Department of Health and Human Services

Office of Inspector General

WORK PLAN

FISCAL YEAR 2005

Department of Health and Human Services

Office of Inspector General

Mission

Under the authority of the IG Act, we improve the Department of Health and Human Services (HHS) programs and operations by protecting them against fraud, waste, and abuse. By conducting independent and objective audits, evaluations, and investigations, we provide timely, useful, and reliable information and advice to Department officials, the administration, the Congress, and the public.

Vision

We Are Guardians of the Public Trust

- Working with management, we will ensure effective and efficient HHS programs and operations.
- Working with decision-makers, we will minimize fraud, waste, and abuse in HHS programs.
- Working with our talented and motivated staff, we will manifest the highest standards as a Federal OIG.

Values

- Quality products and services that are timely and useful.
- A service attitude that is responsive to the needs of decision-makers.
- Fairness, integrity, independence, objectivity, proficiency, and due care in performing our work.
- Teamwork and open communication among OIG components.
- A positive environment that supports our personal and professional needs and encourages us to be innovative and reach our full potential.

Office of Inspector General
Fiscal Year 2005 Work Plan

Introduction

The Office of Inspector General (OIG) Work Plan is set forth in four chapters. The first three chapters present the full range of projects planned by each of the major entities of the Department of Health and Human Services (HHS): the Centers for Medicare & Medicaid Services (CMS); the public health agencies; and the Administrations for Children, Families, and Aging. The fourth chapter embraces those projects related to issues that cut across Department programs, including State and local government use of Federal funds, as well as the functional areas of the Office of the Secretary. Each of the chapters encompasses projects undertaken by the four operational components of OIG: the Office of Audit Services (OAS), the Office of Evaluation and Inspections (OEI), the Office of Investigations (OI), and the Office of Counsel to the Inspector General (OCIG).

The OIG Work Plan briefly describes the various project areas that we perceive as critical to the mission of OIG and the Department. However, as the work-planning process tends to be ongoing and dynamic, the focus and timing of many of these projects may evolve in response to new information, new issues, and shifting priorities of the Congress, the President, and the Secretary, and thus may be altered over time.

Given these variables, OIG's objective remains the targeting of available resources on those projects that best identify vulnerabilities in the Department's programs and activities and that promote the economy, efficiency, and effectiveness of those programs. The Health Insurance Portability and Accountability Act of 1996 through the Health Care Fraud and Abuse Control (HCFAC) program brought much-needed authorities and resources to achieving this objective.

To ensure that our studies do not duplicate existing work and to build on such work, we will continue to identify and evaluate audits, inspections, and studies performed by others, such as the Government Accountability Office, Centers for Medicare & Medicaid Services and the Office of Management and Budget as part of its Program Assessment and Rating Tool. We also seek to determine the effectiveness of management actions designed to correct the deficiencies cited in these prior studies.

Program Audits

OAS conducts comprehensive financial and performance audits of departmental programs and operations to determine whether objectives are being achieved and which program features need to be performed more efficiently and to identify systemic weaknesses that give rise to

fraud, waste, and abuse. OAS also provides overall leadership and direction in carrying out the responsibilities mandated by the Chief Financial Officers Act of 1990 and the Government Management Reform Act of 1994 relating to financial statement audits.

Program Inspections

OEI seeks to improve the effectiveness and efficiency of departmental programs by conducting program inspections to provide timely, useful, and reliable information and advice to decision-makers. These inspections are program and management evaluations that focus on specific issues of concern to the Department, the Congress, and the public. The inspections identified in this Work Plan focus on programs with significant expenditures of funds and services to program beneficiaries or in which important management issues have surfaced. The results of these inspections should generate accurate and up-to-date information on how well those programs are operating and offer specific recommendations to improve their overall efficiency and effectiveness.

Investigative Focus Areas

OI conducts investigations of fraud and misconduct to safeguard the Department's programs and protect the beneficiaries of those programs. OI concentrates its resources on criminal investigations relating to HHS programs and operations. However, OI's activities are broad-ranging and are designed to prevent fraud and abuse in departmental programs by identifying systemic weaknesses in areas of program vulnerability that can be eliminated through corrective management actions, regulation, or legislation; by pursuing criminal convictions; and by recovering damages and penalties through civil and administrative proceedings.

Legal Counsel Focus Areas

OCIG coordinates OIG's role in the resolution of fraud and abuse cases involving HHS programs, including the litigation and imposition of administrative sanctions, such as program exclusions and civil monetary penalties and assessments; the global settlement of cases arising under the Civil False Claims Act; and the development and monitoring of corporate integrity agreements for certain providers that have settled their False Claims Act liability with the Federal Government. It also develops and promotes industry-specific voluntary compliance program guidance. In addition, OCIG issues to the public special fraud alerts, special advisory bulletins, and advisory opinions regarding the application of OIG's sanction authorities. OCIG is responsible for developing new, and modifying existing, safe harbor regulations under the anti-kickback statute. Finally, OCIG provides general legal services to OIG, including advice and representation on HHS programs and operations, administrative law issues, and criminal procedure.

Centers for Medicare & Medicaid Services

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Medicaid/State Children's Health Insurance Program

Medicaid Drug Reimbursement

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Medicare Hospitals

Quality Improvement Organization Mediation of Beneficiary Complaints

We will assess the early experiences of Medicare Quality Improvement Organizations with using a mediation process for beneficiary complaints. Quality Improvement Organizations must review all written complaints from beneficiaries about the quality of services covered by Medicare and inform the beneficiary of the results of that review. Their current contracts also require use of case managers and offer mediation as an alternative mechanism for resolving complaints, unless "serious quality of care issues" are involved.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medical Education Payments for Dental and Podiatry Residents

We will continue to determine the appropriateness of including dental and podiatry residents in hospitals' counts of full-time equivalent residents for purposes of direct and indirect graduate medical education (GME) payments. In addition, we will review the written agreements to determine the financial arrangement between the teaching hospital and dental school. Under the Balanced Budget Act (BBA) of 1997, dental and podiatry residents are excluded from caps on the number of residents that hospitals are allowed to count for purposes of direct and indirect GME payments. Hospitals are allowed to count residents at nonhospital sites for purposes of direct and indirect GME payments if they incur all or substantially all of the costs of the training program in the site and meet other regulatory requirements.
(OAS; W-00-05-35025; A-04-00-00000; expected issue date: FY 2005; new start)

Nursing and Allied Health Education Payments

We will determine the appropriateness of payments for nursing and allied health (NAH) education programs. The Medicare program makes payments to hospitals for provider-operated NAH programs on a reasonable cost basis. We will perform our work at various fiscal intermediaries and providers to determine the validity of claims for these payments. The Office of Management and Budget (OMB) has expressed interest in this area.
(OAS; W-00-05-35123; A-00-00-00000; expected issue date: FY 2005; new start)

Graduate Medical Education Voluntary Supervision in Nonhospital Settings

We will study the appropriateness of alternative payment methodologies for GME involving the costs of training residents in nonhospital settings. This study is required by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).
(OAS; W-00-05-35157; A-02-00-00000; expected issue date: FY 2005; new start)

Postacute Care Transfers

We will assess the ability of Medicare contractors to limit payments to acute care hospitals for patients who are discharged from a prospective payment system inpatient hospital and admitted to one of several postacute-care settings. This limitation applies to certain diagnosis-related groups (DRG). Our prior reviews indicated that a lack of controls had resulted in significant overpayments.
(OAS; W-00-04-35102; various reviews; expected issue date: FY 2005; work in progress)

Diagnosis-Related Group Coding

We will examine DRGs that have a history of aberrant coding to determine whether some acute care hospitals exhibit aberrant coding patterns. Under the prospective payment system, the DRGs for inpatient acute care depend on accurate coding of diagnoses and procedures. Inaccurate coding by hospitals can lead to Medicare overpayments. We will determine coding payment error rates and incorporate the results of a recent review by quality improvement organizations.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Inpatient Prospective Payment System Wage Indices

We will determine whether hospital and Medicare controls are adequate to ensure the accuracy of the hospital wage data used for calculating wage indices for the inpatient prospective payment system. We believe that the wage indices are vulnerable to inaccuracy because the data used to calculate them for many metropolitan statistical areas are significantly influenced by information reported by a single hospital. Consequently, a hospital that reports incorrect wage data through its Medicare cost report could receive incorrect DRG reimbursement. We will determine the effect on the Medicare program in terms of incorrect DRG reimbursement.
(OAS; W-00-04-35100; various reviews; expected issue date: FY 2005; work in progress)

Inpatient Outlier and Other Charge-Related Issues

We will continue to determine whether claims for inpatient outlier payments were submitted in accordance with Medicare laws and regulations. We will also continue to assess program vulnerabilities in the current reimbursement policies for outlier payments, including the mechanisms used to establish the outlier threshold.
(OAS; W-00-04-35056; various reviews; expected issue date: FY 2005; work in progress)

Inpatient Rehabilitation Facilities Payments

We will review payments to inpatient rehabilitation facilities under the prospective payment system to determine the extent to which they were made in accordance with Medicare laws and regulations. We will determine the extent to which admissions to inpatient rehabilitation facilities (IRF) met specific regulatory requirements and whether the facilities billed for services in compliance with Medicare prospective payment system regulations, such as the regulations

concerning interrupted stays. We will also review outlier payments made to inpatient rehabilitation facilities. In addition, we will review rural IRFs' patients' length of stay and cost of services to determine whether the Medicare payment increase is justified.
(OAS; W-00-04-35103; various reviews; expected issue date: FY 2005; work in progress)

Inpatient Rehabilitation Payments—Late Assessments

We will determine the accuracy of Medicare payments for inpatient rehabilitation stays when patient assessments are entered late. Under the inpatient rehabilitation facility prospective payment system, admission and discharge assessments must be entered and transmitted within defined time limits or payment is reduced. We will determine how fiscal intermediaries make these adjustments and confirm that payments are accurate.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medical Necessity of Inpatient Psychiatric Stays

This review will determine the extent of any improper Medicare payments for inpatient psychiatric stays due to medical necessity or coverage issues. We will also assess the accuracy of controls to detect any such improper payments. Prospective payment system-exempt psychiatric units and specialty hospitals received over $2.8 billion for Medicare inpatient stays in 2000. Medical reviews of outpatient psychiatric services provided by prospective payment hospitals and specialty psychiatric hospitals found very high rates of unsupportable or unallowable services (58 percent and 42 percent, respectively). Hence, it is prudent to also review these services in the inpatient setting.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Consecutive Inpatient Stays

We will examine the extent to which Medicare beneficiaries received acute and postacute care through sequential stays at different hospitals. Although Medicare allows care in different facilities according to the beneficiary's needs, payments may be denied when one or multiple stays constitute an attempt to circumvent the prospective payment system. We will analyze claims to identify questionable patterns of inpatient and long-term care.
(OEI; 03-01-00430; expected issue date: FY 2005; work in progress)

Long-Term Care Hospitals Payments

We will review payments to long-term care hospitals under the prospective payment system to determine the extent to which these payments were made in accordance with Medicare laws and regulations. We will review the appropriateness of early discharges to home, interrupted stays, and outlier payments to these hospitals.
(OAS; W-00-04-35128; various reviews; expected issue date: FY 2005; work in progress)

Level of Care in Long-Term Care Hospitals

We will determine whether Medicare beneficiaries in long-term care hospitals are receiving acute-level services or could be cared for in skilled nursing facilities. Explosive growth in the long-term care hospital provider group has raised questions about the type of care being provided. These acute-care hospitals receive payments that can be several times higher than those that skilled nursing facilities receive, so we are responding to concerns that beneficiaries may be inappropriately referred for the level of services they need.
(OEI; 01-04-00300; expected issue date: FY 2005; work in progress)

Critical Access Hospitals

We will review hospital cost reports to examine the administrative and other costs incurred by critical access hospitals for inpatient and outpatient services for time periods both prior and subsequent to their conversion to critical access hospitals status. The Medicare Rural Hospital Flexibility Program, established in 1997, designated certain limited service hospitals as critical access hospitals. This program provided that such hospitals would be reimbursed for their reasonable costs in lieu of reimbursement through the prospective payment system.
(OAS; W-00-04/05-35101; A-06-00-00000; expected issue date: FY 2005; work in progress)

Organ Acquisition Costs

We will determine whether organ acquisition costs claimed on Medicare hospital cost reports were accurate and appropriate and excluded costs that should have been allocated to posttransplant activities or other benefiting cost centers. Medicare uses a reasonable cost basis to retrospectively reimburse hospitals for the costs of acquiring organs for transplant. Overpayments can occur if hospitals claim expenses not related to organ acquisition by shifting costs from posttransplant to pretransplant activities and from other hospital cost centers to the organ acquisition cost center. We will also examine Medicare payments related to organ procurement organizations.
(OAS; W-00-05-35083/04-35083; various reviews; expected issue date: FY 2005; work in progress)

Rebates Paid to Hospitals

This review will determine whether hospitals are properly identifying purchase credits as a separate line item in their Medicare cost reports. We will visit several large vendors and determine the amount of rebates paid to hospitals in a given year. We will then examine a sample of hospitals' Medicare cost reports to determine if the rebates are properly credited.
(OAS; W-00-05-35161; A-05-00-00000; expected issue date: FY 2005; new start)

Coronary Artery Stents

We will review inpatient and outpatient claims involving arterial stent implantation to determine whether Medicare payments for these services were appropriate. Through medical reviews, we

will determine if the services were medically necessary and supported by adequate documentation. We will also review claims for beneficiaries who had stent implantations during multiple surgical procedures to determine if the implantations should have been performed simultaneously.
(OAS; W-00-05-35124; W-00-05-35124; A-00-00-00000; expected issue date: FY 2005; new start)

Outpatient Cardiac Rehabilitation Services

At the request of CMS, we will attempt to determine whether cardiac rehabilitation services provided by hospital outpatient departments met Medicare coverage requirements. Medicare covers such rehabilitation under the "incident-to" a physician's professional services benefit, which requires that the services of nonphysician personnel be furnished under the physician's direct supervision.
(OAS; W-00-04-35059; various reviews; expected issue date: FY 2005; work in progress)

Outpatient Outlier and Other Charge-Related Issues

We will determine whether outlier payments to hospital outpatient departments and community mental health centers were in accordance with Medicare laws and regulations and whether current Medicare reimbursement mechanisms appropriately reimburse providers as intended.
(OAS; W-00-04-35105; various reviews; expected issue date: FY 2004/05; work in progress)

Lifetime Reserve Days

We will determine how hospitals comply with the current requirement to notify Medicare beneficiaries about the use of lifetime reserve days and also assess the appropriateness and feasibility of providing an additional notification prior to a beneficiary's exhaustion of them. Medicare beneficiaries are entitled to an unlimited number of 90-day episodes of hospital care. They may also extend their inpatient benefit by up to a lifetime total of 60 days. These are called lifetime reserve days; they are not renewable. The MMA requires us to examine both current notice requirements and a contemplated additional notice at the end of this benefit.
(OEI; 09-04-00100; expected issue date: FY 2005; work in progress)

Hospital Reporting of Restraint-Related Deaths

We will assess hospital compliance with Medicare conditions of participation issued in July 1999, which require hospitals to report all patient deaths that may have been caused by restraints or seclusion. We will examine CMS's early experiences with hospital reporting and review Medicare claims and enrollment data to determine whether patient deaths have been adequately reported.
(OEI; 09-04-00350; expected issue date: FY 2005; work in progress)

Medicare Home Health

Beneficiary Access to Home Health Agencies

We will assess the effect of the prospective payment system on access to home health services by Medicare beneficiaries who have been discharged from the hospital. Since October 2000, when the home health prospective payment system was implemented, the average number of visits per episode of care has fallen dramatically. Home health agencies may be reluctant to accept beneficiaries who need extensive services. We will update our previous work in this area.
(OEI; 02-04-00260; expected issue date: FY 2005; work in progress)

Effect of Prospective Payment System on Quality of Home Health Care

This study will assess the quality of home health care since the implementation of the home health prospective payment system. In October 2000, reimbursement for home health services changed from a cost-based system to a prospective payment system of fixed, predetermined rates. We will determine whether any changes have occurred in the number of hospital readmissions or emergency room admissions.
(OEI; 01-04-00160; expected issue date: FY 2005; work in progress)

Home Health Outlier Payments

We will determine whether outlier payments to home health agencies were in compliance with Medicare regulations. Intended to be a loss-sharing mechanism for costly cases, an outlier payment is made for an episode whose estimated cost exceeds a threshold amount for each case-mix group. We will evaluate the frequency of outliers and whether they cluster in certain Home Health Resource Groups or geographical areas. We also plan to determine whether the current outlier methodology is equitable to all home health agencies.
(OAS; W-00-04-35107; various reviews; expected issue date: FY 2005; work in progress)

Enhanced Payments for Home Health Therapy

We will determine whether home health agencies' therapy services met the threshold for higher payments in compliance with Medicare regulations. We will analyze the number and the duration of therapy visits provided per episode period.
(OAS; W-00-04-35108; A-01-04-00000; expected issue date: FY 2005; work in progress)

Medicare Nursing Homes

Access to Skilled Nursing Facilities Under the Prospective Payment System

We will determine whether the prospective payment system for skilled nursing facilities has adversely affected Medicare beneficiaries' access to care. Studies in 1999, 2000, and 2001 found that under the system, beneficiaries generally had access to needed skilled nursing facilities. However, some patients with certain medical conditions or service needs experienced delays, and some discharge planners attributed these delays to the prospective payment system. We will update our previous work in this area.
(OEI; 02-04-00270; expected issue date: FY 2005; work in progress)

Use of Additional Funds Provided to Skilled Nursing Facilities

In July 2003, CMS published a skilled nursing facility (SNF) payment rule which incorporated a cumulative market basket forecast error correction of 3.26 percent to adjust for the difference between actual and forecasted data since 1998. The forecast error correction rule added an additional $6.9 billion in SNF Medicare payments over 10 years. The nursing home industry committed to using these funds to improve patient care. We will review how the funds for the forecast error correction have been utilized and determine whether SNFs have used the funds to improve patient care.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Nurse Aide Registries

