deliveries of test strips) involving their home blood glucose monitors, test strips, or related supplies to their durable medical equipment regional carriers (DMERCs).

**Status**

**Management Response**

The CMS concurred with our recommendations. The CMS noted a number of initiatives that have reduced the incidence of improper payments in recent years. To specifically address our recommendations, CMS stated that (1) DMERCs will continue to stress the importance of properly completed documentation through a combination of published guidance in supplier manuals and bulletins and supplier education and outreach seminars, (2) it issued a program memorandum on November 15, 2001 which instructs DMERCs to inform suppliers that they must fill in the start and ends dates on the claim form and to deny claims when there is a duplicate start and end date, (3) it will work with the National Supplier Clearinghouse to include language in the notifications sent to suppliers awarding them billing numbers to read and adhere to OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, and (4) beneficiary outreach efforts encouraging the reporting of abusive supplier practices continues as an ongoing CMS effort. Advice to beneficiaries has been included in the booklet, "Blood Sugar Testing: The Power to Control Diabetes is in Your Hands."

## Centers for Medicare and Medicaid Services

*-Medical Equipment and Supplies-*

### Eliminate Abusive Marketing Practices Associated With Blood Glucose Test Strips

Report Number:

OEI-03-98-00231

Final Report:

06/2000

#### Finding

Diabetic supply advertisements offer inducements and can be misleading. Coinsurance information in diabetic supply advertisements can be misleading and suppliers did not always collect coinsurance from beneficiaries. Beneficiaries also reported receiving incentives, such as free monitors; and receiving test strips automatically from mail-order suppliers, even after new guidelines that were issued on July 1, 1998 prohibit automatic shipping.

#### Current Law

Medicare covers home blood glucose monitors and test strips for beneficiaries who must periodically test their blood sugar levels as part of their diabetes management, regardless of insulin usage. Prior to July 1, 1998, Medicare coverage was restricted to beneficiaries with insulin-treated diabetes.

#### Recommendation

Legislative

Administrative

Material Weakness

The CMS should take several steps to increase supplier and beneficiary awareness of fraudulent and abusive practices relating to blood glucose test strips. These include (1) issue bulletins reminding suppliers who routinely waive deductibles and/or coinsurance or who engage in misleading advertising practices that they may be in violation of the Medicare and Medicaid anti-kickback law; (2) remind suppliers that beneficiaries must specifically request new supplies of test strips before they are dispensed; (3) promote supplier concurrence and cooperation with OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry; and (4) advise beneficiaries, as part of its outreach service, to report any instances of fraudulent or abusive practices (such as misleading advertising and excessive or unrequested deliveries of test strips) involving their home blood glucose monitors, test strips, or related supplies to their durable medical equipment regional carriers.

#### Status

##### Management Response

The CMS concurred with our recommendations. As part of an intensive campaign to reduce and eliminate fraudulent and abusive supplier practices, including those detailed in our findings, CMS cited a number of ongoing and planned initiatives. These initiatives include (1) plans to discuss routine waivers of deductibles and coinsurance in addition to misleading advertising at the next Beneficiary Integrity Conference, (2) updated supplier manuals (Spring 1999) to reflect that new test strips must be requested by the beneficiary or their caregivers, (3) working with the National Supplier Clearinghouse to include language in the notifications sent to suppliers awarding them billing numbers to read and adhere to the OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, and (4) continuing beneficiary outreach efforts, which include tips on identifying improper practices involving home blood glucose monitors and related supplies. Advice to beneficiaries has been included in the booklet, "Blood Sugar Testing: The Power to Control Diabetes is in Your Hands."

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

**Educate Beneficiaries on Reducing Financial Liability for DME**

Report Number: OEI-07-99-00510 Final Report: 01/2001

**Finding**

In 1999, beneficiaries paid \$41 million above the Medicare allowed amounts for medical equipment and supplies. Most surveyed beneficiaries are unaware of the differences in assigned and non-assigned claims and participating and non-participating suppliers. Based on a review of 1999 claims data, we found that ostomy supplies have a higher non-assigned rate than supplies overall.

**Current Law**

Under Medicare Part B, physicians and suppliers submit both assigned and non-assigned claims for these services and items. For assigned claims, physicians and suppliers agree to accept the amount allowed by Medicare as full payment. In non-assigned claims, the physician or supplier bills the beneficiary for the total charge for the service or item provided, which can exceed the amount allowed by Medicare. Medicare pays the beneficiary 80 percent of the allowed amount; the beneficiary pays all remaining charges. We define balance billing as the portion of the charge in excess of the Medicare allowed amount.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should educate beneficiaries on ways to reduce financial liability for medical equipment and supplies and re-evaluate Medicare fee schedules for ostomy supplies.

**Status**

**Management Response**

The CMS concurred with our recommendations and has undertaken a number of efforts to increase beneficiary education and awareness about the consequences of assigned and non-assigned claims. The Participating Physician Directory is available on-line, and will be expanded to include supplier information. The CMS is committed to examining the payment for ostomy supplies once it has published a final rule concerning its inherent reasonableness authority. The CMS's publications continue to address the recommendation concerning educating beneficiaries on ways to reduce financial liability for medical equipment and supplies. "Medicare and You 2002" makes mention of this, as does the separate publication, "Does Your Doctor or Supplier Accept Assignment?"

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

**Change DME Payment Category for Respiratory Assist Devices**

Report Number: OEI-07-99-00440 Final Report: 06/2001

**Finding**

Supplier services of the bi-level respiratory assist device consist primarily of routine maintenance and patient monitoring. For most beneficiaries, visits do not meet supplier protocols for frequency. Contrary to supplier protocols, the number of beneficiaries receiving visits declines over time. Covering the respiratory assist device under capped rental would have saved Medicare \$11.5 million annually

**Current Law**

Under the Medicare frequent and substantial payment category, suppliers are paid an established monthly rental fee as long as the device is medically necessary. Under the capped rental payment category, suppliers are paid a monthly fee for a stipulated amount of time at which point Medicare purchases the machine on behalf of the beneficiary or the beneficiary continues to rent the device on their own.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should move the bi-level respiratory assist device with a back-up rate from the frequent and substantial servicing payment category to the capped rental payment category.

**Status**

**Management Response**

The CMS concurred with our recommendation, stating that it plans to move the bi-level respiratory assist device with a back-up rate from the "frequent and substantial servicing" payment category to the capped rental payment category. It believes this change is needed to reflect the requirements of Section 1834 (a) (3) of the Social Security Act.

**Centers for Medicare and Medicaid Services**

*-Medical Equipment and Supplies-*

**Improve Medical Equipment Suppliers' Compliance With Medicare Standards**

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

**Finding**

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

**Current Law**

In order for medical equipment suppliers to be able to bill the Medicare program, they must meet 11 standards.

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The CMS concurred with our findings and outlined several initiatives, including increased site visits on noncompliant suppliers, to address the recommendations.

## Centers for Medicare and Medicaid Services

-Nursing Homes-

### Ensure Appropriate Mental Health Services Delivered in Nursing Homes

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

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS concurred with the recommendation. It is taking steps to ensure that appropriate services are delivered. The CMS 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 CMS'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. The CMS has also made revisions to its training curriculum for nursing home surveyors. In addition, CMS offered a national satellite broadcast, "Mental Illness in Nursing Homes," on July 20, 2001.