We will evaluate nursing home and State compliance with Federal nurse aide registry requirements. Federal regulations require that each State establish and maintain a registry of nurse aides and that nursing homes verify the registry status of a nurse aide before employing the individual. This study will evaluate how registries are established and maintained, how consistently nursing homes check registries, and how State nursing home surveyors assess compliance with registry requirements.
(OEI; 07-03-00830; 07-04-00140; expected issue date: FY 2005; work in progress)

Nursing Home Deficiency Trends

We will examine the nature and extent of survey and certification deficiencies in nursing homes. In a 2002 report, we found that the proportion of nursing homes cited for deficiencies, the total number of deficiencies, and the key categories of deficiencies directly related to quality of care had all increased since 1998. We will update our previous work in this area. We will also identify patterns of repeated noncompliance with Federal quality standards.
(OEI; multiple reviews; expected issue date: FY 2005; new start)

Nursing Home Compliance With Minimum Data Set Reporting Requirements

We will examine nursing home compliance with reporting requirements related to the Minimum Data Set. The Minimum Data Set is one of the primary mechanisms for addressing residents' quality of care. This assessment tool partially determines payment for Part A stays and Medicare conditions of participation require that it be reported on all residents for quality oversight purposes as well. We will review data submissions and nursing home records to assess the timeliness of reporting for all nursing home residents and the accuracy of reporting for beneficiaries in Part A covered stays.
(OEI; 02-02-00830; 06-02-00180; expected issue date: FY 2004; work in progress)

Nursing Home Resident Assessment and Care Planning

We will examine the type, frequency, and severity of deficiencies related to assessment and care planning for nursing home residents. In previous studies, we have identified increases in deficiencies related to comprehensive assessments, care planning, and the provision of services in accordance with the care plan. We will update our previous work in this area. We will also examine compliance issues and methods that State survey agencies use to identify and deal with MDS assessments and care plans that do not address all the needs of residents.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Enforcement Actions Against Noncompliant Nursing Homes

We will examine the effectiveness of CMS and State enforcement actions taken against noncompliant nursing homes. Under contracts with CMS, States conduct surveys at least every 15 months to certify that nursing facilities meet the required standards for the Medicare and Medicaid programs. For noncompliant Medicare facilities, CMS is responsible for enforcement actions, including denial of payments, collection of civil monetary penalties, loss of Nurse Aide Training and Competency Evaluation Programs, and other mandatory enforcement actions. We will also assess compliance with and the effectiveness of nursing home plans of correction and determine if States appropriately refer nursing home enforcement cases to CMS.
(OEI; various reviews; expected issue date: FY 2005; work in progress)

Nursing Home Informal Dispute Resolution

This study will review trends and outcomes of the nursing home Informal Dispute Resolution process. By law, CMS is required to provide nursing homes an informal opportunity to dispute cited deficiencies. We will determine whether States are offering and providing informal dispute resolution and whether they are following Federal requirements in the way they do this.
(OEI; 06-02-00750; expected issue date: FY 2005; work in progress)

Nursing Home Residents' Rights

We will assess the extent to which nursing home residents and their families are aware of their rights. Nursing home facilities are required to care for their residents in a manner that promotes

maintenance or enhancement of each resident's quality of life and promotes each resident's dignity and respect. We will also determine how nursing homes ensure the personal rights of residents.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Skilled Nursing Facilities' Involvement in Consecutive Inpatient Stays

This study will determine whether skilled nursing facility care provided to Medicare beneficiaries with consecutive inpatient stays was medically reasonable and necessary. All skilled nursing facility stays must be preceded by an inpatient hospital stay. This study will focus on beneficiaries who experience three or more consecutive stays, including at least one skilled nursing facility stay. We will also examine the extent and nature of consecutive Medicare hospital inpatient stays.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Imaging and Laboratory Services in Nursing Homes

We will determine the extent and nature of any medically unnecessary or excessive billing for imaging and laboratory services provided to nursing home residents. Medicare pays more than $200 million a year for such imaging and laboratory services. We will review a sample of services and examine utilization patterns in nursing facilities.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Skilled Nursing Facility Rehabilitation and Infusion Therapy Services

Through medical review, we will analyze whether rehabilitation and infusion therapy services provided to Medicare beneficiaries in skilled nursing facilities were medically necessary, adequately supported, and actually provided as ordered. The skilled nursing facilities provide infusion and rehabilitation therapy services to Medicare beneficiaries for a variety of medical and postsurgical conditions. These services are provided as ordered by a physician and are administered on-site by the skilled nursing facilities' nursing staff.
(OAS; W-00-04-35110; various reviews; expected issue date: FY 2005; work in progress)

State Compliance With Complaint Investigation Guidelines

We will determine the extent to which States follow CMS guidelines, as well as their own procedures, in investigating abuse complaints. States must investigate all allegations of immediate jeopardy within 2 days and all allegations of actual harm within 10 days. We will examine the procedures that States use to receive, investigate, and resolve complaints.
(OEI; 01-04-00340; expected issue date: FY 2005; work in progress)

Medicare Physicians and Other Health Professionals

Billing Service Companies

We will identify and review the relationships among billing companies and the physicians and other Medicare providers who use their services. We will also identify the various types of arrangements physicians and other Medicare providers have with billing services and determine the impact of these arrangements on the physicians' billings.
(OAS; W-00-05-35162; various reviews; expected issue date: FY 2005; new start)

Medicare Payments to VA Physicians

We will assess the validity of Medicare reimbursement for services billed by physicians who receive remuneration from the Department of Veterans Affairs (VA) for the time the physicians reported as being on duty at a VA hospital. Physicians employed by VA may not bill Medicare for services rendered at other hospitals during the times they were on duty at a VA hospital. Our preliminary work has identified a number of VA physicians who received Medicare reimbursements totaling approximately $105 million for services rendered between January 1, 2001 and June 30, 2003. Using time reporting and payroll documentation from the VA, we will identify the services rendered while the physicians were reported as on duty at the VA hospitals and remunerated for such duty.
(OAS; W-00-04-35155; A-00-00-0000; expected issue date: FY 2005; work in progress)

Care Plan Oversight

We will evaluate the efficacy of controls over Medicare payments for care plan oversight claims submitted by physicians. Under the Medicare home health and hospice benefits, care plan oversight is physician supervision of beneficiaries who need complex or multidisciplinary care requiring ongoing physician involvement. Reimbursement for care plan oversight increased from $15 million in 2000 to $41 million in 2001. We will assess whether these services were provided in accordance with Medicare regulations.
(OAS; W-00-04-35114; A-02-00-00000; expected issue date: FY 2005; work in progress)

Ordering Physicians Excluded From Medicare

This review will quantify the extent of services, if any, ordered by physicians excluded from Federal health care programs and the amount paid by Medicare Part B. Under Federal regulation, physicians who are excluded from Federal health care programs generally are precluded from ordering or performing services for Medicare beneficiaries. During a current review, we identified a significant number of services that had been ordered by excluded physicians.
(OAS; W-00-04-35116; various reviews; expected issue date: FY 2005; work in progress)

Physician Services at Skilled Nursing Facilities

We will examine Medicare Part A and Part B claims with overlapping services for skilled nursing facility patients and determine whether duplicate payments were made to either the physicians or the nursing homes for the same patient services. Physicians may bill Medicare only for the professional component of a service on behalf of skilled nursing facility patients. The technical component of physicians' services is covered under the patient's Medicare Part B stay in the skilled nursing facilities and should not be billed separately by the nursing home. Under an exception to this rule, nursing homes may receive Part B payments for both the professional and technical components of physicians' services if both parties have an agreement under which only the nursing home may bill and receive these Part B payments.
(OAS; W-00-05-35163; various reviews; expected issue date: FY 2005; new start)

Physician Pathology Services

Our review will focus on pathology services performed in physicians' offices. Pathology services include the examination of cells or tissue samples by a physician who prepares a report of his findings. Medicare pays over $1 billion annually to physicians for pathology services. We will identify and review the relationships between physicians who furnish pathology services in their offices and outside pathology companies.
(OAS; W-00-05-35164; various reviews; expected issue date: FY 2005; new start)

Cardiography and Echocardiography Services

We will review Medicare payments for cardiography and echocardiography services to determine whether physicians billed appropriately for the professional and the technical components of the services. Like many physician services, cardiography and echocardiography include both technical and professional components. When a physician performs the interpretation separately, the modifier 26 should be used to bill Medicare for professional services.
(OAS; W-00-05-35165; various reviews; expected issue date: FY 2005; new start)

Physical and Occupational Therapy Services

We will review Medicare claims for therapy services provided by physical and occupational therapists to determine whether the services were reasonable and medically necessary, adequately documented, and certified by physician certification statements. Physical and occupational therapies are medically prescribed treatments concerned with improving or restoring functions, preventing further disability, and relieving symptoms.
(OAS; W-00-04-35141; various reviews; expected issue date: FY 2005; work in progress)

Part B Mental Health Services

We will determine whether Medicare Part B mental health services provided in physicians' offices were medically necessary and billed in accordance with Medicare requirements.

Payments for mental health services provided in the physician's office setting accounted for approximately 55 percent of the $1.3 billion in Medicare payments for Part B mental health services in 2002. In a prior report, we found that Medicare allowed $185 million for inappropriate mental health services in the outpatient setting. We will also determine the financial impact of claims that do not meet Medicare requirements.
(OEI; 09-04-00220; expected issue date: FY 2005; work in progress)

Wound Care Services

We will determine whether claims for wound care services were medically necessary and billed in accordance with Medicare requirements. Medicare-allowed amounts for certain wound care services billed by physicians increased from approximately $98 million in 1998 to $147 million in 2002. We will also examine the adequacy of controls to prevent inappropriate payments for wound care services.
(OEI; 02-04-00410; expected issue date: FY 2006; work in progress)

Coding of Evaluation and Management Services

We will examine patterns of physician coding of evaluation and management services and determine whether these services were coded accurately. In 2003, Medicare allowed over $29 billion for evaluation and management services. In prior work, we found that a significant portion of certain categories of these services is billed with incorrect codes resulting in large overpayments. We will also assess the adequacy of controls to identify physicians with aberrant coding patterns.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Use of Modifier –25

We will determine whether providers used modifier –25 appropriately. In general, a provider should not bill evaluation and management codes on the same day as a procedure or other service unless the evaluation and management service is a significant, separately identifiable service from such procedure or service. A provider reports such a circumstance by using modifier –25. In 2001, Medicare allowed over $23 billion for evaluation and management services. Of that amount, approximately $1.7 billion was for evaluation and management services billed with modifier –25. We will determine whether these claims were billed and reimbursed appropriately.
(OEI; 07-03-00470; expected issue date: FY 2005; work in progress)

Use of Modifiers With National Correct Coding Initiative Edits

We will determine whether claims were paid appropriately when modifiers were used to bypass National Correct Coding Initiative edits. The initiative, one of CMS's tools for detecting and correcting improper billing, is designed to provide Medicare Part B carriers with code pair edits for use in reviewing claims. A provider may include a modifier to allow payment for both services within the code pair under certain circumstances. In 2001, Medicare paid $565 million to providers who included the modifier with code pairs within the National Correct Coding

Initiative. We will determine whether modifiers were used appropriately.
(OEI; 03-02-00771; expected issue date: FY 2005; work in progress)

"Long Distance" Physician Claims

We will review Medicare claims for face-to-face physician encounters where the practice setting and the beneficiary's location were separated by a significant distance. While all beneficiaries may seek professional services for specialized consultation during leisure travel, those with ongoing illnesses requiring skilled care would be unlikely to travel long distances from home. We will examine these claims to confirm that services were provided and accurately reported. If warranted, we will recommend enhancements to existing program integrity controls.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Provider-Based Entities

We will determine the extent to which health care entities that have been designated as "provider based" are in compliance with requirements for receiving this designation. In prior work, we found that hospital ownership of physician practices is widespread and that fiscal intermediaries are frequently unaware whether these hospitals are being treated as provider based or freestanding. Medicare and its beneficiaries may be paying excessive amounts for services inappropriately billed as provider based. We will also determine the impact on Medicare reimbursements of entities billing as provider based instead of freestanding.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medicare Medical Equipment and Supplies

Medical Necessity of Durable Medical Equipment

This review will determine the appropriateness of Medicare payments for certain items of durable medical equipment, such as power wheelchairs and therapeutic footwear. We will assess whether the suppliers' documentation supports the claim, whether the item was medically necessary, and whether the beneficiary actually received the item.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicare Pricing of Equipment and Supplies

We will compare Medicare payment rates for certain medical equipment and supplies with the rates of other Federal and State health programs, as well as with wholesale and retail prices. Our review will cover such items as wheelchairs, enteral nutrition, and oxygen equipment and supplies.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicare Drug Reimbursement

Prescription Drug Cards

We will review the processes and controls for the prescription drug discount card program. Effective June 2004, beneficiaries entitled or enrolled under Part A or Part B of the Medicare program are eligible to participate in the prescription drug discount card program. The program will allow them to enroll with Medicare-endorsed sponsors who will negotiate prices on prescription drugs, effectively allowing the beneficiaries to pay lower amounts. Specifically, we will address general and application system controls at CMS and for selected sponsors participating in the program. As part of the program, beneficiaries whose incomes fall within certain ranges of the poverty level qualify for Federal assistance (transitional assistance). Our review will ascertain whether controls are in place to minimize or eliminate fraud, waste, and abuse in transitional assistance payments.
(OAS; W-00-05-35166; various reviews; expected issue date: FY 2005/2006; new start)

Employer Subsidies for Drug Coverage

The MMA includes a provision that provides for making subsidy payments to sponsors of qualified retiree prescription drug plans. The subsidy payments will start in calendar year 2006. To qualify for these subsidies, sponsors must certify to CMS that a qualified retiree's health coverage was at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D (MMA drug benefit). We will ascertain the strength of the controls that CMS will implement to administer this aspect of MMA. This may include verifying some of the sponsors' data, both the actuarial equivalency and qualified retiree information. The sponsors will most likely be submitting these data to CMS prior to 2006.
(OAS; W-00-05-35175; various reviews; expected issue date: FY 2006; new start)

Beneficiary Understanding of Drug Discount Card Program

We will assess beneficiary understanding of the Medicare Prescription Drug Discount Card program and materials CMS provides to beneficiaries. The Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 broadened prescription drug benefits to Medicare beneficiaries beginning in 2006, while creating an interim discount card program. The interim program is available to Medicare beneficiaries without Medicaid prescription drug coverage or other outpatient drug insurance. We will also determine if beneficiary materials comply with MMA requirements and if beneficiaries understand the program.
(OEI; 05-04-00190; 05-04-00200; expected issue date: FY 2005; new start)

Computation of Average Sales Price

We will evaluate drug manufacturers' methodologies for computing the average sales price (ASP). This calculation will be used for determining the Medicare reimbursement of certain

classes of drugs. It is a new requirement enacted as part of MMA.
(OAS; W-00-05-35174; various reviews; expected issue date: FY 2005; new start)

Collecting and Maintaining Average Sales Price Data

This study will evaluate CMS's system for collecting and maintaining ASP data. Medicare Part B currently covers prescription drugs furnished incident to physician services, prescription drugs used with durable medical equipment, and other statutorily covered drugs. Under MMA, Medicare will base payments for most of these drugs on ASP. The Act requires manufacturers to report accurate ASP information to CMS. We will also assess CMS's oversight of ASP reporting.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Adequacy of Reimbursement Rate for Drugs Under ASP

According to the MMA, the Inspector General will conduct a study that determines whether physicians' practices in the specialties of hematology, hematology/oncology, and medical oncology are able to purchase drugs at the new reimbursement amounts, which are to be based on ASP. The MMA specifies that the study must take into account practices of different sizes, especially particularly large practices, in determining the adequacy of Medicare reimbursement.
(OEI; 00-00-00000; OAS; W-00-05-35167; various reviews; expected issue date: FY 2005; new start)

Payments for Non-End-Stage Renal Disease Epoetin Alfa

We will determine the appropriateness of Medicare payments for epoetin alfa used by beneficiaries who have not been diagnosed with end-stage renal disease (ESRD). In 2001, Medicare paid over $800 million for epoetin alfa, nearly four times more than the $212 million paid in 1998. We will conduct a medical review based on supporting documentation to determine whether the drug was medically necessary, administered in the proper manner, and provided for an indicated usage.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Other Medicare Services

Laboratory Services Rendered During an Inpatient Stay

We will determine the extent to which laboratory services rendered during an inpatient stay are unallowable. The CMS reimbursement for laboratory services is based on two components—physician and technical. The technical component is unallowable under Medicare. Preliminary work indicated that $73 million of laboratory services were rendered in a hospital setting during inpatient stays nationwide in calendar year 2001. This was a considerable increase in cost over

similar services provided in prior periods. Our review will determine what percentage of these costs are unallowable.
(OAS; W-00-05-35168; various reviews; expected issue date: FY 2005; new start)

Laboratory Proficiency Testing

We will assess laboratory compliance with Clinical Laboratory Improvement Amendments (CLIA) of 1988 requirements to participate in proficiency testing. Proficiency testing is a statutorily mandated condition of participation in which laboratories are graded for their accuracy in analyzing clinical specimens. It is one of the primary mechanisms for ensuring quality testing. Medicare pays over $4 billion annually for clinical laboratory services, all of which must meet CLIA requirements.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Independent Diagnostic Testing Facilities

We will review the medical necessity of Medicare services provided to beneficiaries by independent diagnostic testing facilities. These facilities (formerly known as independent physiological laboratories) may be fixed-location or mobile entities that are independent of a hospital or a physician's office. Medicare covers diagnostic tests performed by such facilities when the services are medically necessary and satisfy certain criteria regarding, among other things, physician supervision and the qualifications of nonphysician personnel. We will determine whether (1) individual facilities provided services for which they had prior approval, (2) the designated level of physician supervision was provided, and (3) the nonphysician personnel who performed the diagnostic tests were properly licensed.
(OAS; W-00-04-35066; various reviews; expected issue date: FY 2005; work in progress)

Therapy Services Provided by Comprehensive Outpatient Rehabilitation Facilities

We will determine whether comprehensive outpatient rehabilitation facilities (CORF) provided and billed physical therapy, speech language pathology, and occupational therapy services in accordance with Medicare eligibility and reimbursement requirements. The Balanced Budget Act of 1997 required a prospective payment system for all CORF services. The Medicare physician fee schedule is used as the prospective payment system for CORF services dated on or after July 1, 2000. Prior OIG reviews found that Medicare paid significant amounts for unallowable or highly questionable therapy services in outpatient rehabilitation facilities and nursing homes. The majority of these services were not reasonable and necessary for the beneficiary's health condition or lacked sufficient documentation.
(OAS; W-00-04-35119; various reviews; expected issue date: FY 2005; work in progress)

New Payment Provisions for Ambulance Services

This review will determine whether payments for ambulance services complied with new Medicare reimbursement regulations. In accordance with the BBA, CMS implemented a national fee schedule covering five levels of service intensity for ground transport and two levels

for air transport. The fee schedule is being phased in over the 5 years that began April 1, 2002. We will determine whether the payments to suppliers during the first year of the ambulance fee schedule exceeded levels that would have been paid if the ambulance fee schedule was not in effect.
(OAS; W-00-04-35076; A-01-04-00000; expected issue date: FY 2005; work in progress)

Air Ambulance Services

Our review will determine whether air ambulance services were provided in accordance with Medicare guidelines. Medicare pays for ambulance transportation services (ground and air) when other means of transportation are contraindicated. It covers air ambulance services when the beneficiary requires immediate and rapid transportation that could not have been provided by land ambulance, when the pickup point is inaccessible by land vehicle, or when great distances or other obstacles (for example, heavy traffic) hinder getting the patient to the nearest hospital with appropriate facilities.
(OAS; W-00-04-35158; various reviews; expected issue date: FY 2005; work in progress)

Quality of Care in Dialysis Facilities

We will examine the level of CMS oversight of ESRD facilities. Previous reports showed that the length of time between ESRD facility surveys is increasing and that State agencies conduct few complaint investigations due to a lack of resources. We will assess the current level of oversight, especially for facilities showing indications of possible poor quality of care.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Monitoring of Market Prices for Part B Drugs

The MMA made significant changes to the way Medicare reimburses for Part B drugs. Beginning in 2005, Medicare will generally pay for drugs based on the average sale price methodology. The MMA mandates that OIG conduct studies, which may include market surveys, to determine market prices for Part B drugs. The market prices will then be compared to average sales prices.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Followup on Medicare Part B Payments for Ambulance Services

We will determine whether ambulance companies were paid for services provided to beneficiaries who were in an inpatient status. A recent survey indicated that a significant amount of calendar year 2001 ambulance services were improperly paid by Medicare Part B for periods when the beneficiary was an inpatient. This followup review will cover calendar years 2001 and 2002.
(OAS; W-00-05-35085; A-01-05-00000; expected issue date: FY 2005; new start)

Followup on Medicare Part B Payments for Radiology Services

We will determine whether Medicare Part B paid for services provided to beneficiaries who were in an inpatient status. A recent survey indicated that a significant amount of calendar year 2001 radiology services were improperly paid by Medicare Part B for periods when the beneficiary was an inpatient. This followup review will cover calendar years 2001 and 2002.
(OAS; W-00-05-35169; A-01-05-00000; expected issue date: FY 2005; new start)

Emergency Health Services for Undocumented Aliens

We will determine whether the $250 million appropriation enacted by the MMA for emergency health services furnished to undocumented aliens is appropriately distributed to each State and provider and is used for its intended purpose. The MMA has appropriated $250 million for each of fiscal years 2005 through 2008 for eligible States and providers. Two-thirds of the funds are to be distributed according to the estimated proportion of undocumented aliens residing in each State; the remaining third is designated for the six States with the highest number of apprehensions of undocumented aliens as reported by the Department of Homeland Security. The new funds are to be paid directly to eligible providers, such as hospitals, physicians and ambulance services, for emergency medical services furnished to undocumented aliens. We will coordinate with departmental components which are also evaluating these distributions.
(OAS; W-00-05-35170; various reviews; expected issue date: FY 2005; new start)

Medicare Managed Care

Benefit Stabilization Fund

This review will examine CMS's controls over payments into and withdrawals from the adjusted community rate proposal benefit stabilization fund. If the estimated capitation paid to the managed care organization (MCO) exceeds the estimated amount for Medicare-covered services, MCOs must use any excess as prescribed by law, including offering additional benefits, reducing members' premiums, accepting a capitation payment reduction for the excess amount, or depositing funds into a stabilization fund administered by CMS. The stabilization fund acts like a savings account in that the MCO can withdraw monies from the fund in future years when capitation payments from Medicare fall short of the MCO's estimated costs of serving Medicare enrollees. In 2001, there was $100 million in the benefit stabilization fund. All monies in the stabilization fund on January 1, 2006 will be forfeited to the Medicare Trust Funds. The MMA established a new $10 billion "regional plan stabilization fund" to be used for either 1-year national bonus payments or multiyear adjustments.
(OAS; W-00-05-35171; various reviews; expected issue date: FY 2005; new start)

Adjusted Community Rate Proposals

This review will determine whether modifications to the 2001 and 2004 adjusted community rate proposals were properly supported. Based on payment increases resulting from the Benefits Improvement and Protection Act of 2000 and the MMA, MCOs may make one or more of the following changes to the proposals: reduce beneficiary premiums; reduce beneficiary cost sharing; enhance benefits; put additional payment amounts received after March 1, 2001 in a benefit stabilization fund; or use additional payment amounts to retain providers (stabilize access) or expand the provider network (enhance access), as long as this stabilization or enhancement does not result in increased premiums, increased cost sharing, or reduced benefits. We will verify documentation that MCOs used the additional payments in accordance with the Acts. We will also determine whether changes in adjusted community rate values to reflect updated per-member-per-month cost, utilization, and membership assumptions were appropriately documented by MCOs.
(OAS; W-00-04-35041; various reviews; expected issue date: FY 2005; work in progress)

Followup on Adjusted Community Rate Proposals

This review will examine CMS's actions to resolve the problems identified in prior audits of adjusted community rate proposals and remedies to ensure that future proposals are accurate and that repayments or enhanced benefits are provided to account for audit findings. Under the BBA of 1997, CMS is required to audit at least one-third of the adjusted community rate proposals of the MCOs participating in the Medicare+Choice program each year. With the start of FY 2003, audits covering 3 years should have been completed. Errors in the proposals identified during the audits may affect Medicare beneficiaries' additional benefits or reduced cost-sharing amounts.
(OAS; W-00-04-35077; various reviews; expected issue date: FY 2005; work in progress)

Administrative Costs

Using the Federal Employees Health Benefit guidelines, we will examine the administrative amounts currently claimed by MCOs. Under the MMA legislation, beginning in 2006, MCOs will negotiate monthly bid amounts to cover administrative costs such as marketing, taxes, depreciation, reinsurance, interest, and other nonmedical costs. In this new arrangement, the Secretary's negotiating authority will be similar to that exercised by the Office of Personal Management under the benefit program. The Congress has expressed interest in how MCOs determine funding amounts to meet administrative costs, which must be allocable, allowable, reasonable, and limited under the program.
(OAS; W-00-05-35173; various reviews; expected issue date: FY 2005; new start)

Managed Care Encounter Data

This review will determine the accuracy of Part A encounter data on Medicare beneficiaries. All MCOs are required to submit these data for CMS's use in developing a portion of each organization's monthly capitation rate. The portion of the monthly rate that relates to the encounter data is the risk-adjusted portion, which comprises 10 percent of the rate. The risk-

adjusted portion will eventually comprise 100 percent of the monthly rate. Thus, incorrect or incomplete encounter data could have a significant impact on future Medicare reimbursement. *(OAS; W-00-03-35078; various reviews; expected issue date: FY 2005; work in progress)*

Enhanced Managed Care Payments

We will complete several reviews to determine whether CMS made proper enhanced capitation payments to MCOs. Medicare provides enhanced capitation payments for beneficiaries who are institutionalized, in ESRD status, or dually eligible for Medicare and Medicaid. Our reviews are focused on the accuracy of controls at both CMS and the MCOs regarding special status categories warranting these enhanced payments.
(OAS; W-00-03-35054; various reviews; expected issue date: FY 2005; work in progress)

Enhanced Payments Under the Risk Adjustment Model

We will review CMS's actuarial assumptions and calculations applicable to current payment rates for special status beneficiaries, as well as any projection of future rates. Medicare has traditionally paid an enhanced monthly rate for beneficiaries who are institutionalized or dually eligible for Medicaid. To help ensure that payments more closely reflect the costs of providing care, CMS is currently phasing risk adjustment factors into the payment system; some portion of the current payment enhancement may be left in place. Prior OIG work has shown significant overpayments and underpayments attributable to the enhanced rate system. Given the phase-in of risk adjustment, we will examine the need for continuing enhanced payments.
(OAS; W-00-04-35120; various reviews; expected issue date: FY 2005; work in progress)

Managed Care Excessive Medical Costs

This review will analyze the cost of health care services furnished to beneficiaries enrolled in Medicare+Choice MCOs. Federal rules do not limit the amount that MCOs pay for health care services. They only require the organizations to report actual expenses derived from an accrual accounting system that uses generally accepted accounting principles. Also, Medicare regulations require that MCOs have effective procedures to monitor utilization and control the costs of basic and supplemental health services. We noted that some MCOs reported certain medical costs that were two to three times higher than the national average of all MCOs or significantly higher than similar costs at other plans in the same geographic area or under Medicare fee-for-service. Although CMS has no control over the costs paid by MCOs for services, we believe that understanding the reasons for wide cost variations could help in evaluating the adequacy of Medicare payments.
(OAS; W-00-04-35121; various reviews; expected issue date: FY 2005; work in progress)

Duplicate Medicare Payments to Cost-Based Plans

This review will quantify the extent, if any, of duplicate Medicare capitation and fee-for-service payments to selected cost-based MCOs. Generally, under capitation agreements, health care providers are paid for services furnished to an MCO's Medicare enrollees through monthly per

capita payments from the MCO. The MCO receives Medicare reimbursement for these payments by claiming them on Medicare cost reports. Accordingly, any Medicare fee-for-service billings that the capitated providers submit for services provided to the MCO's Medicare enrollees will result in duplicate payments. Under CMS regulations, the MCO is responsible for establishing internal controls to detect and prevent such duplicate reimbursement.
(OAS; W-00-04-35122; various reviews; expected issue date: FY 2005; work in progress)

Prompt Payment

We will determine whether MCOs have adhered to Medicare+Choice prompt payment requirements for noncontracting providers. Regulations require that written agreements between MCOs and providers contain a prompt payment provision, the terms of which are developed and agreed to by both the MCO and the relevant provider. Claims must be approved or denied within 30 calendar days from the date of the request. We will examine CMS's oversight of MCOs' compliance with the regulation.
(OAS; W-00-03-35072; various reviews; expected issue date: FY 2005; work in progress)

Marketing Practices of MCOs

We will determine whether Medicare MCOs market their plans to beneficiaries according to CMS guidelines and assess how CMS monitors compliance with Federal marketing requirements. CMS prohibits discriminatory marketing activities, such as selectively enrolling beneficiaries, soliciting enrollment door-to-door, and using providers to distribute or accept plan materials. In a 1998 study, we found that 43 percent of beneficiaries were asked about health problems when applying with an MCO.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Managed Care "Deeming" Organizations

This study will determine whether CMS effectively oversees the Medicare+Choice "deeming" organizations. The BBA and the Balanced Budget Refinement Act of 1999 authorized CMS to establish and oversee a program that allows private, national accreditation organizations to deem compliance with certain Medicare+Choice requirements.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medicare Contractor Operations

Preaward Reviews of Contract Proposals

At the request of the CMS contracting officer, we will review the cost proposals of various bidders for Medicare contracts. The reports produced by these reviews should assist CMS in negotiating favorable and cost-beneficial contract awards.
(OAS; W-00-04-35002; various reviews; expected issue date: FY 2005; work in progress)

CMS Oversight of Contractor Performance

This study will evaluate CMS oversight of contractor performance. In prior work, OIG has found problems with CMS oversight of contractors and identified serious breaches of integrity among individual contractors. We will review performance evaluation findings and recommendations, corrective action plans, and CMS actions taken as a result of evaluation findings. We will also determine whether the evaluation process is an effective mechanism for monitoring contractor performance.
(OEI-00-00-00000; expected issue date: FY 2006; new start)

Program Safeguard Contractor Performance

We will examine the effectiveness of CMS program safeguard contractors in identifying fraud and abuse. In 2000, CMS began transferring benefit integrity functions from carriers and fiscal intermediaries to specialized entities called program safeguard contractors. We will also evaluate whether program safeguard contractors effectively coordinate information with CMS and its other contractors, determine whether inefficiencies result from any duplication of effort, and determine the adequacy of CMS oversight of these entities.
(OEI; 03-04-00050; 00-00-00000; expected issue date: FY 2005; new start)

Accuracy of the Provider Enrollment, Chain, and Ownership System

We will assess the accuracy of the provider enrollment information in the Provider Enrollment, Chain, and Ownership System and determine whether it contains providers that should have been deactivated in the system. The purpose of the system is to enable Medicare contractors to ensure that only qualified providers and suppliers are enrolled and eligible for Medicare payments; it includes information on Social Security numbers, owners with 5 percent or more investment, exclusions and other sanctions, business history, and other affiliations. In prior reports, both the U.S. Government Accountability Office and OIG have found problems with contractors not verifying enrollment information and not removing unused provider numbers. We will also determine whether the new system has simplified the enrollment process.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Handling of Beneficiary Inquiries

We will assess Medicare carriers' handling of beneficiary inquiries and complaints. Carriers receive nearly 15 million calls from beneficiaries annually. Our previous work identified some beneficiary problems with access to and accuracy of information. We will evaluate the accuracy of information provided by carriers and assess beneficiary satisfaction with carrier services.
(OEI; 07-04-00030; expected issue date: FY 2005; work in progress)

Carrier Medical Review: Progressive Corrective Action

We will determine whether Medicare Part B carriers have implemented medical review progressive corrective action strategies in line with CMS guidelines. In FY 2000, CMS revised

its program integrity policy to include a new plan for conducting medical review. Under this revised policy, carriers are required to apply progressive corrective action strategies when conducting any focused medical reviews of Medicare participating provider claims. We will also determine the extent to which the progressive corrective action is achieving desired results. *(OEI; 02-03-00300; expected issue date: FY 2005; work in progress)*

Duplicate Medicare Part B Payments

We will determine if carriers made duplicate payments for the same Medicare Part B services. In prior inspections, we found that Medicare carriers made potential duplicate payments within the same carrier and among multiple carriers. Both reports illustrated a significant vulnerability in Medicare's claims processing systems that could lead to substantial losses for the program. We will identify whether CMS or its carriers have taken sufficient corrective actions to prevent such duplicate payments from occurring.
(OEI; 03-04-00090; expected issue date: FY 2005; work in progress)

Contractors' Administrative Costs

As requested by CMS, we will review administrative costs claimed by various contractors for their Medicare activities, with special attention to costs claimed by terminated contractors. We will determine whether the costs claimed were reasonable, allocable, and allowable under the terms of the contract with CMS as well as applicable Federal Acquisition Regulations. We will coordinate the selection of contractors with CMS staff.
(OAS; W-00-04-35005; various reviews; expected issue date: FY 2005/06; work in progress)

Pension Segmentation

At CMS's request, we will determine whether Medicare contractors have fully implemented contract clauses requiring them to determine and separately account for the assets and liabilities of the Medicare segments of their pension plans. We will also assess Medicare's share of future pension costs on a segmented basis.
(OAS; W-00-04-35094; various reviews; expected issue date: FY 2005/06; work in progress)

Pension Costs Claimed

At CMS's request, we will determine whether Medicare contractors have calculated pension costs claimed for reimbursement in accordance with their Medicare contracts and Cost Accounting Standards. We will also determine whether the costs claimed were allocable and allowable under the Medicare contracts.
(OAS; W-00-04-35067; various reviews; expected issue date: FY 2005/06; work in progress)

Unfunded Pension Costs

This review, which was requested by CMS, will determine whether Medicare contractors identified and eliminated unallowable costs when computing pension costs charged to the

Medicare program. Additionally, we will determine whether pension costs that would have been tax deductible had they been funded were reassigned to future periods.
(OAS; W-00-04-35148; various reviews; expected issue date: FY 2005/06; work in progress)

Pension Segment Closing

As requested by CMS, we will review Medicare carriers and fiscal intermediaries whose Medicare contracts have been terminated, resulting in the closing of their Medicare segments. We will determine the amount of any excess pension assets related to each Medicare segment as of the segment closing date. Regulations and Medicare contracts provide that pension gains that occur when a Medicare segment closes should be credited to the Medicare program.
(OAS; W-00-04-35067; various reviews; expected issue date: FY 2005/06; work in progress)

Postretirement Benefits and Supplemental Employee Retirement Plan Costs

At CMS's request, we will review the postretirement health benefit costs and the supplemental employee retirement plans of fiscal intermediaries and carriers. Our reviews will determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts.
(OAS; W-00-04-35095; various reviews; expected issue date: FY 2005/06; work in progress)

Medicaid Hospitals

Medicaid Graduate Medical Education Payments

This review will examine Medicaid Graduate Medical Education (GME) payment programs and the coordination of these payments with Medicare GME payments. Although GME is generally considered a part of the Medicare program, States may elect to provide funds under Medicaid through CMS-approved waivers or State plan amendments.
(OAS; W-00-03-31018; various reviews; expected issue date: FY 2005; work in progress)

Hospital Outlier Payments

We will determine whether Medicaid State agencies ensured that day and cost outliers paid under State Medicaid programs were limited to extraordinarily long lengths of stay or high costs. Prior OIG work involving Medicare claims for hospital outliers identified vulnerabilities in the Medicare payment methodology. We will expand our efforts to several States.
(OAS; W-00-04-31069; various reviews; expected issue date: FY 2005; work in progress)

Medicaid Diagnosis-Related Group Payment Window

This review will determine whether prospective payment system hospitals submitted Medicaid claims for inpatient-stay-related laboratory and other services within 3 days of hospital

admission and the potential cost savings that would result from State prohibition of this practice. Several previous reviews found that hospitals had improperly submitted separate Medicare billings for inpatient-stay-related laboratory and other services performed within 3 days of admission. Such billings are prohibited by Medicare regulations because the costs of these services are already included in each hospital's diagnosis-related group (DRG) discharge rate.