**Centers for Medicare and Medicaid Services**

*-Nursing Homes-*

**Improve Nursing Home Surveyor Staffing and Training**

Report Number: OEI-02-98-00330 Final Report: 03/1999

**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**

Nursing home surveyors are required to complete mandatory standard surveys of each nursing home 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 CMS-sponsored training and pass the required Standard Minimum Qualifications Test.

**Recommendation**

Legislative

Administrative

Material Weakness

We recommend that CMS (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; and (2) provide additional training to State surveyors.

**Status**

**Management Response**

The CMS concurred with our recommendations. The CMS indicated that it reviews State surveyor staffing as part of the survey and certification budget process. The CMS 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 CMS to perform survey activities. The CMS also indicated that the issue of training is being addressed by the new Federal Monitoring System and that feedback from the States on that system will guide training and coordination efforts. In addition to Federal monitoring system feedback, CMS is in the process of implementing an automated system for tracking surveyor training. More training initiatives are being geared toward the experienced surveyor.

**Centers for Medicare and Medicaid Services**  
*-Nursing Homes-*

**Develop Nurse Staffing Standards for Nursing Homes**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

We recommend that CMS develop staffing standards for registered nurses and certified nurse assistants in nursing homes to assure sufficient staff on all shifts and to enable residents with proper care. Staffing standards should account for the intensity of care needed, qualifications of the staff, and the specific characteristics of both the nursing home and the residents.

**Status**

**Management Response**

At the request of Congress, CMS has conducted a study examining the relationship of staffing levels to the quality of care received by nursing home residents. A Phase I Report to Congress was delivered in July 2000. The report indicated a relationship between staffing ratios and quality of nursing home care and have identified staffing thresholds that maximize quality outcomes. Although many States will look to the report for standards upon which to base minimum staffing requirements under their State licensure authority, CMS does not think there is currently sufficient information upon which to base a Federal requirement for all certified nursing homes.

**Centers for Medicare and Medicaid Services**  
*-Nursing Homes-*

**Improve Resident Assessment Instruments**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The CMS generally concurred with our recommendations for improved data definitions and training, but did not concur with our recommendation to establish an audit trail. In 1998, CMS devoted significant resources to the development of an accuracy improvement program by letting a contract to develop MDS accuracy review protocols. Once the protocols were developed, CMS funded a program safeguard contractor in September 2001, known as the data assessment and verification contractor, to audit and verify MDS data. An integrated system for auditing MDS is currently under development by this contractor.

**Centers for Medicare and Medicaid Services**  
*-Nursing Homes-*

**Improve Assessments of Mental Illness**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The CMS concurred with most of our recommendations. As a result of OIG's recommendations, CMS has made revisions to its training curriculum for nursing home surveyors. In addition, CMS offered a national satellite broadcast, "Mental Illness in Nursing Homes," on July 20, 2001. The program was designed to increase surveyor knowledge of and ability to recognize mental illness, to educate surveyors on PASRR implementation and oversight, and to improve surveyors' abilities to determine facility compliance with assessment and care requirements. The 2-1/2 hour program was archived and is available for viewing via the Internet until July 2002.

## Centers for Medicare and Medicaid Services

*-Nursing Homes-*

### Identify Nursing Home Residents With Serious Mental Illness

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

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS concurred with most of our recommendations, except for reporting MDS records by primary, secondary, and tertiary diagnoses. The CMS does not feel that adding space to the MDS to record diagnoses would solve the problem. Instead, CMS believes it would be beneficial to educate facility staff to identify the diagnosis and related systems. On July 20, 2001, CMS conducted a multimedia broadcast (satellite, web, video) entitled, "Mental Illness in Nursing Facilities."

**Centers for Medicare and Medicaid Services**  
*-Physicians/Allied Health Professionals-*

**Extend PRO Review of Physician Office Surgery**

Report Number: OEI-07-91-00680 Final Report: 06/1993

**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**

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, CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Physicians/Allied Health Professionals-*

**Improve Oversight of the Rural Health Clinics**

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

**Finding**

Rural health clinics and associated Medicare and Medicaid expenditures have grown substantially since 1990. Four interrelated factors appear to be driving the recent growth of rural health clinics: providing access to care, reimbursement, managed care, and the certification process.

Rural health clinics may be increasing access to care in some areas but not in others.

Rural health clinics are paid based on their costs, which may be inflated or inappropriate but are difficult and sometimes impossible to verify or audit without significant resource expenditure by the Government.

**Current Law**

The Rural Health Clinic program created in 1977 by Public Law 95-210 is intended to increase access to health care for rural medically underserved areas and to expand the use of midlevel practitioners in rural communities.

**Recommendation**

Legislative



Administrative

Material Weakness

The CMS, 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 CMS should expedite the issuance of the regulations now under development.

The CMS should take immediate steps to improve the oversight and functioning of the current cost reimbursement system, with a long term goal of implementing a different method.

**Status**

**Management Response**

The CMS 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 CMS developed a program memorandum consolidating and clarifying the policy regarding provider-based and free-standing designation decisions. The CMS 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.

## Centers for Medicare and Medicaid Services

*-Physicians/Allied Health Professionals-*

### Improve Oversight of the Medicare Risk HMO Program

Report Number: OEI-06-95-00430 Final Report: 03/1998

#### 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

The CMS 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 CMS 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 CMS concurs with the recommendations. The CMS is striving to improve beneficiary outreach and education to make them aware of their appeal and grievance rights. The CMS has developed a Medicare managed care data base to assist in improving beneficiaries' understanding of procedures and restrictions within managed care plans. In addition, CMS'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 CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Physicians/Allied Health Professionals-*

**Improve Medicare's Oversight of Managed Care Plan Performance**

Report Number: OEI-01-96-00190 Final Report: 04/1998

**Finding**

Our inspection found that (1) CMS'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, CMS is not taking widespread advantage of available data that could be used for ongoing, systematic oversight of plans; and (3) that CMS is missing opportunities to capture additional data that could assist the agency in monitoring plans' performance.

**Current Law**

The CMS 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 CMS 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 CMS concurs with the intent of all the recommendations. The CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Physicians/Allied Health Professionals-*

**Ensure Expertise in CMS Staff for Managed Care Oversight**

Report Number: OEI-01-96-00191      Final Report: 04/1998

**Finding**

We found that CMS 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**

The CMS 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 CMS should develop, coordinate, and provide a comprehensive training program for regional office staff with responsibility for oversight of managed care plans. (2) As CMS 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 CMS 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 CMS 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 CMS has also conducted outpatient encounter training for the Medicare+Choice organizations.

## Centers for Medicare and Medicaid Services

*-Physicians/Allied Health Professionals-*

### Address Problems Identified by Beneficiaries in Medicare Risk HMOs

Report Number: OEI-06-95-00434 Final Report: 08/1998

#### 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

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 CMS 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, CMS 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 CMS 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 CMS 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 CMS issued a new monitoring guide in December 1999. This guide, used by CMS 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.