As a result of our prior reviews in the Medicare program, fiscal intermediaries recovered over $100 million in overpayments for the period 1983 to 1991, and as a result of an OIG-Department of Justice project, over $100 million was collected for the period 1992 to 1996. We will determine if these types of overpayments exist in State Medicaid programs that have regulations similar to those of the Medicare program.
(OAS; W-00-03-31029; various reviews; expected issue date: FY 2005; work in progress)

Disproportionate Share Hospital Payments

At CMS's request, we are reviewing several States' disproportionate share hospital (DSH) payments to selected hospitals to verify that the States calculated the payments according to their approved State plans and that the payments to individual hospitals did not exceed the limits imposed by the Omnibus Budget Reconciliation Act of 1993. Under section 1923(g) of the Social Security Act, DSH payments to an individual hospital may not exceed that hospital's uncompensated care costs.
(OAS; W-00-04-31001; various reviews; expected issue date: FY 2005; work in progress)

Hospital Eligibility for Disproportionate Share Hospital Payments

This review will determine whether States are appropriately determining hospitals' eligibility for Medicaid DSH payments. Section 1923 of the Social Security Act requires hospitals to meet certain criteria before being deemed eligible to receive DSH payments. During several prior reviews, we found that States were making DSH payments to hospitals that did not meet the eligibility standards in section 1923 of the Social Security Act.
(OAS; W-00-05-31084; various reviews; expected issue date: FY 2006; new start)

Medicaid Long-Term and Community Care

Payments to Public Nursing Facilities

We will determine the adequacy of Medicaid payments to public nursing facilities in States that have enhanced payment programs for such facilities. Focusing on those facilities that have been identified as providing low quality of care, we will determine if such care resulted from inappropriately spent Medicaid payments or from Medicaid payment rates that were not adequate to support higher quality of care. If we find that the rates were inadequate, we will determine whether enhanced Medicaid payments remained at the nursing facilities or were returned to the States through intergovernmental transfers. During prior reviews of upper

payment limits, we identified millions of dollars in Medicaid payments that public nursing facilities had returned to State governments through intergovernmental transfers.
(OAS; W-00-03-31030; various reviews; expected issue date: FY 2005; work in progress)

Community Residence Claims

This review will determine if States have improperly claimed Federal financial participation under the Medicaid program for beneficiaries who reside in community residences for the mentally ill or mentally disabled. OIG work in one State indicated that some providers were improperly claiming Medicaid reimbursement for beneficiaries who had changed living arrangements and were no longer living at the community residences.
(OAS; W-00-05-31087; various reviews; expected issue date: FY 2005; new start)

Assisted Living Facilities

In several States, we will determine whether providers were improperly reimbursed for services provided to residents of assisted living facilities and the financial impact on the Medicaid program. In some States, assisted living facilities receive a daily Medicaid rate for their residents' home care services. Outside providers should not submit separate claims for home care services because these services are included in the Medicaid rates paid to the assisted living facilities.
(OAS; W-00-04-31076; various reviews; expected issue date: FY 2005; work in progress)

Medicaid Home Health Care Services

This review will examine Medicaid home health services in one State. As part of these services, the State administers the elderly home care waiver program that provides for reimbursement of traditional home health care services as well as nonmedical home care services. The purpose of this program is to avoid or postpone long-term institutionalization of elderly homebound Medicaid beneficiaries. Services covered under this waiver program include case management, home-delivered meals, homemaker services, companion services, and adult day care. Our review will determine if the services paid under this waiver program were in accordance with the State plan waiver. We will also review the traditional home care services provided to dually eligible beneficiaries to ensure that Medicaid payments did not duplicate any Medicare coverage.
(OAS; W-00-04-39008; A-01-04-00007; expected issue date: FY 2005; work in progress)

Targeted Case Management

We will determine whether Medicaid payments claimed by States for targeted case management services were in accordance with Federal requirements. The Social Security Act defines case management as services that assist individuals eligible under the State plan in gaining access to needed medical, social, educational, and other services. However, payments for such services cannot duplicate payments made to public agencies under other program authorities for the same service.
(OAS; W-00-04-39010; various reviews; expected issue date: FY 2005; work in progress)

Personal Care Services

At CMS's request, this review will determine if States have improperly claimed Federal financial participation for personal care services provided under the Medicaid program. Personal care services relate to assistance in activities of daily living such as eating, bathing, and dressing. Prior reviews in one State noted problems in this area. For the 6-month period from April 1 through September 30, 2002, that State claimed over $489 million of Federal financial participation for personal care services.
(OAS; W-00-05-31035; various reviews; expected issue date: FY 2005; new start)

Home- and Community-Based Services Administrative Costs

At the request of CMS, we will determine whether selected States claimed costs for home- and community-based services in accordance with Federal and State regulations and whether the States are properly monitoring compliance with the requirements of the program. These waivers allow States to provide health care services and personal care in the home and community to help individuals avoid or delay the need to enter an institution. In one State, we will review how a mental retardation agency administers services under a waiver. The agency retains a portion of the amounts due to service providers to cover administrative costs. Our review will determine whether this State has properly followed Federal antifactoring and other rules governing provider rate setting and payment.
(OAS; W-00-03-39003; various reviews; expected issue date: FY 2005; work in progress)

Medicaid Eligibility and the Working Disabled

We will evaluate how Federal and State agencies determine Medicaid eligibility for working disabled individuals. The Congress created a variety of programs, frequently called Medicaid pathways, which allow low-income disabled individuals to keep or obtain Medicaid coverage as earnings increase. Medicaid eligibility is determined by Medicaid and Social Security Administration offices. CMS has requested OIG to ascertain how effectively the State and local offices are assuring eligibility for working disabled individuals.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicaid Mental Health Services

Nursing Home Residents With Mental Illness and Mental Retardation

We will the assess the Preadmission Screening and Resident Review (PASRR) program for Medicaid nursing facility residents aged 22 to 64 with a serious mental illness or mental retardation. The Omnibus Budget Reconciliation Act of 1987 requires preadmission screening for mental illness and mental retardation. In a January 2001 report, we found that PASRRs were not in compliance with Federal requirements. We will update our previous work in this area. This review will evaluate CMS's oversight of States' PASRR programs, State Medicaid

agencies' oversight of the PASRR process, and the extent to which nursing facilities comply with PASRR requirements.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Claims for Residents of Institutions for Mental Diseases

Our review will determine whether States improperly claimed Federal Medicaid funds for 21- to 64-year-old residents of private and county institutions for mental diseases. Our prior work found that some States did not comply with Federal regulations prohibiting Federal funding for services provided to such patients. We will also determine if improper claims were made for residents of institutions for mental diseases who were under age 21.
(OAS; W-00-03-31005; various reviews; expected issue date: FY 2005; work in progress)

Medicaid Services for Mentally Disabled Persons

At the request of CMS, we will review the methodology under which one State claims costs for services to mentally disabled persons. In some cases, the State reimburses its providers less than the actual amount it claims as Federal financial participation on the Medicaid expenditure reports. This may result in the State claiming excess Federal financial participation.
(OAS; W-00-04-39012; A-04-00-00000; expected issue date: FY 2005; work in progress)

Rehabilitation Services for Persons With Mental Illnesses

At the request of CMS, we will review one State's claims for Medicaid rehabilitation services for persons with mental illnesses to determine the allowability of those claims. The costs and number of providers associated with providing rehabilitation services has increased significantly. The State Medicaid agency under review is also reporting payments for rehabilitation services made by three other agencies of the State. We have found that State Medicaid agency scrutiny of claims from sister State agencies can be inadequate, which increases the Federal financial risk.
(OAS; W-00-04-39013; A-06-04-00033; expected issue date: FY 2005; work in progress)

Community Mental Health Centers

At the request of CMS, we will determine whether Medicaid payments to community mental health centers are made in accordance with applicable Federal and State regulation and guidance. Specifically, we will review a proposal for claiming administrative costs in one State to determine whether claims submitted under this proposal were eligible for Federal financial participation. Prior reviews of Medicare payments to community mental health centers identified problems including payments for noncovered services and payments for services provided to beneficiaries who did not meet eligibility requirements.
(OAS; W-00-04-39020; A-05-00-00000; expected issue date: FY 2005; work in progress)

Medicaid Reimbursement for Intermediate Care Facilities

We will determine if the Medicaid per diem rates for intermediate care facility services are reasonable and adequately supported. In one State, we found that per diem rates for developmentally disabled clients were paid without independent verification that the rates are based on accurate or correct costs. During FY 2001-2002, the State paid about $102 million to intermediate care facilities. We will examine whether States are monitoring the development of per diem rates to ensure that they are based on accurate costs.
(OAS; W-00-05-31086; various reviews; expected issue date: FY 2005; new start)

Restraint and Seclusion in Children's Psychiatric Residential Treatment Facilities

This study will determine whether psychiatric residential treatment facilities for children are in compliance with CMS regulations regarding the use of restraint and seclusion. In January 2001, CMS issued regulations establishing standards for the use of restraints and seclusion for residential treatment facilities serving those under age 21. The standards limit the use of restraints or seclusion to emergency safety situations, and include age-specific time limits for restraints or seclusion orders. States are required to conduct on-site inspections of 20 percent of their residential treatment facilities. We will review CMS oversight of State monitoring activities as well as State oversight.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medicaid/State Children's Health Insurance Program

Duplicate Claims for Medicaid and State Children's Health Insurance Program

At the request of CMS, we will determine whether States have obtained Federal funds under both the Medicaid program and the State Children's Health Insurance Program (SCHIP) for services provided to the same beneficiary. Preliminary information indicates that one State may have claimed Federal funding through both programs for services provided to the same beneficiary. We will determine if this situation exists in other States and the financial impact of the problem.
(OAS; W-00-03-31041; various reviews; expected issue date: FY 2005; work in progress)

Enrollment of Medicaid Eligibles in SCHIP

We will determine whether States have enrolled Medicaid-eligible children in SCHIP. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 requires that OIG examine this issue every 3 years. We issued the first of these studies in February 2001. As mandated by the Act, we took our sample from those States that operate separate SCHIP programs and concluded that Medicaid-eligible children were not being enrolled in SCHIP. We will expand the scope of our followup study to include an examination of enrollment

experiences in a sample of States that use the two other SCHIP models.
(OEI; 07-03-00220; expected issue date: FY 2005; work in progress)

State Evaluations of SCHIP Programs

We will assess States' evaluations of their SCHIP performance goals, particularly those focused on reducing the number of uninsured children. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 requires that OIG make this assessment every 3 years. Our first study, issued in February 2001, found that questionable evaluations undermined the reliability of State reports of success and that the evaluations demonstrated technical and conceptual weaknesses. We recommended that CMS develop a more specific framework for the content and structure of the State reports and that CMS and the Health Resources and Services Administration provide guidance and assistance to States in conducting useful evaluations. This followup study will assess the extent to which the Department has enhanced its technical assistance to States on using program evaluations to reduce the number of uninsured children.
(OEI; 05-03-00280; expected issue date: FY 2004; work in progress)

Detecting and Investigating Fraud and Abuse in SCHIP

We will determine the extent to which separate SCHIP programs are in compliance with Federal regulations for detecting and investigating fraud and abuse, and examine States' experiences with fraud and abuse. Regulations at 42 CFR 457.915(a) requires States to establish procedures for ensuring program integrity and detecting fraudulent or abusive activity for their separate SCHIP programs. This inspection will not only evaluate States' compliance with Federal regulations and their experiences with fraud and abuse, but it will also establish a benchmark for SCHIP fraud and abuse activities for future work in this area.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicaid Drug Reimbursement

Average Manufacturer Price and Average Wholesale Price

This review will examine the relationship between average manufacturer price (AMP) and average wholesale price (AWP). AMP is used for Medicaid drug rebate purposes and is based on actual sales data for drug manufacturers. AWP is a published catalogue price that most States use as a basis for Medicaid drug reimbursement. AWP has been the subject of numerous reviews and its shortcomings as a basis for reimbursement have been widely documented. This review will provide additional information to help ensure that Medicaid does not overpay for prescription drugs. We will also examine other Medicaid drug rebate trends, such as the significance of the best price in the rebate amount, to determine whether drug manufacturers are circumventing the requirements of the Medicaid drug rebate legislation.
(OAS; W-00-04-31072; various reviews; expected issue date: FY 2005; work in progress)

Medicaid Drug Rebates—Computation of AMP and Best Price

We will evaluate the adequacy of drug manufacturers' methodologies for computing AMP and best price. Both the AMP and the best price reported to CMS by manufacturers are used to determine the drug rebates paid to States. Any inaccuracies in the amounts reported can significantly affect rebate amounts. Our prior reports, issued in 1992, 1995, and 1997, noted that drug manufacturers did not consistently define the retail class of trade in their computations. In addition, we will assess CMS's oversight of drug manufacturers' recalculations of AMP and best price. It is critical that CMS effectively oversee the recalculation process to ensure that State Medicaid programs are receiving the appropriate drug rebates.
(OEI; 00-00-00000; OAS; W-00-03-31042; various reviews; expected issue date: FY 2005; new start for OEI, work in progress for OAS)

Oversight of Drug Manufacturer Recalculations for Medicaid Drug Rebates

We will assess CMS's oversight of drug manufacturers' recalculations of AMP and best price. For each Medicaid covered drug, manufacturers must submit AMP and best price data to CMS on a quarterly basis. Manufacturers may request rebate recalculations, which may result in downward adjustments to previously paid rebates and credits to the manufacturer. It is critical that CMS effectively oversee the recalculation process to ensure that State Medicaid programs are receiving the appropriate drug rebates.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Indexing the Generic Drug Rebate

We will analyze generic drug expenditures over a period of time to determine whether pricing substantially increased compared with the consumer price index for urban consumers. For brand-name drugs under the Medicaid rebate program, the AMP is indexed to the consumer price index for urban consumers using a baseline AMP. No such comparisons and indexing are made for rebates for generic drugs, which are simply set at AMP times a fixed percentage. Our review will quantify any potential savings from indexing generic drugs.
(OAS; W-00-04-31073; various reviews; expected issue date: FY 2005; work in progress)

Drug Rebate Impact From Drugs Incorrectly Classified as Generic

We will determine whether drug manufacturers are incorrectly classifying brand-name drugs as generic drugs for rebate purposes. Drug manufacturers issue rebates to States, which remit to the Federal Government a percentage of the rebate amount based on their level of Federal financial participation. For generic drugs, the rebates represent 11 percent of the drugs' AMP; for brand-name drugs, the rebates represent the greater of 15.1 percent of AMP or the difference between AMP and best price. Both AMP and the best price reported to CMS by manufacturers are used in determining drug rebates paid to States. We will select a sample of the most utilized drugs for this review.
(OAS; W-00-05-31085; A-06-00-00000; expected issue date: FY 2005; new start)

Dispute Resolution in the Medicaid Prescription Drug Rebate Program

This study will assess how Medicaid drug rebate disputes between State Medicaid programs and drug manufacturers are resolved. For Medicaid drug rebates, CMS calculates the unit rebate amount for each drug; State Medicaid agencies use this information, along with their own utilization data, to calculate total rebates owed by drug manufacturers. CMS developed a Dispute Resolution Program to address manufacturers' disputes about State utilization data. When disputes are not properly resolved, State Medicaid programs are at risk for not receiving drug rebates. We will review the dispute process and how CMS facilitates resolution between States and manufacturers.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicaid Drug Rebate Collections

This review will determine the amount of uncollected drug rebates that States have billed to drug manufacturers as well as the controls that States have for their rebate programs. In order for a manufacturer's drugs to be eligible for reimbursement by State Medicaid programs, the manufacturer is required to enter into a rebate agreement with CMS and pay quarterly rebates to States. Our reviews in the early 1990s found large amounts of rebates in dispute; as a result, CMS established a dispute resolution team to aid the States and drug manufacturers in settling disputes. Recent information indicates that large amounts of drug rebates remain uncollected due to disputes by drug manufacturers.
(OAS; W-00-03-31043; various reviews; expected issue date: FY 2005; work in progress)

Overprescribing of OxyContin and Other Psychotropic Drugs

This review will analyze Medicaid paid claims data to identify beneficiaries who have received significant amounts of OxyContin and the prescribing physicians. OxyContin is a pain medication with a very high street value. In 1999, various strengths of OxyContin represented three of the top four most-reimbursed generic drugs (in terms of dollars) in the Medicaid program. Through analyses involving medical reviews, the nature of diagnoses, and physician specialties, we will evaluate the appropriateness of the prescriptions. As part of this review, we will examine prescribing patterns for other psychotropic drugs, including Hydrocodone, Xanax, Diazepam, and Soma.
(OAS; W-00-04-31075; A-06-04-00000; expected issue date: FY 2005; work in progress)

Accuracy of Pricing Drugs in the Federal Upper Limit Program

We will examine how CMS administers the Federal Upper Limit Program for drugs covered under Medicaid. In 1987, CMS regulations created upper limit standards to limit the amount that Medicaid could reimburse for certain generic drugs. Our previous studies indicated that the published Federal Upper Limit prices often did not reflect true market prices, costing the Medicaid program millions of dollars. This study will determine whether CMS is setting appropriate prices for drugs under the Medicaid Federal Upper Limit Program.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicaid Drug Utilization Review Program