**Centers for Medicare and Medicaid Services**  
*-Physicians/Allied Health Professionals-*

**Improve Controls to Monitor Chiropractic Care**

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

**Finding**

We found that Medicare, Medicaid, and private insurers rely on utilization caps, x-rays, physician referrals, 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**

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

**Status**

**Management Response**

The CMS 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.

## Centers for Medicare and Medicaid Services

*-Physicians/Allied Health Professionals-*

### Eliminate Inappropriate Payments for Hyperbaric Oxygen Therapy

Report Number:

OEI-06-99-00090

Final Report:

10/2000

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative



Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS generally concurred with our recommendations, and reports several on-going efforts to address concerns raised in this report (e.g., reviewing coverage policy and alerting carriers to vulnerabilities associated with this procedure). It stated that the issue will be added in the next vulnerability report to be issued in early 2002.

## Centers for Medicare and Medicaid Services

*-Physicians/Allied Health Professionals-*

### Eliminate Inappropriate Payments for Mental Health Services

Report Number: OEI-03-99-00130 Final Report: 05/2001  
OEI-02-99-00140 01/2001

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

The CMS should promote provider awareness of documentation and medical necessity requirements, develop a comprehensive list of psychological testing tools that can be correctly billed, target problematic services for pre-payment edits or post-payment medical review, and encourage carriers to take advantage of the Minimum Data Set, especially for its assessment of patient cognitive level.

#### Status

##### Management Response

The CMS generally concurred with our recommendations. It plans to explore a variety of educational efforts and will refer the reports to the carrier clinical workgroup on psychiatric services. Carriers will conduct data analysis of psychological testing and psychotherapy claims and will conduct medical review, if indicated.

**Centers for Medicare and Medicaid Services**  
*-Prescription Drugs-*

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

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

**Finding**

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

**Current Law**

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 CMS for each covered outpatient drug for a base period. On a quarterly basis, the manufacturer is then required to report the AMP and the best price for each covered outpatient drug.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should survey manufacturers to identify the various calculation methods used to determine AMP. The CMS 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 CMS 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 agreements defined AMP but did not provide specific written methodology for computing AMP. In previous discussions, CMS informed us that the Medicaid drug rebate regulation would provide additional guidance in calculating AMP, but that regulation has not yet been published. Although CMS does provide individual guidance to drug manufacturers, our concern is that the guidance might not be consistent. Our audits point out this inconsistency.

**Centers for Medicare and Medicaid Services**  
*-Prescription Drugs-*

**Implement Proper Accountability Over Billing and Collection of Medicaid Drug Re bates**

Report Number: OAS-06-92-00029                      Final Report: 05/1993

**Finding**

None of the eight States reviewed maintained general ledger control accounts for Medicaid drug rebates, and only four States maintained even informal receivable listings for each manufacturer. Additionally, it did not appear that the States reviewed were generally 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**

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

**Status**

**Management Response**

The CMS 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 CMS issued a notice of proposed rulemaking in FY 1996.

## Centers for Medicare and Medicaid Services

*-Prescription Drugs-*

### Lower Medicaid Expenditures on HIV/AIDS Drugs

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

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

For the 16 HIV/AIDS drugs examined in our study, we recommend that (1) CMS review the current reimbursement methodology and work with States to find a method that more accurately estimates pharmacy acquisition cost. For this recommendation, we suggested three options: that CMS either develop safeguards to protect Medicaid from average wholesale price (AWP) manipulations; create a national estimated acquisition cost for the States based upon the average manufacturers price (AMP); or share AMP data with States so they can accurately set Medicaid reimbursement amounts. (2) CMS initiate a review of Medicaid rebates for the 16 HIV/AIDS drugs examined. For this recommendation, we suggested two options: that CMS increase the rebate percentage of AMP or base the rebates on AWP rather than AMP.

#### Status

##### Management Response

The CMS agreed with the overall intent of our recommendations, but expressed reservations with many of the specific suggestions we offered for achieving them. Primarily, CMS felt that it does not have the statutory authority to make the suggested changes.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Establish a National Medicaid Credit Balance Reporting Mechanism

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

#### Finding

Previous OIG reports indicated that significant 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

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

#### Management Response

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

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Improve Enrollment in the Children's Health Insurance Program

Report Number: OEI-05-98-00310 Final Report: 05/1999

#### 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

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 CMS are encouraging States to streamline Title XXI applications and the application process.

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS concurred with our recommendations. Over the past 4 years, CMS has worked closely with the States to streamline the enrollment and renewal processes. To date, substantial improvements in the SCHIP application and enrollment process have taken place with a significant spillover effect on children's Medicaid enrollment. States have undertaken numerous strategies to make it easier for children to apply for, obtain, and retain health coverage.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Strengthen Review and Accountability of Hospital Quality

Report Number:

OEI-01-97-00050

Final Report:

07/1999

#### Finding

The current system of hospital oversight has both significant strengths and major deficiencies. The CMS 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

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 CMS should hold the Joint Commission and State agencies more fully accountable to CMS 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 CMS should periodically assess the justification for the Joint Commission's deemed status authority. The CMS should also determine the appropriate cycle for conducting certification surveys of nonaccredited hospitals.

#### Status

##### Management Response

The CMS 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. Additionally, in response to OIG's recommendations, CMS established a steering committee to coordinate the agency-wide efforts to improve hospital oversight. The CMS has met the majority of its identified goals and continues to pursue system changes in other areas that require ongoing efforts. The quality assessment and performance improvement regulation was carved out of the hospital regulations and revised. There are plans to publish a final regulation in 2002.

**Centers for Medicare and Medicaid Services**

*-CMS Administration-*

**Require Complete Documentation of Home Oxygen Therapy**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The CMS concurred with the recommendations. In order to reduce paperwork burden on suppliers and be more responsive to providers, CMS has eliminated the requirement that suppliers maintain certain original certificates of medical necessity. The CMS will consider medical review, possibly focusing on portable oxygen systems. The CMS is planning to issue service standards for home oxygen suppliers; education efforts are delayed pending review of service standards.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Consolidate Medicare Administrative Appeals**

Report Number:	OEI-04-97-00160	Final Report:	09/1999
	OEI-04-01-00290		10/2001
	OEI-04-01-00290		10/2001

**Finding**

The number of appeals being heard by administrative law judges (ALJ) is increasing and the system is backlogged and overwhelmed. 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**

The Social Security Administration manages ALJs who hear both Medicare and Social Security appeals. The Benefits Improvement and Protection Act of 2000 (BIPA) modifies administrative aspects of the appeals process and creates new time frames for adjudication of appeals at each level.

**Recommendation**

Legislative

Administrative

Material Weakness

Delay implementation of Section 521 of BIPA; establish an administrative appeals process that is dedicated to Medicare; ensure adequate resources for each level of the appeals process; modify the time frames mandated by BIPA; provide opportunity for CMS representation at higher levels of review; develop parallel training for reviewers at all levels of appeals; create formal communication and information networks that span the entire appeals system; and, modernize appeals processing mechanisms.

**Status**

**Management Response**

The CMS supports many of the recommendations, especially the recommendation to delay implementation of BIPA's section 521 provisions.