This study will assess Drug Utilization Review programs in the Medicaid program and how States monitor the cost of drugs and safety to patients. The Omnibus Budget Reconciliation Act of 1990 requires States to establish Drug Utilization Review programs to monitor and control the cost of prescription drugs. States are required to provide for prospective review of the appropriateness of prescriptions prior to dispensing and for retrospective review through analysis of claims processing data. We will evaluate those prepayment and postpayment controls and outcomes.
(OEI; 04-04-00250, expected issue date: FY 2005; new start)

Other Medicaid Services

Family Planning Services

At the request of CMS, we will determine whether several States improperly claimed enhanced Federal funding for family planning services and the financial impact on the Medicaid program. States may claim Medicaid reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. Prior work identified services that should not have been claimed at the enhanced rate.
(OAS; W-00-04-31078; various reviews; expected issue date: FY 2005; work in progress)

School-Based Health Services

We will determine whether Medicaid payments for school-based health services were in accordance with laws and regulations. States are permitted to use their Medicaid programs to help pay for certain health care services, such as physical and speech therapy, delivered to children in schools. Schools may also receive Medicaid reimbursement for the costs of administrative activities, such as Medicaid outreach, application assistance, and coordination and monitoring of health services. Some of this work was requested by CMS.
(OAS; W-00-03-31048/31050/31051/39002/31017/31061/31062; various reviews; expected issue date: FY 2005; work in progress)

Adult Rehabilitative Services

At the request of CMS, we will determine whether adult rehabilitative services claimed by a selected State met Federal Medicaid reimbursement requirements. Preliminary work related to child rehabilitation services identified numerous claims for services not eligible for Medicaid. We will determine if similar problems exist in the adult services program.
(OAS; W-00-03-39005; various reviews; expected issue date: FY 2005; work in progress)

Controls Over the Vaccine for Children Program

At the request of CMS, we will review a few States to determine whether controls are in place to prevent Medicaid payments to providers for vaccines obtained through the Vaccines for Children Program. The program provides free vaccines to low-income children who are eligible for Medicaid, have no health insurance, are Native American, and/or are underinsured. The Centers for Disease Control and Prevention pays for the vaccines, either directly or through reimbursement to States. There have been reports of improper and potentially fraudulent practices in this area.
(OAS; W-00-04-39015; various reviews; expected issue date: FY 2005; work in progress)

Outpatient Alcoholism Services

We will determine whether providers were reimbursed for improper claims for outpatient alcoholism services. Medicaid reimbursement is available for outpatient alcoholism services provided in hospital-based or freestanding clinics. Prior work identified significant noncompliance with Federal and State regulations. In several States, we will conduct reviews at the providers that receive the largest amounts of Medicaid reimbursement.
(OAS; W-00-04-31079; various reviews; expected issue date: FY 2005; work in progress)

Claims Paid for Clinical Diagnostic Laboratory Services

This review will assess whether Medicaid payments for certain laboratory and pathology tests exceeded Medicare rates for the same tests. The Social Security Act limits Medicaid payments for clinical laboratory tests to the amounts payable for the same tests on the Medicare fee schedule. Prior OIG work, as well as discussions with CMS officials, indicated that one State continues to submit Medicaid claims that exceed the allowable rates for laboratory and pathology tests.
(OAS; W-00-05-31093; A-01-05-00000; expected issue date: FY 2005; new start)

Payments for Services Provided After Beneficiaries' Deaths

In selected States, we will determine whether providers billed and were reimbursed for Medicaid services that occurred after beneficiaries' dates of death. One State auditor's review determined that the State paid $82 million for services to almost 27,000 apparently deceased beneficiaries during a period of almost 6 years.
(OAS; W-00-03-31021; various reviews; expected issue date: FY 2005; work in progress)

Marketing and Enrollment Practices by Medicaid Managed Care Entities

We will determine whether managed care entities used appropriate marketing and enrollment practices for Medicaid beneficiaries. Under the Balanced Budget Act of 1997, managed care entities may not distribute marketing materials without prior State approval; may not distribute false or misleading information; must distribute marketing materials within the entire service area specified in their contract; and may not conduct door-to-door, telephone, or other cold-call

marketing practices. We will also review how States ensure compliance with these rules.
(OEI; 07-04-00170; expected issue date: FY 2005; work in progress)

Factors Affecting the Development, Referral, and Disposition of Medicaid Fraud Cases: State Agency and Medicaid Fraud Control Unit Experiences

We will review how State Medicaid agencies identify and refer suspected fraud cases to Medicaid Fraud Controls Units (MFCUs). Federal law requires that State Medicaid agencies refer suspected fraud cases to MFCUs, which are responsible for investigating and prosecuting Medicaid fraud cases. In prior work, we found that a significant number of potential fraud cases were not being referred to MFCUs. We will evaluate State processes and the effectiveness of Medicaid fraud referrals to MFCUs.
(OEI-07-04-00180; expected issue date: FY 2005; work in progress)

Medicaid Administration

Contingency Fee Payment Arrangements

We will determine the extent to which State Medicaid agencies have contracted with consultants through contingency fee payment arrangements and the impact of these arrangements on the submission of questionable or improper claims to the Federal Government. Some State Medicaid agencies use consulting firms to help identify ways to maximize Federal Medicaid reimbursement. In some cases, the States pay the consulting firms a percentage of the increase in Federal Medicaid funding.
(OAS; W-00-04-31045; various reviews; expected issue date: FY 2005; work in progress)

Upper Payment Limits

We will determine how CMS's March 2001 revised regulations have affected State enhanced payments. States have the flexibility to pay different rates to the same class of providers, such as hospitals or nursing facilities, as long as the payments, in aggregate, do not exceed the upper payment limit (UPL) (what Medicare would have paid for the services). The revised CMS regulations include three separate aggregate limits—one each for private, State-operated, and city/county-operated facilities. Our work will focus on the amount of Medicaid funding claimed by selected States as part of UPL programs, as well as the use of the funds.
(OAS; W-00-03-31002; various reviews; expected issue date: FY 2005; work in progress)

Calculation of Upper Payment Limits for Transition States

At the request of CMS, we will determine whether State UPLs were reasonable and calculated in accordance with CMS's March 2001 revised regulations and the approved State plans. In addition, for States with UPL methodologies for hospitals, we will determine if States properly included UPL payments when calculating disproportionate share hospital-specific payment

limits. Since the revised regulations include transition periods for State compliance, we will also determine whether selected States are properly transitioning to the new regulations.
(OAS; W-00-03-39001; various reviews; expected issue date: FY 2005; work in progress)

State Match for Medicaid Upper Payment Limit Reimbursement

This review will determine whether States are appropriately contributing at least 40 percent of the required Medicaid State/local match for Medicaid UPL payments and whether certified public expenditures are being used inappropriately as the State's share of Medicaid UPL payments. While certified public expenditures may be used to cover a portion of a State's matching costs, a State plan for medical assistance must provide for financial participation by the State equal to at least 40 percent of the non-Federal share of the expenditures. OIG's work in one State showed that certified public expenditures at qualified non-State government-owned or operated public hospitals were inappropriately used as State match for private hospitals' Medicaid UPL payments for a 9-month period ending June 30, 2001.
(OAS; W-00-05-31088; various reviews; expected issue date: FY 2005; new start)

Medicaid Provider Tax Issues

At the request of CMS, we will examine State and health care-related taxes imposed on various Medicaid providers to determine whether those taxes comply with applicable Federal regulations and are being used for the stated purposes. The Social Security Act limits Federal financial participation in States' medical assistance expenditures when the States receive funds from other sources, including impermissible health-care related taxes. Prior OIG work has raised concerns regarding States' use of health-care related taxes, including whether taxes received by States adversely affect the providers required to pay the taxes.
(OAS; W-00-04-39019; various reviews; expected issue date: FY 2005; work in progress)

State-Employed Physicians and Other Practitioners

We will review Medicaid payments to physicians and other health care practitioners who are State employees. Recently, several States submitted State plan amendments to CMS requesting that enhanced payments be made to State-employed physicians. Often, these payments were supplemental values based on a relationship between regular physician payments and the physician's customary charges. Although CMS denied these proposed amendments, we are interested in further analyzing physician payments. OMB has expressed interest in this area.
(OAS; W-00-04-31081; various reviews; expected issue date: FY 2005; work in progress)

Skilled Professional Medical Personnel

At the request of CMS, we will determine whether States have improperly claimed enhanced Federal funding for skilled professional medical personnel. For these professionals, States may claim Federal funds at the enhanced rate of 75 percent.
(OAS; W-00-04-31077/39017; various reviews; expected issue date: FY 2005; work in progress)

Physician Assistant Reimbursement

We will determine if improper or ineligible claims for physician assistant reimbursement have been made to Medicaid. Many doctors' offices employ physician assistants, often in areas where doctors are difficult to recruit. To claim Medicaid reimbursement, physician assistants must be enrolled as nonbilling providers and have their claims submitted by the employing physician or physician group. Among other requirements, the employing physician or physician group must directly supervise the physician assistants and no duplication or increase in Medicaid charges may be made by the physician for a service solely because assistance has been provided by a physician assistant.
(OAS; W-00-05-31089; various reviews; expected issue date: FY 2005; new start)

Medicaid Claims for Excluded Providers

This review will determine if States have improperly claimed Federal financial participation under the Medicaid program for providers who have been excluded from participation. OIG excludes providers primarily because of fraud and abuse or other adverse actions. States receive notification of these excluded providers and should not be paying their claims.
(OAS; W-00-05-31090; various reviews; expected issue date: FY 2005; new start)

Administrative Costs of Other Public Agencies

At the request of CMS, we will determine whether the administrative costs claimed by selected States were reasonable, allocable, and allowable for reimbursement under the Medicaid program. State Medicaid agencies have limited incentive or capacity to carefully scrutinize Medicaid administrative claims generated by other State agencies. Our work will include costs claimed at the regular 50-percent matching rate and at the enhanced 75-percent rate.
(OAS; W-00-03-39004; various reviews; expected issue date: FY 2005; work in progress)

Administrative Costs for Medicaid Managed Care Contracts

This review will determine administrative cost levels for each managed care organization, health insuring organization, prepaid inpatient health plan, and prepaid ambulatory health plan in all States with managed care programs. We will survey all State Medicaid agencies with managed care programs to determine the breakdown of capitation payments by medical and administrative/profit components. Managed care regulations effective August 13, 2002 require actuarially sound capitation rates based on costs and utilization of Medicaid State plan services and populations (42 CFR § 438.6(c)). In a prior review, we found that administrative costs in one State totaled 8 percent in State FY 2001 and 11.1 percent in State FY 2002. However, for the same years, administrative costs in counties exceeded 15 percent and several counties exceeded 25 percent in administrative costs each year.
(OAS; W-00-05-31070; various reviews; expected issue date: FY 2005; new start)

University-Contributed Indirect Costs

We will determine whether State agencies are claiming indirect costs related to contracts with State universities as Medicaid administrative costs, although the State agencies do not pay these indirect costs. An audit of one State agency's Medicaid administrative costs revealed that the agency had several service contracts with State universities under which the State agency did not pay the universities all indirect costs associated with providing the services but only the amount the State was contracted to pay. However, the State agency claimed the indirect costs as Medicaid administrative costs and received additional Federal total reimbursement.
(OAS; W-00-05-31091; various reviews; expected issue date: FY 2005; new start)

Federal Financial Participation for Medicaid Cost Allocation Plans

This review will determine whether Medicaid administrative costs claimed through cost allocation plans are allowable, reasonable, and supported in accordance with applicable laws, regulations, program policies, and the State plan. Section 1903(a)(2) through (5) and (7) of the Social Security Act allows States to claim Federal matching funds ranging from 50 percent to 100 percent for administrative costs. CMS requires States to submit cost allocation plans to identify, measure, and allocate all costs to each of the programs operated by the State Medicaid agency.
(OAS; W-00-05-31092; various reviews; expected issue date: FY 2005; new start)

Medicaid Accounts Receivable

At the request of CMS, we will examine States' procedures for identifying, recording, and collecting Medicaid overpayments from providers. We will also determine whether States have refunded the Federal share of collected overpayments to the Federal Government, including Medicaid recoveries resulting from fraud and abuse collection efforts. According to recent information, one State may have written off overpayments without reporting these amounts to CMS and may not have pursued the most prudent methods for recovering identified overpayments. In such cases, the State may have avoided repayment of the Federal share of overpayments.
(OAS; W-00-03-31047; various reviews; OEI; 00-00-00000; expected issue date: FY 2005; work in progress)

Section 1115 Demonstration Waiver

At CMS's request, we will evaluate the financial management of a demonstration project for a county with a large Medicaid population. Specifically, CMS requested that OIG review the flow of funding, expenditures claimed for ambulatory services, and administrative costs. Section 1115 of the Social Security Act authorizes demonstration projects that are likely to assist in promoting the objectives of the Medicaid program.
(*OAS; W-00-04-39006; A-09-04-00038; expected issue date: FY 2005; work in progress*)

Medicaid Management Information System Expenditures

At the request of CMS, we will review a State's Medicaid Management Information System (MMIS). This MMIS has experienced major startup problems and the State has made substantial Medicaid claims without a thorough review of documentation to support them. The State is using an "enterprisewide" MMIS, which processes claims for the State employee and university health programs as well as Medicaid claims. We will determine whether MMIS expenditures claimed at the 75-percent Federal financial payment reimbursement level are reasonably supported and properly classified.
(OAS; W-00-04-39011; A-04-04-00002; expected issue date: FY 2005; work in progress)

Appropriateness of Medicaid Payments

We will identify Medicaid expenditures for services such as home health, dental, and outpatient mental health that are duplicative, unsupported, or unnecessary. Prior OIG investigations and evaluations have found inappropriate or fraudulent payments for services in Medicare. We will examine the extent of inappropriate Medicaid payments for various types of services.
(OEI; 04-04-00210; 00-00-00000; expected issue date: FY 2006; work in progress)

Medicaid FFS Payments for Beneficiaries Enrolled in Managed Care

This study will determine the appropriateness of Medicaid fee-for-service provider payments made on behalf of beneficiaries enrolled in Medicaid or Medicare managed care organizations. Previous OIG audits have found millions of dollars worth of duplicate fee-for-service payments for managed care enrollees. We will identify duplicate fee-for-service payments and vulnerabilities in State processes.
(OEI; 00-00-00000, expected issue date: FY 2005; new start)

CMS Oversight of Home- and Community-Based Waivers

We will evaluate CMS regional office oversight of Medicaid Home and Community Based Services (HCBS) waivers funded under the authority of section 1915(c) of the Social Security Act. Under section 1915(c) States are allowed to offer support services to Medicaid recipients in the community who would otherwise require institutional care. In January 2001, CMS implemented a national review protocol for use by CMS regional offices in its oversight of State waiver programs; previously, each region used its own protocol. In a further effort to make monitoring more effective and efficient, CMS issued interim guidance in January 2004 which established a national review process that places reliance on documentation submitted by State agencies to CMS regional offices. Our study will review the new CMS regional office oversight process.
(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Information Systems Controls

Security Planning for CMS Systems Under Development

We will determine whether CMS has adequately addressed information systems security requirements as major new systems are designed, developed/acquired, and implemented. Federal law and departmental policy require that information security be practiced throughout the life cycle of each system. CMS uses a Systems Development Life Cycle roadmap to manage the design, development, and implementation of new systems. At CMS's central office, we will determine whether the roadmap was appropriately structured to meet all Federal information security requirements. Subsequently, we will review security plans and related internal control deliverables for major new systems, such as the Health Insurance General Ledger Accounting System, the Medicare Managed Care Systems Redesign, and the Common Working File System Redesign, to determine whether they conform to Federal guidelines and incorporate best practices from the public and private sectors.
(OAS; W-00-04-41001; various reviews; expected issue date: FY 2005; work in progress)

Accuracy of the Fraud Investigation Database

We will determine the uses, accuracy, and reliability of CMS's Fraud Investigation Database. The database was developed in 1996 to assist in the prevention, detection, and deterrence of fraudulent activity in the Medicare and Medicaid programs. With increased use of computerized data to identify Medicare and Medicaid program vulnerabilities, the integrity of this database is essential. This study will also follow up on specific complaints about the database and identify ways to correct any problems identified.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Medicaid Statistical Information System

In two States, we will determine the integrity and completeness of eligibility and claim data in the Medicaid Statistical Information System. Federal legislation requires that all States submit their eligibility and claim data on a quarterly basis to CMS by using the system. The data are subject to quality edits to ensure that they fall within certain acceptable error tolerance guidelines. CMS then creates tape files which serve as a historical source of nationwide Medicaid eligibility and paid claim data. These files are used for such purposes as health care research and evaluation, program utilization and expenditure forecasting, analyses of policy alternatives, and responses to congressional inquiries.
(OAS; W-00-04-41003; A-02-00-00000; expected issue date: FY 2005; new start)

State Controls Over Medicaid Payments and Program Eligibility

We will evaluate State information systems controls over Medicaid claim processing and program eligibility. Medicaid uses several systems to process Medicaid claims and claims for beneficiaries who are dually eligible for Medicaid and Medicare. We have not reviewed these

systems to determine the security of the data. Our review will cover (1) entitywide security program planning and management, (2) access controls, (3) application software development and change controls, (4) system software, (5) segregation of duties, and (6) service continuity. In addition, we will follow up on unresolved findings from self-assessments and any other relevant audit reports on information systems controls.
(OAS; W-00-04-40019; various reviews; expected issue date: FY 2005; work in progress)

Replacement State Medicaid System

We will assess the effectiveness of one State's monitoring of a replacement Medicaid system. The review will focus on the State's oversight of key dates for implementing system components and actions taken to ensure that effective controls are in place as the new system goes online. The State's $340 million contract to develop the system calls for the establishment of an extensive data warehouse environment for analyzing hundreds of millions of annual Medicaid claims, the upgrade of the existing MMIS software, and the development of a new Electronic Medicaid Eligibility Verification System.
(OAS; W-00-05-41004; A-02-00-00000; expected issue date: FY 2005; new start)

Smart Card Technology

At CMS's request, we will assess the use of "smart card" technology in Medicare demonstrations as a means of creating portable, electronic patient medical records. Our review will focus on information security, data privacy, and program integrity concerns. The Secretary's Advisory Commission on Regulatory Reform recommended that HHS establish a multidisciplinary panel to evaluate the use of this technology in the Medicare program and that OIG provide technical assistance to prevent fraud and abuse. We plan to determine the current state of the technology; identify risk assessments performed by information security, data privacy, and insurance fraud experts; and provide recommendations on the suitability of using smart cards in Medicare health care demonstration projects, as well as measures to mitigate potential risks.
(OAS; W-00-05-41005; A-00-00-00000; expected issue date: FY 2005; new start)

Compliance With the Health Insurance Portability and Accountability Act Privacy Final Rule—University Hospital

Our review will determine whether a university hospital meets the requirements of the Health Insurance Portability and Accountability Act (HIPAA) Final Privacy Rule with respect to protected health information of Medicare beneficiaries. The Final Rule mandated that, by April 15, 2003, HIPAA-covered providers meet minimum requirements for protecting all health information that is individually identifiable. We will determine whether Medicare beneficiaries' HIPAA privacy rights are being met at the University hospital; that is, that mandated protections are in place to ensure that internal use, disclosure, and amendment of protected health information is in accordance with the Final Rule.
(OAS; W-00-04-41006; A-05-04-00000; expected issue date: FY 2005; work in progress)

MCO's Compliance With HIPAA

We will evaluate an MCO's general and application controls over electronic transmission of patient data to determine compliance with HIPAA security requirements. The HIPAA Security Rule required covered entities to maintain reasonable procedures to prevent accidental or intentional disclosure of electronic patient health care data.
(OAS; W-00-05-41007; A-04-00-00000; expected issue date: FY 2005; new start)

General Administration

FY 2004 Medicare Error Rate Estimate

This annual review will determine whether CMS has produced a valid and reliable Medicare fee-for-service paid claims error rate estimate for FY 2004. FY 2004 will be the second year that CMS has developed the error rate, but the first year that the projection will include data on all provider types for a full year. We will examine whether CMS has adequately implemented its Comprehensive Error Rate Testing (CERT) program to review all Medicare fee-for-service claims except prospective payment system inpatient claims, and we will examine the Hospital Payment Monitoring Program (HPMP) to produce an error rate for prospective payment system hospitals.
(OAS; W-00-04-40011; A-17-00-00000; expected issue date: FY 2005; work in progress)

FY 2005 Medicare Error Rate Estimate

This annual review will determine whether CMS has produced a valid and reliable Medicare fee-for-service paid claims error rate estimate for FY 2005. FY 2005 will be the third year that CMS has developed the error rate and the second year that the projection will include data on all provider types for a full year. We will examine whether CMS has adequately implemented its CERT program to review all Medicare fee-for-service claims except prospective payment system inpatient claims and we will examine the HPMP to produce an error rate for prospective payment system hospitals.
(OAS; W-00-05-40011; A-17-00-00000; expected issue date: FY 2006; new start)

Group Purchasing Organizations

We will continue to determine how group purchasing organizations (GPOs) and their members used revenue obtained from vendor fees. We will analyze the impact of GPO arrangements on the Medicare program, including how GPO owners and members report vendor fees on Medicare cost reports.
(OAS; W-00-04-35093; various reviews; expected issue date: FY 2005; work in progress)

Contractual Arrangements With Suppliers

We plan to evaluate contractual arrangements in which a supplier, such as a laboratory or durable medical equipment company, agrees to operate the service on behalf of a physician's practice or a hospital. We will review the structure of financial arrangements and will determine whether these arrangements are having an effect on the Medicare program.
(OAS; W-00-05-35172; various reviews; expected issue date: FY 2005; new start)

Corporate Integrity Agreements

We will continue to review compliance audit work plans and annual audit reports submitted by health care providers as required by the corporate integrity agreements that the providers signed to settle false claims actions. The objective of our reviews is to ensure that the requirements of the settlement agreements have been met.
(OAS; W-00-04-35028; various reviews; expected issue date: no report; work in progress)

State Medical Boards as a Source of Patient Safety Data

We will examine the extent and type of patient safety data available to State medical boards concerning possible systemic problems, as well as the extent that these data are shared or could be shared with CMS and health care facilities to reduce preventable medical errors. This inquiry is directly related to the central charge of the Secretary's Patient Care Task Force, which seeks to identify data sources that can improve patient safety. Our prior reviews of medical boards indicated that they were a potentially important, but largely untapped, source of patient safety data. Since the Institute of Medicine has indicated that preventable medical errors account for as many as 98,000 deaths a year, making full use of the boards' patient safety data is vital.
(OEI; 01-02-00690; expected issue date: FY 2005; work in progress)

Payments for Services to Dually Eligible Beneficiaries

This study will determine whether State Medicaid agencies and Medicare contractors have complied with Medicare and Medicaid requirements when paying dually eligible claims. When individuals are dually eligible for both Medicare and Medicaid, Medicare is responsible for paying the Medicare benefits. When States identify a Medicare liability, they must submit claims to Medicare within certain time limits and request recovery. We will examine how effectively States and Medicare contractors coordinate to ensure timely and adequate payments.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Nursing Home Quality of Care: Promising Approaches

In a series of reviews, we will examine effective practices that lead to high quality of care in nursing homes. For example, we will examine functional status outcomes; staffing measures, including salary, training, recruitment, and retention levels; and organizational characteristics

and model practice systems associated with positive outcomes. We will also explore ways to assess the impact of reimbursement levels on quality of care.
(OEI; 01-04-00070; expected issue date: FY 2005; work in progress)

Payments to Psychiatric Facilities Improperly Certified as Nursing Facilities

We will determine whether psychiatric facilities have been improperly certified as nursing homes and quantify any resulting inappropriate Medicare and Medicaid expenditures. Medicare is prohibited by statute from certifying any nursing facility that is "primarily for the care and treatment of mental diseases." We will identify nursing facilities that operate primarily as psychiatric facilities, examine their State certification, and determine the amount of any inappropriate Medicare and Medicaid reimbursement.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Investigations

The Office of Investigations (OI) conducts investigations of fraud and misconduct to safeguard the Department's programs and to protect the beneficiaries of those programs.

Investigative activities are designed to prevent waste, fraud, and abuse in departmental programs by identifying systemic weaknesses in vulnerable program areas. These weaknesses can be eliminated through corrective management actions, regulations, or legislation; by pursuing criminal convictions and program exclusions; and by recovering damages and penalties through civil and administrative proceedings. Each year, thousands of complaints from various sources are brought to OIG's attention for development, investigation, and appropriate conclusion. This Work Plan identifies investigative focus areas in which we will concentrate our resources, subject to the demands of current case referrals.

Health Care Fraud

OIG spends significant resources in the investigation of fraud committed against the Medicare and Medicaid programs. OI conducts many investigations in conjunction with other law enforcement agencies, such as the Federal Bureau of Investigation, the United States Postal Inspection Service, the Internal Revenue Service, and the various State Medicaid Fraud Control Units.

OI will investigate individuals, facilities, or entities that bill Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, and other false claims submitted to obtain program funds. OI will also investigate business arrangements that violate the Federal health care anti-kickback statute.

Investigative focus areas include pharmaceutical fraud. Working jointly with such partners as the Drug Enforcement Administration and State and local authorities, OI will continue to identify and investigate illegal schemes to market, obtain, use, and distribute prescription drugs.

By investigating these schemes, OI aims to stop the inflating of drug prices common in the pharmaceutical industry, protect the Medicare and Medicaid programs from making improper payments, deter the illegal use of prescription drugs, and curb the danger associated with street distribution of highly addictive medications.

OI will also increase its attention to quality-of-care issues for beneficiaries residing in nursing facilities. With the continuous growth of the elderly population, nursing facilities and their residents have become common victims of fraudulent schemes. All too often, Medicare and Medicaid programs are improperly billed for medically unnecessary services and for services either not rendered or not rendered as prescribed. We are also working to protect the vulnerable Medicare population from scams involving identity theft related to the new prescription drug discount card program.

OI does not investigate individuals, facilities, or entities that merely commit errors or mistakes on claims submitted to the Medicare or Medicaid program. OI works with CMS contractors, specifically the program safeguard contractors, to identify specific patterns of misconduct by reviewing a compilation of integrated Medicare Part A, Part B, and Part C and Medicaid claims.

Provider Self-Disclosure

To encourage health care providers to promptly self-disclose improper conduct that threatens Federal health care programs, including Medicare and Medicaid, OIG has made a concerted effort to educate providers on the advantages of self-disclosure.

In October 1998, OIG announced a flexible self-disclosure protocol for use by all health care providers doing business with Federal health care programs. The protocol offers health care providers specific steps including a detailed audit methodology that they may undertake if they wish to work openly and cooperatively with OIG. Numerous providers have been accepted under this protocol. These providers range from hospitals to laboratories to physicians. OIG believes that both the Federal Government and the providers benefit from this program.

The self-disclosure protocol is designed only for providers that believe a potential violation of the law has occurred. Matters exclusively involving overpayments or errors that do not indicate violations of the law should be brought directly to the attention of the entity responsible for claim processing and payment.

Legal Counsel

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General (OCIG) coordinates OIG's role in the resolution of civil and administrative health care fraud cases, including the litigation of program exclusions and civil monetary penalties and assessments, as well as the negotiation and monitoring of corporate

integrity agreements. OCIG also issues special fraud alerts, special advisory bulletins, and advisory opinions regarding the application of OIG's sanction authorities and is responsible for developing OIG regulations, including new safe harbor regulations under the anti-kickback statute. Work planned in FY 2005 includes the following:

Compliance Program Guidance to the Health Care Industry

We will continue to issue compliance program guidance to assist the health care industry in establishing voluntary corporate compliance programs and in developing effective internal controls that promote adherence to applicable Federal statutes, regulations, and the program requirements of Federal health care plans. The adoption and implementation of voluntary compliance programs significantly advance the prevention of fraud, abuse, and waste in Federal health care programs while furthering the health care industry's fundamental mission to provide quality patient care. We published Draft Supplemental Compliance Program Guidance for Hospitals on June 8, 2004, with public comments due by July 23, 2004. We will review all comments and plan to issue final supplemental guidance during FY 2005.

Resolution of False Claims Act Cases and Negotiation of Corporate Integrity Agreements

We will continue to work closely with OIG investigators and auditors and with prosecutors from DOJ to develop and pursue False Claims Act cases against individuals and entities that defraud the Government, where adequate evidence of violations exists. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases. We also will continue to consider whether to implement OIG's exclusion authority based on these defendants' conduct. When appropriate and necessary, we will continue to require these defendants to implement compliance measures, in the form of integrity agreements, aimed at ensuring future compliance with Federal health care program requirements.

Providers' Compliance With Corporate Integrity Agreements

We will continue to assess the compliance of providers with the terms of over 375 corporate integrity agreements (and settlements with integrity provisions) into which they entered as part of the settlement of fraud and abuse allegations. We will continue to conduct site visits to entities that are subject to the integrity agreements to verify compliance efforts, to confirm information submitted by the entities to OIG, and to assist with compliance generally. Included in this
monitoring process will be systems reviews to determine whether a provider's compliance mechanisms are appropriate and to identify any problem areas and establish a basis for corrective action. Where appropriate, we will continue to impose sanctions on providers that breach their integrity agreement obligations.

Advisory Opinions and Fraud Alerts

As part of OIG's ongoing efforts to foster compliance efforts by providers and industry groups, we will respond to requests for formal advisory opinions on the application of the anti-kickback

statute and other fraud and abuse statutes to particular business arrangements or practices. We will also issue special fraud alerts and advisory bulletins, as warranted, to inform the health care industry more generally of particular practices that we determine are suspect.

Anti-Kickback Safe Harbors

In FY 2005, we anticipate publishing regulations for several new safe harbor exemptions from the anti-kickback statute, including safe harbors related to the new MMA. Also, we will continue to evaluate comments that we solicited from the public concerning proposals for additional safe harbors.

Patient Anti-Dumping Statute Enforcement

We expect to continue to review and, when appropriate evidence exists, continue the negotiation, settlement, and litigation of cases involving violations of the patient anti-dumping statute, the Emergency Medical Treatment and Labor Act.

Program Exclusions

Based on cases developed by OI, we anticipate reviewing and implementing the exclusion of several thousand providers from participation in Federal health care programs. When warranted, we also expect to affirmatively initiate program exclusions against individuals and entities that submitted false or fraudulent claims, failed to provide services that met professionally recognized standards of care, or otherwise engaged in conduct actionable under section 1128 of the Social Security Act or other statutes authorizing exclusions by OIG.

Civil Monetary Penalties

We will continue to pursue civil monetary penalty cases, when supported by appropriate evidence, based on the submission of false or fraudulent claims; the offer, payment, solicitation, or receipt of remuneration (kickbacks) in violation of section 1128B(b) of the Social Security Act; and other offenses actionable under section 1128A of the Act and other civil monetary penalty authorities delegated to OIG.

Public Health Agencies

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Agency for Health Care Research & Quality

Grants Management Activities

We will evaluate the Agency for Healthcare Research and Quality (AHRQ) monitoring and oversight of its research and training grant program, which was funded at $113 million for FY 2004. For FY 2005, AHRQ has requested $85.8 million for research grants and $13.1 million for training grants. We will evaluate whether selected AHRQ grantees, including patient safety grantees, have followed Federal guidance in their administration of grants activities and use of grant funds.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Centers for Disease Control and Prevention

Strategic National Stockpile

We will review efforts by the Centers for Disease Control and Prevention (CDC) to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss; are maintained in an environmentally appropriate condition; and are available for immediate use as needed. The Strategic National Stockpile Program, for which CDC and the Department of Homeland Security share management responsibility, is designed to supplement and restock State and local public health agency pharmaceutical supplies in the event of a biological or chemical incident in the United States or its territories. These stockpiles are stored at strategic locations for the most rapid response possible, and CDC is responsible for ensuring that the materials in these facilities are adequately protected and stored.
(OAS; W-00-04-52001; A-04-04-00000; expected issue date: FY 2005; work in progress)

Bioterrorism Preparedness: Distribution of CHEMPACK

This study will evaluate the extent of State and local government preparedness for distribution of the Strategic National Stockpile (SNS) CHEMPACK assets and determine the extent of CDC's role in providing support for these activities. The Stockpile Program, established in 1999, is a repository of drugs, antidotes, and medical supplies designed to supply States and localities in the event of biological or chemical disasters. The program has developed a pilot project in a limited number of States and localities for the forward placement of nerve gas antidotes, known as the "SNS CHEMPACK." Because exposure to chemical agents requires immediate response, States and localities need to have pharmaceuticals on hand at all times to ensure rapid distribution in the event of a disaster.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Bioterrorism Preparedness and Response Cooperative Agreements: Oversight of Grants Monitoring

We will review current mechanisms for monitoring grants awarded by CDC's Bioterrorism Preparedness and Response Cooperative Agreement Program. This Program began in 1999 with $40 million and has rapidly grown to over $2 billion dollars in funding available for grantees. CDC has undertaken considerable efforts to assist States and localities in implementing the Program, and has recently issued new guidance. At the same time, CDC has a limited number of staff dedicated to monitoring States' use of these funds. We will review various aspects of grants monitoring, including grant requirements, roles and responsibilities of grants officers and project officers, as well as training for these staff and education for grantees. *(OEI; 00-00-00000; expected issue date: FY 2005; new start)*

Local Health Departments' Bioterrorism Preparedness

We will follow up on our 2002 report, "State and Local Bioterrorism Preparedness," which found that all 12 sampled States and 36 sampled local health departments were underprepared to detect and respond to bioterrorism. This study will assess the progress made by the same local health departments during the last 2 years. We will ask health department officials to complete a self-assessment tool based on the Core Capacity Project, which included CDC's most current preparedness benchmarks in 2002, and to provide documentation on how they fund their preparedness programs.
(OEI; 02-03-00056; expected issue date: FY 2005; work in progress)

Bioterrorism Preparedness: State 24/7 Reporting Systems

We will determine the capacity of State and local health departments to receive and process disease reports 24 hours a day, 7 days a week (24/7). Most health departments use communicable disease reporting as their primary method for bioterrorism surveillance. However, our 2002 review found that many local health departments still did not have the capacity to receive and process these reports on a 24/7 basis. CDC's Bioterrorism Preparedness and Response Cooperative Agreement Program has funded the improvement of surveillance capacity since 1999. As of 2002, States were required to develop the "capacity for detecting biopathogens through a highly functioning mandatory reportable disease surveillance system . . ." and to prepare a timeline for developing such a system at the State and local levels. We will assess States' progress in meeting this required critical capacity.
(OEI; 04-03-00540; expected issue date: FY 2005; work in progress)

State Public Health Laboratories' Bioterrorism Preparedness

We will determine the extent to which laboratories that confirm the presence of bioterror agents are prepared to handle increased testing in a bioterrorism event or public health emergency, and we will assess the extent to which these laboratories are receiving support from CDC to strengthen their testing capacity. Since 1999, CDC has funded State public health laboratories,

with a goal of helping laboratories build up their own capacity as well as to help strengthen collaboration among laboratories through the formation of the Laboratory Response Network. A recent OIG review, "States' Laboratory Response Programs for Bioterrorism: Level A Laboratory Participation" (OEI-02-03-00030), examined the coordination between sentinel laboratories (referred to as Level A) and reference laboratories, and found that although some coordination is occurring between them, many were overwhelmed during the 2001 anthrax events. This study will address whether reference laboratories are now better prepared to handle a bioterror event.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Health Alert Network

We will evaluate State health departments' implementation of the Health Alert Network, which CDC established to improve communication between public health agencies and their partners and to aid in CDC distance learning activities. Our 2002 review of State and local bioterrorism preparedness found that while the network appeared to work at the State and Federal levels, it was not fully operational at the local level. Specifically, two-way communication between States and local health departments was not common, and information technology capacity was limited.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Early Implementation of Biowatch: An Interagency Review