**Centers for Medicare and Medicaid Services**

*-CMS Administration-*

**Identify and Monitor Hospital Ownership of Physician Practices**

Report Number:

OEI-05-98-00110

Final Report:

09/1999

**Finding**

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

**Current Law**

The CMS 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 CMS 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, CMS 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 CMS seek legislation to be able to sanction hospitals for failure to report the ownership of physician practices.

**Status**

**Management Response**

The CMS 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 CMS require that CMS determine that an entity meets the criteria for establishing provider-based status.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Improve the Accuracy of Unique Physician Identification Number Data

Report Number:

OEI-07-98-00410

Final Report:

09/1999

#### Finding

Twenty-three percent of active unique physician identification numbers (UPINs) and 39 percent of provider identification numbers (PINs) had no claims activity in the last year. Coding instructions created inconsistent entry of State license numbers, professional school codes, physician specialty, and board certification. A small subset of providers had more than 10 PINs associated with a single UPIN. Some data fields are inconsistent between UPIN and PIN records for the same physician. Addresses for 28 percent of a sample of mental health service providers were returned as undeliverable.

#### Current Law

The CMS 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 CMS 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. We recommend that CMS should reconcile identical data fields between UPIN and all associated PINs, as well as validate accurate addresses, before implementing the national provider identification initiative.

#### Status

##### Management Response

The CMS concurs with the report recommendations. Specifically, CMS agrees that the Carrier Performance Evaluation review should include deactivation of UPINs and PINs according to policy. The CMS plans to release additional instructions for coding and data entry. The CMS 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 CMS plans to release additional instructions to carriers to deactivate the PINs within 6 consecutive months with no Medicare claims.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Improve Medicaid Mental Health Programs**

Report Number: OEI-04-97-00340 Final Report: 01/2000

**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**

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 CMS should work with SAMHSA to develop and implement outcome measurement systems that can be used as a condition of waiver approval. The CMS 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, CMS should ensure that States obtain the required 1115 waiver to expand services to non-Medicaid populations.

**Status**

**Management Response**

The CMS 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, CMS will work with States to ensure that appropriate measurements for mental health services are utilized. The CMS 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 CMS 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 CMS disagreed with the final recommendation indicating that the "recommendation was based on an incorrect understanding of the statute;" therefore, CMS specified no action. The SAMHSA generally was not in agreement with the study methodology and, therefore, did not view the findings as very conclusive.

## Centers for Medicare and Medicaid Services

-CMS Administration-

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

Report Number:

OEI-04-97-00344

Final Report:

01/2000

#### 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

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 CMS 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 CMS 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 CMS will emphasize to States the importance of managed care contracts defining clearly what mental health services must be provided to enrolled children. The CMS published Review Criteria for Children with Special Needs on January 19, 2001. States, which mandatorily enroll children in capitated plans, will respond to these criteria as part of their waiver. In regard to the second recommendation, CMS plans to highlight the importance of effective State-level coordination of all services to special needs populations in its Report to Congress on the special needs of vulnerable populations enrolled in Medicaid managed care.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Improve Review and Tracking of Managed Care Marketing Materials

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

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS has fully updated the National Marketing Guide (which is now called "Chapter 3" of the Medicare Managed Care Manual) and is now updating the chapter on a quarterly basis. It provides a checklist to health plans for the 2002 model Evidence of Coverage and is considering adding checklists for other marketing material. The CMS provides models for the Annual Notice of Change, Evidence of Coverage, the enrollment form, and many enrollment and disenrollment letters. It is in the midst of working with the industry and beneficiary advocacy groups to revise and consumer test the 2003 model Evidence of Coverage to ensure that it is a more consumer-friendly document.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Improve DMERC Fraud Data**

Report Number: OEI-04-97-00330 Final Report: 02/2000

**Finding**

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

**Current Law**

On October 1, 1993, CMS 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 CMS to improve ineffective and costly claims processing under the 34 carrier system.

**Recommendation**

Legislative

Administrative

Material Weakness

We recommend that CMS 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 CMS concurred with OIG's recommendation and continues development of the Program Integrity Management Report (PIMR) system. The PIMR for Part B was implemented in January 2001; PIMR for Part A data is scheduled for September 2002. Tied in with implementing the OIG's recommendation will be a provision of access to the Fraud Investigation Database (FID) for overpayment data. This tie-in will follow FID becoming available in a Windows-based environment.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Improve Medicare Billing for Orthotic Devices**

Report Number: OEI-02-99-00120 Final Report: 03/2000

**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**

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 CMS 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 CMS require standards for suppliers of custom molded and custom fabricated orthotic devices.

**Status**

**Management Response**

The CMS generally concurred with the recommendations. The CMS 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, CMS has worked with the statistical analysis durable medical equipment regional carriers to create a product classification list for L0430 "Thoracic Lumbar-Sacral-Othosis."

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Prevent Payments for Services After Date of Death**

Report Number: OEI-03-99-00200      Final Report: 03/2000

**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**

The CMS's Common Working File (CWF), which is queried by contractors before payment is made, receives updated beneficiary information, including the date of death, from CMS'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 CMS should require Medicare contractors to conduct annual post-payment reviews to identify and recover payments for services after the date of death. In addition, CMS should revise its CWF system edit to ensure that durable medical equipment payments are not made for deceased beneficiaries. Finally, CMS should periodically reconcile date of death information between the Enrollment Database and the CWF system.

**Status**

**Management Response**

The CMS concurred with the recommendations. The CMS's analysis of the problem has been shared with all CMS 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, CMS 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, CMS had initially planned to issue contractor instructions through its budget performance requirements for Fiscal Year 2001, requiring all Medicare contractors to perform these reviews.

**Centers for Medicare and Medicaid Services**

*-CMS Administration-*

**Increase the Accountability of Dialysis Facilities for Quality of Services**

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

**Finding**

The CMS 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 CMS to provide oversight.

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

We recommend that CMS hold ESRD facilities more accountable through the following actions: revising the conditions of participation, strengthening the complaint system, instituting minimum cycle times for surveys, requiring Network/State agency joint initial surveys, and facilitating publicly accountable means for identifying serious medical injuries. We recommend that CMS improve Network and State agency accountability by developing performance-based evaluations of Networks, improving assessment of surveys, and increasing public disclosure of both.

**Status**

**Management Response**

The CMS generally concurs with our recommendations. The CMS plans to publish revised conditions for coverage in the Summer 2002, 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.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Identify Primary Health Insurance: Medicare Secondary Payer Auxiliary File**

Report Number: OEI-07-98-00180      Final Report: 06/2000

**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 CMS's Medicare secondary payer data system.

**Current Law**

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

**Status**

**Management Response**

The CMS 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 CMS 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.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Improve CMS Management of Provider-Based Reimbursement to Hospitals

Report Number:

OEI-04-97-00090

Final Report:

08/2000

#### Finding

The CMS regional offices use different processes and standards, and require varying levels of documentation for approving provider-based status for hospital owned entities. In addition, CMS 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 CMS approval.