As part of an interagency effort with the Department of Homeland Security's (DHS) and Environmental Protection Agency's (EPA) OIGs, we will review the early implementation of the Biowatch Program. DHS provides the funding, management, and policy oversight for Biowatch; through CDC, HHS provides laboratory expertise. CDC's role is to provide separate laboratories within the Laboratory Response Network to analyze daily readings collected by EPA. In addition, CDC provides guidance to State and local health departments on planning for public health emergencies which might arise from the detection of a biological pathogen. We will assess current capacities of Network laboratories to undertake these tasks and review how CDC is assisting the coordination of State and local entities responsible for this initiative.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Compliance With Select Agent Regulations by Private and State Laboratories

We will assess private and State laboratory compliance with HHS select agent regulations. Select agents are substances that could be used in bioterrorist attacks. Earlier reviews assessed compliance only at Federal and university laboratories. Consistent with the objectives of our FY 2004 university reviews, we will assess select agent management oversight, security planning and implementation, accountability, and the identification and screening of personnel with access to select agents.
(OAS; W-00-05-52006; A-00-00-00000; expected issue date: FY 2005; new start)

Review of Surveillance System

We will follow up our FY 2004 review of CDC's National Electronic Disease Surveillance System, which is being developed to transfer appropriate public health, laboratory, and clinical data efficiently and securely over the Internet. CDC contracted for systems development and awarded grants to State and local health agencies for implementation. We will determine (1) the overall project status, (2) States' progress, (3) whether CDC is monitoring the extent of States' progress, and (4) whether CDC is monitoring the contractor to ensure it meets project needs and schedule goals.
(OAS; W-00-05-40022; A-03-00-00000; expected issue date: FY 2005; new start)

Tuberculosis Control Among Undocumented Immigrant Detainees Released Into the Community

We will evaluate whether undocumented immigrant detainees with tuberculosis (TB) who are released into the community are completing TB treatment. CDC is responsible for preventing, controlling, and eliminating TB in the United States. CDC funds State and local health departments to carry out many of these activities at a level of about $136 million annually. Undocumented persons apprehended by the Department of Homeland Security's Bureau of Immigration and Customs Enforcement are detained pending deportation or released into the community in the U.S. to await a court hearing of their immigration case. The TB rate in the bureau's processing centers (where many detainees are held) is 12 times higher than the national average and 2.5 times the rate for the U.S. foreign-born population. Of particular concern is compliance with the TB treatment regimen after release from detention into the community; if treatment is discontinued, a person can develop multidrug-resistant TB. We will examine the procedures and practices in place to screen and treat detainees for TB and to follow up with released detainees to assure TB treatment is completed.
(OEI; 00-00-0000; expected issue date: FY 2005; new start)

Controls Over Grantee Cash Withdrawals

We will determine whether CDC and the Division of Payment Management have properly managed open grant accounts on the Payment Management System. This system is used to transfer cash available from Federal grants to grantees. We will review the management and accounting controls that CDC and the system use to ensure that grantees' withdrawals are limited to authorized amounts and within appropriate time limits.
(OAS; W-00-05-52007; A-04-00-00000; expected issue date: FY 2006; new start)

Food and Drug Administration

Integrity of Research Involving Human Subjects

We will determine whether the Food and Drug Administration (FDA) is conducting research involving human subjects in a manner consistent with applicable laws, regulations, and policies. The Commissioner of Food and Drugs requested that we assess the effectiveness of corrective actions the agency has implemented in recent years to strengthen the integrity of clinical research conducted within the agency. Such corrective actions include implementing quality control programs and requiring training and certifications of its clinical investigators.
(OAS; W-00-04-53001; A-06-03-00087; expected issue date: FY 2005; work in progress)

Implementation of Clinical Trials Data Bank

We will evaluate drug industry compliance with the 1997 statutory requirement (Public Law 105-115 § 113) that drug manufacturers submit information on clinical trials involving life-threatening or serious conditions to the clinical trials data bank (http://ClinicalTrials.gov) maintained by the National Library of Medicine. Effective May 2002, drug sponsors are to submit clinical trial protocol information to the Web site including descriptive information on the trial, recruitment information, location/contact information, and administrative data (protocol number/study sponsor). FDA estimated that drug companies would submit about 1,600 protocols annually. As of April 2004, drug manufacturers submitted a total of 750 protocols for clinical trials that were recruiting patients. We will assess FDA's efforts and identify reasons for the discrepancy.
(OEI; 00-00-0000; expected issue date: FY 2005; new start)

FDA Monitoring of Postmarketing Studies

We will determine to what extent FDA monitors postmarketing study commitments agreed to by drug applicants (pharmaceutical companies), and whether applicants complete postmarket study commitments in a timely manner. FDA requires all pharmaceutical companies seeking approval to market a new drug undertake testing to demonstrate the drug's effectiveness and safety prior to its approval for sale in the United States. Because premarket clinical trails are limited, pharmaceutical companies often agree to conduct additional postmarket studies at the time a drug is approved. As of September 2002, FDA reported that 1,339 postmarket commitments were not yet completed. In prior work, OIG found problems with FDA's ability to monitor postmarket study commitments. We will determine whether FDA has made improvements since our prior work.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Reassignments of National Drug Codes

We will examine FDA's oversight of National Drug Code (NDC) reassignments for pharmaceuticals currently in commercial distribution. The Drug Listing Act of 1972 requires drug manufacturers to register their establishments and list all of their commercially marketed drug products with FDA. Each drug product is assigned an NDC. Drug manufacturers assign a product number and package size code to each drug or class of drugs. Manufacturers must notify FDA of any changes in product characteristics, assign a new NDC number to the new product version, and submit that information to FDA. We will determine the effectiveness of FDA's oversight and monitoring of such reassignments.
(*OEI; 00-00-00000; expected issue date: FY 2005; new start)*

FDA Oversight of Direct-to-Consumer Advertising

We will examine the effectiveness of FDA's oversight of direct-to-consumer advertising. According to the Government Accountability Office, direct-to-consumer advertising is the fastest-growing expenditure for pharmaceutical companies. In 2001, pharmaceutical companies spent $2.7 billion on such advertising, up from $55 million just 10 years earlier. Many restrictions on direct marketing were relaxed in 1997. We will determine the effectiveness of FDA procedures for monitoring direct-to-consumer advertisements and what actions are taken against drug companies that provide false or misleading advertisements.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Off-Label Drug Promotion

We will assess FDA's oversight and review of allowable promotion of off-label drug uses by drug manufacturers and describe FDA's oversight and enforcement of prohibited promotion of off-label drug uses by manufacturers, including challenges to monitoring and enforcing compliance. Under 21 CFR § 201.56(c), "no implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." However, well-publicized accounts of off-label use of drugs suggest that off-label prescribing practices may put patients at risk. Prohibited off-label promotion of drugs presents particular challenges and vulnerabilities because FDA generally does not have access to internal information on drug manufacturers' marketing practices and materials and cannot systematically monitor manufacturers' compliance.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

State Licensure of Drug Wholesalers

We will determine how and to what extent FDA ensures that States are carrying out their licensing responsibilities as stated in the Prescription Drug Marketing Act of 1987. The Act includes a provision that requires a wholesale distributor of prescription drugs to be State licensed and requires the FDA to establish minimum requirements for State licensing. We will also determine how and to what extent wholesale drug distributors that do not meet the

minimum Federal requirements receive licenses from the States. Licensing of wholesale distributors helps to ensure the integrity of the Nation's drug supply. An inadequate system can permit distribution of outdated or counterfeit drugs.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Blood Establishments

We will assess FDA's oversight and review of blood establishments to ensure the safety of the nation's blood supplies. FDA is statutorily required to inspect all registered blood establishments every 2 years. These inspections are conducted by FDA's Office of Regulatory Affairs in coordination with its Center for Biologics Evaluation and Research, which regulates the collection of blood and blood components and regulates related products such as blood collection containers. The center oversees these areas through licensure and inspection of all blood establishments and by monitoring reports of biological product deviations in the manufacturing process.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Adverse Event Reporting for Medical Devices

We will determine the extent to which manufacturers and user facilities comply with mandatory reporting requirements for adverse events associated with medical devices. FDA requires medical device manufacturers to report deaths, serious injuries, and device malfunctions to FDA within 30 calendar days, or within 5 working days if the event requires remedial action to prevent substantial harm to the public. We will assess how and to what extent FDA ensures that manufacturers and user facilities comply with adverse event reporting requirements for medical devices. Device reporting is a key part of FDA's oversight of new medical devices, providing an early warning of problems with devices new to the market. We will also evaluate how and to what extent FDA uses medical device adverse event reports to identify and address safety concerns.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA's Financial Disclosure Requirements for Clinical Investigators

We will assess the nature of financial interests disclosed by clinical investigators to FDA; the extent to which drug, biologic, and device applicants monitor their clinical investigators for conflicting financial interests; and the extent to which FDA monitors the financial interests disclosed by clinical investigators. FDA regulations require clinical investigators who conduct studies in support of a product to disclose their financial interest. Financial conflicts of interest create a potential for bias that may have a negative impact on the integrity of the data and on the protection of human subjects.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Review of FDA Employee Outside Activities

We will describe how FDA addresses issues related to employees' outside activities, which may represent potential conflicts of interest. Federal employees must adhere to both governmentwide and program-specific ethical standards, which include provisions on conflict of interest. The provisions typically require that employees disclose outside activities, which are then screened for their potential to create conflicts of interest, and which should be dealt with by agency officials. A recent incident raised questions about the potential for FDA employees to engage in outside activities with significantly regulated entities.
(OEI: 00-00-00000; expected issue date: FY 2005; new start)

Health Resources and Services Administration

Hospital Surge Capacity

This review will focus on the surge capacity guideline of the Health Resources and Services Administration (HRSA) Hospital Bioterrorism Preparedness Program, which calls for States to accommodate 500 patients per 1 million population. We will conduct onsite evaluations in a small number of States to determine the extent to which the guideline is being met. We will also survey all States to gain a broad overview of how this guideline is being met, if States are encountering barriers, and their interaction with HRSA to facilitate preparedness.
(OEI; 04-03-00500; expected issue date: FY 2005; work in progress)

Ryan White CARE Act—Analysis of the Use of Funding

This review will examine the distribution and use of Ryan White CARE Act funding over a 5-year period by all Title I and II grantees. Based on a recent Institute of Medicine publication and the observations made during our recent audits of Title I and II grantees, we plan to examine the use of funds, including carryover funds, by all grantees. Our analysis will identify variations among grantees and address whether HRSA has adequate authority over the distribution and allocation of funds.
(OAS; W-00-03/04-54250; A-02-00-00000; expected issue date: FY 2005; work in progress)

Ryan White Grant Programs as a Payer of Last Resort for HIV/AIDS Patients

We will examine the use of Ryan White grant programs as a payer of last resort for HIV/AIDS patients. The Ryan White CARE Act of 1990 states that funds received under Title I of the Act may not be used to pay for services that would otherwise be covered "under a State compensation program, an insurance policy, or a Federal or State health benefits program." Therefore, if a Ryan White grantee provides services to a patient who qualifies for and/or is

enrolled in Medicaid or another Federal health benefit program, Medicaid or the other program must be billed first for the services.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Maternal and Child Health Block Grant

We will review HRSA's monitoring of the $750 million Maternal and Child Health Block Grant, which includes funding for special projects of regional and national significance as well as statewide programs for the development and expansion of integrated community service systems. Our evaluation will examine HRSA's use of programmatic and fiscal oversight mechanisms, such as Government Performance and Results Act measures, required reporting by grantees, site visits, and subgrantee monitoring. Several years ago, our review of a set-aside grant identified problems involving monitoring and incomplete data. We will also assess progress in addressing the problems identified in our previous review.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of the Children's Hospital Graduate Medical Education Program

We will evaluate grantee compliance and performance under the Children's Hospital Graduate Medical Education Program and examine HRSA's enforcement of program requirements. In FY 2003, this $290 million program funded 59 children's hospitals in 31 States. These hospitals train approximately 30 percent of the Nation's pediatricians and nearly 50 percent of all pediatric subspecialists. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if HRSA appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

HRSA's Oversight of the Nursing Workforce Development Grants

We will examine the effectiveness of HRSA's oversight and monitoring of the Nursing Workforce Development grant program. Funded at $142 million in FY 2004, this program focuses on ensuring adequate supply and distribution of qualified nurses to meet the Nation's health care needs. Our review will include oversight of reporting requirements, examine grantee financial and performance reporting for completeness and timeliness and determine if HRSA appropriately evaluates the reports and conducts sight visits, and evaluate whether appropriate action is being taken as warranted. The Health Professions Partnership Act of 1998 was amended by the Nurse Reinvestment Act of FY 2002 and gives HRSA additional authorities to enhance the nursing workforce.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Organ Procurement and Transplantation Network

We will assess the nature and extent of the Department's oversight of the Organ Procurement and Transplantation Network. The National Organ Transplant Act of 1984 established the

network, which is charged with operating and monitoring an equitable system for allocating organs, maintaining a waiting list of potential recipients, matching potential recipients with donors, and increasing donation. All transplant centers and organ procurement organizations must be network members to receive Medicare reimbursement. HRSA contracts with the United Network for Organ Sharing for administration of the network. In 1999, the Institute of Medicine found that Federal oversight of the organ transplantation system fell short. Our assessment will encompass the Department's response to the Institute's recommendations.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Followup Actions to 340B Drug Discount Program Report, "Appropriateness of 340B Prices"

OIG will follow up on the price discrepancies discovered in our 2004 evaluation of the 340B Drug Discount Program by exploring potential reasons for price discrepancies within the Department and will provide information to pharmaceutical manufacturers, wholesalers, and covered entities to independently resolve discrepancies. Our report, "Appropriateness of 340B Pricing" (OEI-05-02-00070), found that over one-third of the sampled covered entities' prices exceeded the ceiling price guaranteed in law, resulting in an estimated $41 million in overpayments in 1 month. Thirty-one percent of drug prices sampled were above the mandatory ceiling price, and 36 of the 37 sampled entities were overcharged at least once. The focus of this followup work is to identify the possible reasons for price discrepancies at the Departmental level.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Indian Health Service

Safeguards Over Controlled Substances at IHS

We will evaluate control procedures for pharmaceuticals used in Indian Health Service (IHS) facilities, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and IHS, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices could result in the misappropriation of costly pharmaceutical products, especially controlled substances.
(OAS; W-00-05-55100; A-06-00-00000; expected issue date: FY 2006; new start)

Management of the Special Diabetes Program

We will evaluate IHS grants management activities involving the Special Diabetes Program for Native Americans. The Congress reauthorized the program in 2004 at a level of $150 million for each of the next 5 years. IHS has awarded over 300 noncompetitive grants to tribes and Urban Indian Programs for diabetes prevention/treatment under the authority of the program.

Diabetes has been the most frequently identified health problem in IHS Area Office budget discussions. Type 2 diabetes occurs at dramatically higher rates among Native American adults, who are almost three times more likely to have diabetes than the general U.S. population.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

National Institutes of Health

University Administrative and Clerical Salaries

We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants and cooperative agreements. OMB Circular A-21 provides that such costs should usually be treated as indirect costs. However, direct charging of these costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support.
(OAS; W-00-05-56009; A-00-00-00000; expected issue date: FY 2005; new start)

Recharge Centers

We will determine whether colleges and universities have complied with Federal cost principles. A previous OIG review of recharge centers found that 11 of 12 universities did not maintain adequate accounting systems and records. Weaknesses resulted in duplicate or unallowable costs in billing rates, use of recharge center funds for unrelated purposes, and accumulated surplus fund balances.
(OAS; W-00-05-56008; A-00-00-00000; expected issue date: FY 2005; new start)

Level of Commitment

We will determine whether major research universities committed more than 100 percent of principal investigators' effort when applying for National Institutes of Health (NIH) grants and, if so, whether the resulting grant awards were inflated. The NIH funds grant proposals on a cost-reimbursable basis and considers the investigator's role in deciding whether to fund the proposal. If a university promises more of the proposed investigator's time than is available, the NIH funds intended to pay for salary could possibly be used for costs not included in the proposal and the research quality could be affected
(OAS; W-00-05-56002; A-00-00-0000; expected issue date: FY 2005; new start)

Safeguards Over Controlled Substances at NIH

We will evaluate control procedures for pharmaceuticals used in NIH intramural clinical settings, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and NIH, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices

could result in the misappropriation of costly pharmaceutical products, especially controlled substances.
(OAS; W-00-05-56006; A-00-00-00000; expected issue date: FY 2006; new start)

Royalty Income From Intramural Inventions

We will determine whether NIH collects the royalty income earned from new technologies developed by Federal employees in its research laboratories. NIH has a statutory mandate to ensure that such promising new technologies are transferred to the private sector for commercialization. Typically, NIH seeks patent protection for these inventions and enters into a royalty-bearing licensing agreement with private entities to use or commercialize the technology. This technology transfer licensing program generates over $52 million a year in NIH revenue. Our review will determine whether NIH ensures that it receives royalty income on all products to which it is entitled, the royalties are calculated correctly, and payments are received in a timely manner.
(OAS; W-00-04-56007; A-03-00-00000; expected issue date: FY 2005; work in progress)

Employee Conflicts of Interest at NIH

We will describe how NIH addresses issues related to employee conflicts of interest. Federal employees must adhere to both governmentwide and program-specific ethical standards, which include provisions on conflict of interest. The provisions require that employees disclose all conflicts of interest, which are then screened for severity and handled accordingly. A recent investigation raised questions about employee conflicts of interest at NIH and cited several cases in which senior-level NIH officials responsible for overseeing millions of dollars in research grants concurrently had private business relationships with organizations that had business pending before their divisions. We will compare NIH's policies and practices for employee conflict of interest to those of other Federal agencies, both within and outside of the Department, as well as private organizations to assess their relative rigor and comprehensiveness.
(OEI; 01-04-00150; expected issue date: FY 2005; work in progress)