#### Current Law

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 CMS 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 CMS eliminate the provider-based status as an accounting option for all types of hospital owned entities. If CMS 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 CMS did not concur with our recommendation to eliminate the provider-based program. Instead, CMS has initiated various efforts to improve management of the program including: revising Form CMS-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 CMS 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.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Increase Organ Donation**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

**Material Weakness**

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

**Status**

**Management Response**

The CMS concurred with the recommendations and indicated it will explore ways in which additional data can be used to assess OPO effectiveness and hospital compliance with the donation rule. The CMS plans to publish a Notice of Proposed Regulation Memorandum (NPRM) with new performance standards for organ procurement organizations in 2002. The NPRM will include proposed requirements to address the recommendations made by OIG in its report including requirements for reporting hospital-specific data to CMS. The HRSA also concurred with the recommendations.

**Centers for Medicare and Medicaid Services**  
*-CMS Administration-*

**Improve Credentialing of Medicaid Providers**

Report Number: OEI-07-99-00680 Final Report: 02/2001

**Finding**

One-half of the States are not collecting all the enrollment and credentialing information required by CMS. The verification of providers' exclusion status is incomplete. States are accepting provider enrollment statements without independently verifying the accuracy of the information. Only two-thirds of the States make use of information available from external sources to enhance their credentialing processes. Most States have not established aggressive post-credentialing activities.

**Current Law**

Provider enrollment and credentialing are needed to obtain a Medicaid provider number identification number. Providers use these numbers to submit claims for services and receive reimbursement from the Medicaid program.

**Recommendation**

Legislative

Administrative

Material Weakness

The CMS should: (1) strengthen the enrollment, re-enrollment, and credentialing requirements of Medicaid providers; (2) instruct States to independently verify the provider's exclusion status from all Federal programs; (3) require States to obtain provider information from other States and Federal entities; and (4) establish standards and processes for the deactivation and reactivation of provider identification numbers.

**Status**

**Management Response**

The CMS generally agreed with the underlying intent of our recommendations. However, they believe such improvements should be made by working with and advising States rather than adoption of additional stricter Federal requirements.

## Centers for Medicare and Medicaid Services

-CMS Administration-

### Improve the Medicare Beneficiary Complaint Process

Report Number:

OEI-01-00-00060

Final Report:

08/2001

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The CMS will direct quality improvement organizations (QIOs), formerly called peer review organizations, to implement a revised beneficiary complaint process under the seventh contract cycle which begins in August 2002. The revised beneficiary review process attempts to address deficiencies and recommendations noted in the OIG report. The CMS will work closely with QIOs to provide technical assistance and monitor the effectiveness of beneficiary satisfaction with the revised process.

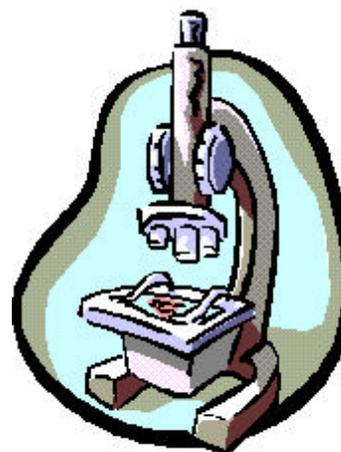
# Public Health Service Agencies

# Public Health Service Agencies

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## Overview

The activities of the Department's Public Health Service 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 Service 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) 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 crosscutting 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.



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## Introduction

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## Related OIG Activities

The Office of Inspector General (OIG) continues to increase oversight of Public Health Service agencies' activities and ensure 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 that 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 Service Agencies**  
*-Biomedical Research-*

**Improve Administration of the NIH Small Business Innovation Research Program**

Report Number: OAS-15-98-00031 Final Report: 11/1999

**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**

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 database with the Patent and Trademark Office (PTO) patent database 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 database 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, modified terms of award letters to emphasize invention reporting requirements, and initiated a proposal to PTO regarding ways to identify patents supported with NIH funds. Also, NIH developed a methodology to evaluate the performance of the SBIR program and planned to complete an evaluation of its SBIR awardees. To place additional emphasis on commercialization, NIH revised its review criteria to emphasize the potential of the proposed research for commercial use.

**Public Health Service Agencies**  
*-Biomedical Research-*

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

Report Number: OAS-15-99-80002 Final Report: 01/2000

**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**

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. The NIH also stated that it was in the process of establishing a database to better track payback activities and was updating its files on NRSA recipients.

**Public Health Service Agencies**  
*-Biomedical Research-*

**Improve Recruiting Practices for Human Research Subjects**

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

**Finding**

Recruitment is a major bottleneck in the flow of drugs developed by industry. Therefore, there is significant pressure for research investigators to recruit subjects quickly. Sponsors and investigators use a variety of recruitment methods 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**

In June 2000, the Office for Human Research Protections (OHRP) was established within the Office of the Secretary and took over much of the responsibilities of the former NIH Office for Protection from Research Risks. OHRP is charged with oversight of all research involving human subjects that is conducted or funded by HHS and conducts investigations at research institutions that have signed assurances. Under this new structure, the NIH will continue its involvement in the funding and oversight of clinical trials and will coordinate with OHRP in activities related to the protection of human subjects. FDA retains its enforcement authority to ensure researcher compliance with HHS patient protection and patient consent requirements in FDA-authorized drug and medical device clinical trials.

**Recommendation**

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

We directed our recommendations jointly to FDA, 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, concerns were expressed regarding risks in human subject recruiting, and it was noted that risk could be reduced to minimal levels if IRBs were uniformly diligent in exercising their oversight authorities. The Department will institute new requirements for continuing education in human subject protection for investigators, IRB members, and staff and officials involved in compliance. The Department has also developed draft interim guidance to address conflicts of interest in research; further work on this document continues. As of October 2000, the NIH has required key personnel to document their completion of human subject protection education, and provide on-line modules as well as funding of research ethics courses to facilitate this objective. The OHRP, in collaboration with NIH, FDA and other stakeholders involved in human subject protection, is working to develop guidance in multiple areas of human subject protection, including conflict of interest, pediatric clinical trials, research involving third-party research, and privacy issues. The FDA has increased its on-site inspections of IRBs and plans to expand the number as resources allow.

**Public Health Service Agencies**  
*-Biomedical Research-*

**Strengthen FDA Oversight of Clinical Investigators**

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

**Finding**

In general, oversight of clinical investigators by sponsors, institutional review boards (IRB), and 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**

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 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 in the evaluation of 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 the Office of Human Research Protection (OHRP) to improve education on human subject protections for investigators, IRB members, and staff and officials involved in regulatory compliance; (4) is working in concert with NIH and OHRP 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. The FDA has also established a new unit, the Office for Good Clinical Practice, within the Office of Science Coordination and Communication in the Commissioner's Office to coordinate and direct human subject protection and good clinical practices issues. The Bioresearch Monitoring Program policy and coordination function has been elevated to this Office, and is responsible for addressing issues identified in the OIG recommendations, specifically defining cross-center goals for the program, and developing criteria to determine whether the program is achieving these goals. Further, the agency is conducting a thorough review of its disqualification process for clinical investigators.

**Public Health Service Agencies**

*-Food and Drug Safety-*

**Enforce State Pharmacy Boards' Oversight of Patient Counseling Laws**

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

**Finding**

(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**

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 CMS should facilitate State efforts to enforce the Medicaid patient counseling mandate. (3) The CMS should develop and assess State progress toward a patient counseling performance objective. (4) The CMS should develop guidelines on State oversight of the Federal patient counseling mandate.

**Status**

**Management Response**

In conjunction with the National Association of Boards of Pharmacy (NABP), FDA conducted an eight-State pilot study in 1998 which collected and evaluated written counseling materials from over 300 pharmacies. In early 2001, FDA again contracted with the NABP to conduct an evaluation of the written medication information given to simulated patients, together with new prescriptions at 380 randomly selected pharmacies across the country. The results of this study are projected to be available for public distribution by March 2002. The FDA has also conducted periodic telephone surveys since 1982 to measure patient-reported receipt of oral and written information about newly prescribed medicines at prescribers' offices and at pharmacies. Each of the studies has evaluated reports of about 1,000 patients receiving new prescriptions. The most recent survey was conducted in late 2001; results should be available by the end of March. The CMS has contracted with U.S. Pharmacopeia to conduct a study reviewing annual Drug Utilization Review reports in order to determine best practices. The study is expected to be completed soon.

**Public Health Service Agencies**  
*-Food and Drug Safety-*

**Strengthen FDA Oversight of State Food Firm Inspections**

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

**Finding**

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**

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 is field testing the following documents: Contract Audit Form, Guidance for Contract Audit, and Field Management Directive 76. The documents will not be finalized until October 2002, after FDA has had at least 1 year's use of them in the field. The first State Contract Audit Course was held in August 2001; the second one in January 2002.

**Public Health Service Agencies**  
*-Food and Drug Safety-*

**Improve Oversight of Tissue Banking**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

On behalf of FDA, we received comments from the Deputy Secretary in December 2000. The Deputy Secretary concurred that FDA should expedite its planned rulemaking activities related to tissues, specifically the final rule to require registration of tissue banks. The Department also found "considerable merit" in the OIG recommendation for an intensified inspection program directed towards entities that procure, process, and store human tissues. The FDA testified before the Senate Permanent Subcommittee on Investigations on May 24, 2001. In its testimony, the agency said that all three of the proposed rules have been published, and one rule (Establishment Registering and Listing) was finalized on January 8, 2001. The FDA also testified that it "intends to inspect" the 36 uninspected banks that the OIG identified and all other uninspected establishments. The FDA has completed contacting the 36 uninspected tissue banks. The results are: 31 inspections were completed, 3 firms were out of business, 1 firm could not be located, and 1 firm was not an FDA obligation since it handles only vascularized organs.

**Public Health Service Agencies**  
*-Food and Drug Safety-*

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

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

We recommend that FDA (1) facilitate greater detection of adverse events by requiring dietary supplement manufacturers to report serious events to FDA for some products; (2) obtain more information on adverse event reports by requiring dietary supplement manufacturers to register themselves and their products with the FDA; (3) notify manufacturers when FDA receives a serious adverse event report and develop a new computer database to track and analyze adverse event reports; (4) expedite the development and implementation of good manufacturing practices for dietary supplement manufacturers; and (5) disclose more useful information to the public about dietary supplement adverse events.

**Status**

**Management Response**

The FDA agreed with the majority of our recommendations. The Center for Food Safety and Applied Nutrition (CFSAN) indicated that it has embarked on significant efforts to enhance its adverse event reporting system through development of a new system called the CFSAN Adverse Event Reporting System (CAERS). Inherent in the design of CAERS is the capture and analysis of all reports of consumer complaints and adverse events related to CFSAN-regulated products, particularly dietary supplements. The new system will incorporate all existing adverse event reporting systems into one state-of-the-art reporting and monitoring system. The CAERS staff will work closely with program experts throughout FDA, other governmental agencies, industry, professional organizations, and other interested parties. The CAERS is in its developmental stages. With new funding in the Fiscal Year 2002 budget, CFSAN will be able to pilot-test the new system this fiscal year.

**Public Health Service Agencies**  
*-Food and Drug Safety-*

**Improve Protection for Research Subjects in Foreign Clinical Trials**

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

**Finding**

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

**Current Law**

In June 2000, the Office for Human Research Protections (OHRP) was established within the Office of the Secretary and took over much of the responsibilities of the former NIH Office for Protection from Research Risks. The OHRP is charged with oversight of all research involving human subjects that is conducted or funded by HHS and conducts investigations at research institutions that have signed assurances. Under this new structure, NIH will continue its involvement in the funding and oversight of clinical trials and will coordinate with OHRP in activities related to the protection of human subjects. The FDA retains its enforcement authority to ensure researcher compliance with HHS patient protection and patient consent requirements in FDA-authorized drug and medical device clinical trials.

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The FDA supported our recommendations but noted that in most cases it did not have the resources to implement the recommendations. Currently, FDA is assessing the legal feasibility of requiring attestations of good clinical practice compliance from investigators outside the United States when their data is submitted to the agency as part of an application. The FDA is also more broadly reviewing its requirements for the acceptance of foreign data in support of submitted applications. The OHRP concurs with our recommendations and emphasized that its new Office of International Activities “will serve as a focal point and coordinating center” for the Department’s efforts to improve human subject protection. In collaboration with FDA and the Fogarty International Center, OHRP is participating in an international Strategic Initiative for Developing Capacity for Ethical Review (SIDCER) with a goal of establishing effective education and review processes around the world. Standardized operational procedures and guidelines were introduced last year, and guidelines will be released soon for surveying and improving the performance of ethics committees in Mexico, Latin America, Southeast Asia, Central Europe, Japan, India, the European Union and countries around the world, including the US and Canada.

## Public Health Service Agencies

*-Indian Health-*

### Improve Management of the Office of Program Integrity and Ethics

Report Number:

OEI-04-97-00060

Final Report:

11/1998

#### 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

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

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 Program Integrity and Ethics Staff's (PIES) policies and procedures and delegations of authority are being reviewed and will be published in the "Indian Health Manual." The IHS has completed a review of the PIES staffing and determined that current levels meet the Agency needs. In addition, new position descriptions have been written and classified and all positions have been filled.

**Public Health Service Agencies**  
*-Indian Health-*

**Improve the Indian Health Service EEO Complaint Process**

Report Number: OEI-05-99-00290 Final Report: 07/2000

**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**

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. In fiscal year 1999, OIG reported 192 active formal Equal Employment Opportunity (EEO) cases in IHS, and as of November 30, 2001, the caseload has been reduced by 35 percent to 125 active cases. The IHS will continue to provide EEO training and implement recommendations identified by OIG.

**Public Health Service Agencies**  
*-Indian Health-*

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

Report Number: OAS-01-99-01502 Final Report: 08/2000

**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**

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 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**

According to IHS, all tribal contracts and compacts in the Nashville area, with the exception of the Pequot Nation contract, were in compliance with our recommendations. The IHS and the Pequot Nation are in litigation concerning these issues.

**Public Health Service Agencies**  
*-Health Resources and Services-*

**Improve Hospital Reporting to the National Practitioner Data Bank**

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

**Finding**

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

**Current Law**

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

**Recommendation**

Legislative

Administrative

Material Weakness

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

**Status**

**Management Response**

The HRSA fully supports the recommendations and has awarded a contract to Price Waterhouse Coopers to look at the feasibility study for assessing compliance with the Data Bank reporting requirements. The feasibility study addresses both hospital and managed care organizations reporting.

**Public Health Service Agencies**  
*-Health Resources and Services-*

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

Report Number: OAS-01-98-01505 Final Report: 12/1999

**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**

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 CMS 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 CMS concurred with the recommendation. According to HRSA, the HRSA and CMS 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 Service Agencies**  
*-Health Resources and Services-*

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

Report Number: OAS-05-99-00017 Final Report: 03/2000

**Finding**

Of 10 educational institutions audited, 8 were carrying uncollectible loans in their accounting records. These schools did not assess the collectibility of their Health Professions Student Loans on a regular basis, and five 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 that may exceed the needs of the schools.

**Current Law**

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 uncollectible, 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 uncollectible. 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 Service Agencies**  
*-Health Resources and Services-*

**Enhance Maternal and Child Health Training Grant Program**

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

**Finding**

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

**Current Law**

The LEND program is a training grant program authorized under the Maternal and Child Health Services Block Grant as part of the "set-aside" for projects of regional and national significance. The LEND program seeks to achieve its mission through funding graduate level, interdisciplinary training which produces professionals to work with special needs children. The program was funded \$18.2 million in FY 2001.

**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 noted that (1) Performance measures for all Special Projects of Regional and National Significance, which includes training grants, continue to be under development in preparation for submission to the Office of Management and Budget. Performance measures specific to LEND are currently being reviewed by program staff, LEND grantees, and the American Association of University Affiliated Programs (AAUP). (2) HRSA is working with AAUP to develop instruments to assist data collection and tracking graduates; tracking graduates is one of the performance measures proposed by HRSA. (3) HRSA is still on schedule to complete its goal of visiting 35 programs over the course of the project period.

## Public Health Service Agencies

-PHS Administration-

### Develop Plan to Address Youth Use of Cigars

Report Number:

OEI-06-98-00020

Final Report:

02/1999

#### 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

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

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

In June 2000, the Department joined with the Federal Trade Commission (FTC) in announcing a consent agreement with the seven major cigar companies that represent over 90 percent of the market. The agreement, which formally took effect on February 13, 2001, resulted in the first comprehensive health warning system for cigar packaging and advertising. The warning system will ensure that cigars marketed by these companies will contain labels based on the latest scientific evidence. This represents the first time a tobacco product has included a warning about environmental tobacco smoke. At the Surgeon General's request, the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention (CDC) reviewed the labels originally under consideration by the FTC to assure that they were consistent with the most current science. In addition, CDC has accelerated its cigar-related education and surveillance activities by coordinating with the Office on Smoking and Health's Media Campaign Resource Center in the development of an innovative Internet strategy and the national dissemination of television and radio counter-advertisements.

The NCI, in collaboration with other Federal agencies, contributes to tracking cigar use patterns via two different surveys. The cancer control module of the "National Health Interview Survey" and the tobacco use supplement to the "Current Population Survey" both ask questions about cigar use. The data from these surveys are available to the Government and the scientific community and have been used in the past to both better understand the use of cigars and provide data that can benefit policy development. These surveys also track smoking policies, including indoor smoking, health care system practices, and smoking cessation products and services.

## Public Health Service Agencies

-PHS Administration-

### Improve Managed Care Organizations Reporting to the National Practitioner Data Bank

Report Number:

OEI-01-99-00690

Final Report:

05/2001

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative



Administrative

Material Weakness

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

#### Status

##### Management Response

The HRSA has awarded a contract to Price Waterhouse Coopers to look at the feasibility study for assessing compliance with the Data Bank reporting requirements. The feasibility study addresses both hospital and managed care organizations reporting.

# **Administration for Children and Families**

# Administration for Children and Families

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## Overview

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

Major types of family support payments to States include: Temporary Assistance for Needy Families (TANF), a cooperative program among Federal, State and local governments that gives States flexibility to design their own programs in ways that require work participation, promote self-sufficiency, and strengthen families; and the Child Support Enforcement (CSE) program, which provides grants to States to ensure that children are financially and emotionally supported by both parents, and to enforce obligations of absent parents 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, Refugee Assistance, and Developmental Disabilities.



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## Introduction

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## 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. Particularly 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.

## Administration for Children and Families

-Child Support Enforcement-

### 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:	03/2000
	OEI-06-98-00042		03/2000
	OEI-06-98-00043		03/2000

#### 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

The Personal Responsibility and Work Opportunity Act of 1996 required Temporary Assistance for Needy Families (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

In September 2001, OCSE conducted a session at a national training conference on the importance of building and maintaining interagency communications between public assistance and child support agencies. The conference highlighted collaborative procedures in areas with high TANF populations. Additionally, OCSE will issue best practice guidance to States informing them of instances where other State or county child support enforcement (CSE) programs are doing a particularly good job of helping TANF clients cooperate with CSE. The OCSE is committed to working with the Office of Family Assistance (OFA) to improve communication between State TANF and child support offices to provide better service to our customers.

**Administration for Children and Families**  
*-Child Support Enforcement-*

**Improve Medicaid-Only Clients Cooperation with Child Support Enforcement**

Report Number: OEI-06-98-00045      Final Report: 04/2000

**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**

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 CMS 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 CMS 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**

In December 2000, CMS issued a letter to State Medicaid Directors explaining the Federal Medicaid requirements and options pertaining to paternity and medical support; and briefly described the child support enforcement services available to families receiving Medicaid. The ACF shared this letter with IV-D Directors through a "Dear Colleague" letter encouraging them "to consult with their Medicaid and State Children's Health Insurance Program (SCHIP) counterparts to clarify how they will be implementing the CMS directive and how State IV-D and Medicaid and SCHIP programs can best collaborate to provide all appropriate health care and child support services to children.

The ACF continues to examine implementation of a medical support performance indicator to measure the effectiveness of IV-D agency activities in this area. The final rule for the National Medical Support Notice was published in the Federal Register in December 2000.

## Administration for Children and Families

*-Child Support Enforcement-*

### Improve Access to Medical Insurance for Dependents Receiving Child Support

Report Number:

OEI-07-97-00500

Final Report:

06/2000

#### Finding

Considerable progress has been made by 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

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

#### Status

##### Management Response

The Child Support Performance and Incentive Act of 1998 directed the Secretary of Health and Human Services and the Secretary of Labor to jointly establish the Medical Child Support Working Group to study and provide recommendations on how to improve the enforcement of medical support obligations for children. On August 15, 2000 the Work Group released a Report to Congress highlighting 76 recommendations. In addition, on June 1, 2000 ACF sent States a compendium of State Best Practices describing States' efforts to address medical support.

The ACF is working with CMS to develop a report from the Secretary of HHS to the Congress recommending legislation to support increased medical coverage for children. The OIG will continue to monitor ACF's activities.

## Administration for Children and Families

*-Child Support Enforcement-*

### Improve the Establishment of Child Support Orders for Low-Income Non-Custodial Parents

Report Number:

OEI-05-99-00391

Final Report:

07/2000

#### Finding

Our inspection revealed that certain methods used to determine financial obligations for low-income non-custodial parents yield poor payment compliance results. The charging of retroactive support, the use of imputed income in the calculation of support amounts and the use of minimum orders are associated with lower rates of payment compliance. We also found that few sampled States provide non-custodial parents with formal linkages to job programs.

#### Current Law

Title IV-D of the Social Security Act enacted the Child Support Enforcement (CSE) program to ensure that children are financially supported by both their parents. States must have guidelines to establish how much a parent should pay for child support. The establishment of child support orders occur through either judicial or administrative processes. Currently, there are three types of guidelines to calculate award amounts: income shares, percentage of income, and the Melson-Delaware formula.

#### Recommendation

Legislative



Administrative

Material Weakness

As opportunities for improvement, the ACF's Office of Child Support Enforcement (OCSE) should work with States to emphasize parental responsibility and improve the ability of low-income non-custodial parents to meet their obligations. This requires a dual approach of setting realistic support obligations and providing employment support with work requirements. Specifically, ACF should facilitate and support State experiments to test the payment effects of using various periods of retroactivity in determining the amount of support owed; facilitate and support State experiences to test negotiating child support debt owed to the States in exchange for improved payment compliance.

#### Status

##### Management Response

The ACF OCSE regional offices convened a meeting of Federal, State and local staff from 15 States to discuss child support arrears management in 2001. The ACF is helping ten States test approaches to serving young, never-married fathers who may have obstacles to employment, and who do not have a child support order. The ACF have granted a contract to determine how computerized income data can be used by local child support offices to independently verify the income of non-custodial parents and be used in the establishment or modification of child support orders where income documentation or verification is lacking or incomplete.

## Administration for Children and Families

-ACF Administration-

### Enhance Implementation of the Interstate Compact for Placement of Children

Report Number:

OEI-02-95-00044

Final Report:

03/1999

#### Finding

The Interstate Compact for Placement of Children (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

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 training to State agencies regarding the functioning of the Interstate Compact for the Placement of Children (ICPC). 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.

## Administration for Children and Families

-ACF Administration-

### Improve Employment Programs for Persons with Developmental Disabilities

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

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

We 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.

## Administration for Children and Families

-ACF Administration-

### Improve TANF Client Sanction Notices

Report Number:

OEI-09-98-00292

Final Report:

10/1999

#### Finding

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

#### Current Law

Public Law 104-193 directs States to sanction 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 our recommendation.

In 1999, the Centers for Medicare and Medicaid conducted Medicaid/TANF access reviews and identified concerns about the clarity of TANF notices. As a result, a number of States have been working on improving their notices.

## Administration for Children and Families

-ACF Administration-

### Strengthen State Licensing of Residential Foster Care

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

#### Finding

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

#### Current Law

Title 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

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

# Administration on Aging

# Administration on Aging

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## Overview

The Administration on Aging (AoA) is the Federal focal point and advocate agency for older persons and their concerns. In this role, AoA works to heighten awareness among other Federal agencies, organization, groups, and the public about the valuable contributions that older Americans make to the Nation and alerts them to the needs of vulnerable older people. Through information and referral and outreach efforts at the community level, AoA seeks to educate older people and their caregivers about the benefits and services available to help them.

Forty-three 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: 3 million Americans aged 85 and older, those living alone without a caregiver, members of minority groups, older persons with physical or mental impairments, low-income older persons, and those who are abused, neglected, or exploited.

One Federal agency, the Administration on Aging 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 caregivers. 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.

Working in close partnership with other agencies in HHS and throughout the executive branch of Government, AoA leads a national aging services 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, caregivers, and volunteers.



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## Introduction

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## 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.

## Administration on Aging

*-Nutrition and Services-*

### Improve Safeguards for Long-Term Care Residents

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

#### Finding

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

#### Current Law

Under CMS statute and regulations, residents of nursing homes and other long-term-care facilities have the right to reside in 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) CMS and AoA work collaboratively with the States to improve the safety of long-term-care residents and to strengthen safeguards against the employment of abusive workers, (2) CMS consider establishing Federal requirements and criteria for performing criminal checks, and (3) CMS consider developing a national abuse registry or expanding the current State registries to include all workers in facilities receiving Federal reimbursement.

#### Status

##### Management Response

The CMS and AoA verbally agreed with our recommendations.

## Administration on Aging

-AOA Administration-

### Improve Long-Term Care Ombudsman Program

Report Number:

OEI-02-98-00351

Final Report:

03/1999

#### Finding

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

#### Current Law

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

#### Status

##### Management Response

The AoA has produced two papers for circulation to all State ombudsmen that highlight and promote strategies for recruiting, training, and supervising volunteers. 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. Broad guidelines, including guidelines for program visibility as well as complaints and resolutions times, are still under development. These guidelines will ultimately be issued as a technical assistance/best practices document. A follow-up study regarding issues in this report is presently in the OIG work plan.

# **General Department Management**

# General Department Management

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## Overview

The Office of Inspector General's (OIG) departmental management and governmentwide oversight role includes reviews of payroll activities, accounting transactions, implementation of the Federal Manager's Financial Integrity Act and the Prompt Pay Act, financial management audits under the Chief Financial Officer's Act, grants and contracts, 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.

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



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## Introduction

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## 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

*-Financial Management-*

### Update Cost Principles for Federally Sponsored Research Activities

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

#### 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

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

The ASBTE circulated several draft iterations of the hospital cost principles to internal users for comment. Many of the policies in the outdated OASC-3 have been incorporated and updated in the draft regulation. The target date for issuing the draft regulation as a notice of proposed rulemaking is no later than September 30, 2002. Once issued in final, a revised OASC-3, renamed ASMB C-3, will be issued. The new ASMB C-3 will contain forms, examples, and other information to implement the revised regulation.

## General Department Management

*-Financial Management-*

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

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

#### Finding

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

#### Current Law

Currently, 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 postretirement benefit expenses should be recognized as a reimbursable cost. Without guidance on whether accrued expenses should be charged, scarce Federal research funds may be used to reimburse unfunded postretirement benefit costs.

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

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

## General Department Management

-Financial Management-

### Improve Recharge Centers' Financial Accounting Systems

Report Number:

OAS-09-92-04020

Final Report:

01/1994

#### 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

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 recordkeeping 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 OMB plans to strengthen the policies concerning recharge centers in the next revision of Circular A-21. Also, ASMB has requested that recharge centers be specifically addressed in the Circular A-133 compliance supplement for schools.

## General Department Management

*-Financial Management-*

### Improve Financial Reporting Processes

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

### 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

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 01-02, 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

*-Financial Management-*

### Improve Financial Reporting Processes (cont.)

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

### Finding

At a number of operating divisions, there were significant delays in providing documentation supporting financial statement balances during the FY 2000 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

The Government Management Reform Act of 1994 requires that many Federal agencies, including HHS, prepare annual financial statements. The OMB Bulletin 01-02, 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

*-Crosscutting Issues-*

### Strengthen State Protections for Persons With Disabilities in Residential Settings

Report Number:

OAS-01-00-02502

Final Report:

05/2001

#### Finding

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

#### Current Law

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

#### Recommendation

Legislative

Administrative

Material Weakness

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

#### Status

##### Management Response

We are awaiting comments on our final report.