Superfund Financial Activities for Fiscal Year 2004

As required by Superfund legislation, we will conduct this annual financial audit of payments, obligations, reimbursements, and other uses of Superfund monies by the National Institute of Environmental Health Sciences. The institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training for people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 2003, agency obligations and disbursements of Superfund resources amounted to $85.7 million and $81.3 million, respectively.
(OAS; W-00-05-56001; A-04-04-00000; expected issue date: FY 2005; new start)

Cross-Cutting Public Health Activities

Implementation of Select Agent Regulations by University Laboratories

Following our first series of reviews, which identified a pattern of weakness in select agent security, we will assess the security of additional university laboratories that have select agents. At each university, we will determine whether (1) laboratories have adequate physical security to prevent unauthorized entry to areas with select agents, (2) adequate inventory controls have been implemented to keep track of select agents, (3) CDC regulations on possessing and transferring select agents are followed, and (4) the institution forwards the names of persons handling select agents to the Attorney General's office for a background search. These additional reviews are important because new legal requirements have been imposed on institutions having select agents since our initial reviews. Further, for selected universities reviewed during FY 2003, we will assess the corrective actions taken in response to our recommendations.
(OAS; W-00-04-56100; various reviews; expected issue date: FY 2005; work in progress)

Implementation of Select Agent Regulations by Departmental Laboratories

We will determine whether CDC, FDA, and NIH have complied with CDC regulations on possessing and transferring select agents and with the Secretary's March 2002 memorandum, which directed the agencies to implement 12 requirements to better control and secure the select agents in their laboratories.
(OAS; W-00-05-58004; various reviews; expected issue date: FY 2005; new start)

Bioterrorism Preparedness Expenditures

Based on the results of limited-scope reviews in 18 States, we will perform detailed reviews of bioterrorism preparedness expenditures in several States with the largest grant awards. In FY 2004, HHS awarded approximately $1.5 billion through cooperative agreements between States and HRSA or CDC for bioterrorism preparedness. We will determine whether States used these funds in accordance with the cooperative agreements and departmental regulations.
(OAS; W-00-05-58005; A-05-00-00000; expected issue date: FY 2005; new start)

Risk Determinations in Grant Management

We will examine CDC and HRSA compliance with departmental grant policy directives (1) to use the HHS Alert List in making risk determinations, and (2) to impose and monitor special award conditions for high-risk grantees on such grantees. For each agency, we will also assess the criteria and process for determining grantee risk and the development and monitoring of corrective action plans for high-risk grantees. CDC and HRSA awarded $9.2 billion in grants in FY 2003.
(OEI; 02-03-00010; expected issue date: FY 2005; work in progress)

Grants to Community Health Centers

We will determine whether HHS-funded community health centers provided nonduplicative services, met program performance measures, and ensured that Federal funds were spent appropriately. Community health centers may receive grants from HRSA, CDC, the Substance Abuse and Mental Health Services Administration, and the Office of Minority Health. Our review of program performance will include an assessment of whether the funded level of services was provided for each HHS program and whether similar program services reached different populations and clients. Our financial reviews will determine whether costs claimed on each grant complied with Federal guidelines, with emphasis on the allocation of costs among the various grants.
(OAS; W-00-04-58006; various reviews; expected issue date: FY 2005; work in progress)

Review of Adverse Event Reports by Institutional Review Boards

We will assess how institutional review boards (IRBs) use adverse event reports as a tool to protect human subjects. Adverse event reports can serve as a key tool to protect human subjects by helping IRBs understand the potential risks associated with ongoing studies. Federal regulations require clinical investigators to report to IRBs "any unanticipated problems involving risks to human subjects or others." The OIG's previous work surfaced concerns with IRBs' use of adverse event reports. We intend to assess the extent to which IRBs receive useful information in adverse event reports, have adequate processes for reviewing adverse event reports, and factor adverse event reports into their decisions to recommend changes to a clinical trial.
(*OEI; 00-00-00000; expected issue date: FY 2005; new start)*

Privacy of Medical Records

We will conduct an early assessment of colleges' and universities' policies and procedures for protecting the privacy of medical records of persons participating in NIH-funded clinical trials and other research. In response to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate, HHS developed the first Federal privacy standards to protect patients' medical records. These new standards, which were effective in April 2003, provide patients with access to their medical records and more control over how their personal health information is used and disclosed. The HHS Office for Civil Rights (OCR) oversees and enforces the standards at colleges and universities that are covered universities. We will seek advice from OCR to ensure that the universities we select for review are covered by the HIPAA privacy rule.
(OAS; W-00-05-58007; A-01-00-00000; expected issue date: FY 2005; new start)

Time and Effort Reporting Compliance Through Single Audits

We will determine how and to what extent single audits assess and document colleges' and universities' compliance with time and effort reporting requirements of OMB Circular A-21.

The single audit process, required by OMB Circular A-133, represents the Federal Government's primary internal control over costs claimed under Federal projects. The annual OMB Circular A-133 Compliance Supplement directs auditors of research and development programs to test the time and effort reporting system to support the distribution of salaries and wages. However, the extent to which the single audits currently assess time and effort reporting systems is largely unknown.
(OEI; 05-03-00230; expected issue date: FY 2005; work in progress)

Investigations

Violations of Select Agent Regulations

Since the events of September 11, 2001, we have received numerous requests for information and investigations on terrorist and bioterrorist activities. On December 13, 2002, HHS issued an interim final rule on Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). We are developing an initiative to pursue violations of these new regulations through civil monetary penalties.

We are also working with CDC, the FBI, and the Department of Agriculture to establish a protocol for the investigation of potential criminal violations of the statute governing the registration, storage, and transfer of select agents and toxins.

Legal Counsel

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General coordinates OIG's role in the resolution of civil and administrative fraud cases and promotes compliance measures by recipients of HHS grant funding. Work planned in FY 2005 includes the following:

Compliance Program Guidance for Recipients of Research Grants

One major initiative of OIG is the issuance of compliance program guidance to assist recipients of HHS funding in establishing voluntary compliance programs and in developing effective internal controls that promote adherence to applicable Federal statutes, regulations, and program requirements. The adoption and implementation of voluntary compliance programs significantly advances the stewardship responsibilities of the Department's grantee institutions. Similar to the compliance program guidance OIG has published for the health care industry, we are developing Draft Compliance Program Guidance for Recipients of NIH Research Grants. We are reviewing public comments received in FY 2004 in response to a Solicitation of Information and Recommendations and plan to issue draft guidance in FY 2005 for further comment.

Resolution of False Claims Act Cases

We will continue to work closely with OIG investigators and auditors and with prosecutors from DOJ to develop and pursue False Claims Act cases against institutions which receive grant funds from NIH and other PHS agencies. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases.

Administrations for Children, Families, and Aging

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Child Support

Review and Adjustment of Child Support Orders

At the request of the Administration for Children and Families (ACF), we will assess the timeliness of State reviews and modifications of child support orders in response to changes in custodial or noncustodial parents' situations. For example, based on periodic reports on wage data, States should assess whether wage increases or decreases might warrant court order modification. We will determine what data are available to States and whether they take appropriate action. States must have in place and use a process to review and adjust child support orders, including challenges to any changes.
(OAS; W-00-05-23001; A-00-00-00000; expected issue date: FY 2005; new start)

Revocation of Federal Licenses

This review, requested by ACF, will determine whether delinquent noncustodial parents hold pilot, truckers, disc jockey, or other licenses issued by Federal agencies, such as the Department of Transportation and the Federal Communications Commission. Federal law permits States to suspend or revoke State-issued licenses to enforce collection of child support payments. The possibility of revocation has resulted in increased collections. Applying this tool to holders of federally issued licenses could enhance the Federal/State partnership and provide an additional means of increasing child support collections and minimizing the need for public assistance to some families. We will determine the feasibility of implementing such a requirement and the amount of child support payments that could potentially be collected, based on the noncustodial parents' ability to pay.
(OAS; W-00-05-23002; A-00-00-00000; expected issue date: FY 2005; new start)

Undistributed Child Support Collections

This review will examine undistributed child support collections and determine whether the Federal Government received its share of any program income earned in interest-bearing accounts or for undistributed balances written off by States. Historically, States have had difficulty in distributing sizeable amounts of support payments because certain identifiers, such as custodial parents' addresses, were not current or the case numbers were omitted from collection receipts.
(OAS; W-00-03-23080; A-00-00-00000; expected issue date: FY 2005; work in progress)

Direct Interstate Income Withholding

We will evaluate the extent to which States use direct income withholding to increase interstate child support collections. Direct interstate income withholding, required since 1998, is intended to increase interstate collections by allowing State child support enforcement agencies to order employers to withhold wages of noncustodial parents located in other States. An

estimated 25 percent of custodial and noncustodial parents live in different States. This inspection will complement and expand upon work being done by the Office of Child Support Enforcement on this issue.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

States' Use of Work Requirements for Noncustodial Parents

This study will evaluate how effectively child support agencies and courts use work requirements when dealing with noncustodial parents and the impact of these requirements on child support collections. Child support agencies often refer low-income, underemployed, or unemployed noncustodial parents to job service programs to help them meet their child support responsibilities. The agencies are eligible for Federal funds for referral, followup, and tracking services offered to noncustodial parents who have been ordered by the courts or required administratively by the child support agency to participate in an employment service program.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Investigations Under the Child Support Enforcement Task Force Model

In 1998, the Office of Investigation (OI) and the Office of Child Support Enforcement developed a task force model to create a coordinated effort to identify, investigate, and prosecute criminal nonsupport cases. This model began as a pilot program in three States. By 2002, the program now known as Project Save Our Children had grown to 10 task forces covering all 50 States and the District of Columbia. These task forces join OI, the U.S. Marshals, U.S. Attorneys' Offices, State and local law enforcement, local prosecutors, State child support agencies, and other interested parties in working to enforce Federal and State criminal child support statutes. For FY 2005, we plan to continue our efforts in this area, particularly in States that have not pursued prosecutions of individuals who failed to meet their child support obligations.

Child Welfare

State Investigations of Abuse and Neglect

We will determine how States investigate allegations of abuse and neglect of Title IV-E foster care children and whether they take appropriate action to prevent further harm. Our primary focus will be on the timeliness and thoroughness of the investigation, including such factors as the previous history of the alleged abuser, whether a background check was performed on members of the foster care household, and how well caseworkers monitored the child/family. We will be looking for root causes that have contributed to any identified weaknesses.
(OAS; W-00-05-24004; A-00-00-00000; expected issue date: FY 2005; new start)

Background Checks on Foster Families and Adoptive Parents

This review will examine State background checks on foster families and potential adoptive parents. We will determine compliance with Federal and State laws on background checks and the reliability of methods used to determine an individual's qualifications. States have flexibility in designing their own requirements. In one State, background checks did not routinely include records on Federal crimes or crimes in other States, including child abuse. Also, according to two foster care providers, State record checks on some potential employees and foster families returned negative, but further checking found Federal or out-of-State crimes and child abuse which would disqualify these individuals.
(OAS; W-00-05-24001; A-00-00-00000; expected issue date: FY 2005; new start)

Kinship Placements in One State

This review will determine (1) whether a State used different standards for approving placements with relatives versus nonrelatives and (2) whether it used Federal funds for approving foster homes that did not meet the Federal standards. ACF requested an audit of the process the State used for approving placement in homes where a relative serves as the foster parent. The Adoption and Safe Families Act of 1997 requires that the same standards be used in the approval process for placement in foster homes of relatives and licensed foster homes of nonrelatives.
(OAS; W-00-04-24005; A-09-00-00000; expected issue date: FY 2005; work in progress)

Tracking Children While in Foster Care

We will determine whether States have met tracking and placement requirements to ensure the safety of children in foster care. In 2004, it is estimated that 233,000 children will be in foster care each month; ACF expects to spend an estimated $4.9 billion on the program. The Social Security Act requires States to develop and implement standards to ensure that foster care children receive quality services that protect their safety and health. We will evaluate the ability of States to track children and provide insight into any underlying problems that States have encountered with Federal and State tracking requirements.
(OEI; 04-03-00350; expected issue date: FY 2005; work in progress)

Foster Care Level-of-Care Classification

This review will determine whether the level-of-care needs of foster care children are periodically reassessed and appropriate reclassifications made and whether children are receiving the required services. If the level-of-care needs are not periodically reassessed, States may be providing and paying for more or less than a child requires, resulting in an improper payment. Also, children not receiving the needed services may not be making the progress expected. Prior reviews have indicated that foster children who are in prolonged placement

through child placement agencies are not reclassified in accordance with their level-of-care needs.
(OAS; W-00-05-24006; A-00-00-00000; expected issue date: FY 2005; new start)

Foster Care Administrative Costs

We will determine whether claims for training and other administrative costs relating to the foster care program are allowable, reasonable, and supported in accordance with laws and regulations. Training and other administrative costs have risen dramatically in relation to maintenance payments in recent years. Reviews in some States found that unallowable costs were claimed, costs were improperly allocated, and/or costs were otherwise unsupported.
(OAS; W-00-03-20008; various reviews; expected issue date: FY 2005; work in progress)

Adoption Assistance Subsidy Payments

This review will determine whether claims for Federal reimbursement of adoption subsidies complied with eligibility requirements. A Federal subsidy is provided to families to ensure that they have the necessary services and financial resources to meet the special needs of some adopted children. A preliminary sample of adoption subsidies in one State identified payments to families that did not meet eligibility requirements.
(OAS; W-00-04-24003; A-01-04-02503; expected issue date: FY 2005; work in progress)

Adoption Assistance Cost Allocations

This review will determine the appropriateness of the adoption assistance allocation rates that States use to calculate training and maintenance payments claimed for Federal reimbursement. ACF reviews in FY 2003 showed that some States' foster care allocations were overstated. Because adoption assistance criteria are more complex than foster care criteria, we believe the adoption assistance allocations could also be overstated. Our preliminary information indicates that certain States did not adjust their adoption assistance allocations when ACF reduced their foster care rates.
(OAS; W-00-03-24003; A-01-00-00000; expected issue date: FY 2005; work in progress)

Statewide Automated Child Welfare Information Systems

This study will assess the usefulness of Statewide Automated Child Welfare Information Systems. The Omnibus Budget Reconciliation Act of 1993 provided Federal funds at an enhanced 75-percent matching rate for States to design, develop, and install the systems. Once the systems are implemented, the Federal matching rate drops to 50 percent to cover operating costs. We will evaluate the outcome of Federal funding for the development and implementation of statewide systems.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Costs for Statewide Automated Child Welfare Information System

At ACF's request, we will examine one State's escalating costs for operating its Statewide Automated Child Welfare Information System. The review will determine whether (1) prior Federal approval was obtained for acquisition of products and services and (2) costs claimed were allowable and allocable to the system. The Omnibus Budget Reconciliation Act of 1993 provided Federal funds at a 50-percent matching rate to operate statewide systems. The systems are intended to improve information exchange among child welfare staff and other social services programs, such as Temporary Assistance for Needy Families, Child Support Enforcement, and Medicaid.
(OAS; W-00-04-24050; A-09-00-00000; expected issue date: FY 2005; work in progress)

Head Start/Child Care

Health and Safety Standards at Child Care Facilities

This review will determine compliance with health and safety standards at selected child care and Head Start facilities. A 1994 audit identified numerous instances in which child care facilities did not comply with the States' health and safety standards. It also showed the need for greater Federal oversight to improve the health and safety conditions of the Nation's child care programs.
(OAS; W-00-05-25005; A-04-00-00000; expected issue date: FY 2005; new start)

Head Start Programs' Use of Quality Improvement Funds

We will evaluate the use of quality improvement funds for Head Start programs. The amended Head Start Act required that at least 50 percent of Head Start teachers in center-based programs nationwide have an associate, a baccalaureate, or an advanced degree in early childhood education or a related field, and experience teaching preschool children. A key priority, linked to improving staff qualifications and retaining experienced staff, is to enhance staff salaries. To assist Head Start programs, the Congress increased the authorization for quality improvement funds. We will determine whether Head Start grantees have complied with the Head Start Act in their use of quality improvement funds.
(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Head Start Enrollment

We will examine the extent to which persistent underenrollment in Head Start programs has been identified and determine whether timely corrective action has been taken to adjust for such underenrollment. Our previous reviews and discussions with program officials indicated that some grantees did not maintain their funded enrollment levels for extended periods. More timely action may be needed to adjust funding levels consistent with the actual number of

children being served or to better recruit eligible children to fill empty slots.
(OAS; W-00-05-25002; A-05-00-00000; expected issue date: FY 2005; new start)

Head Start Compensation Practices

At ACF's request, we will examine the compensation practices of Head Start grantees. For key management officials and other selected grantee staff, we will determine (1) the composition of compensation packages, (2) the funding sources, (3) the approval process for compensation packages, and (4) the basis of any wage comparability study performed to justify the compensation. Several news articles and congressional inquiries have raised concern about apparently excessive executive compensation at some Head Start agencies. In addition, we will review the ACF Regional Offices' oversight of grantee compensation.
(OAS; W-00-04-25004; A-00-00-00000; expected issue date: FY 2005; work in progress)

Head Start Grantee Oversight

This review will examine the effectiveness of Head Start program oversight at the Federal and grantee levels and determine actions needed to avoid recurring audit findings. In past years, most grantees terminated from the program were removed after long periods of noncompliance with fiscal and program requirements.
(OAS; W-00-05-25001; A-02-05-00000; expected issue date: FY 2005; new start)

Head Start Facilities Procurement and Construction Practices

Our review will determine whether Head Start agencies are complying with Federal requirements when purchasing facilities in which to operate. In addition, we will ensure that Federal interest in these facilities has been legally protected. During a prior audit, there were some concerns about the reasonableness of facility purchases, whether competitive bidding was used, and whether the Federal interest in these facilities was documented and protected.
(OAS; W-00-05-25006; A-06-00-00000; expected issue date: FY 2005; new start)

Administration on Aging

Impact of Cost Sharing on Older Americans Act Participation by Low-Income Elderly

At the request of the Administration on Aging, we will determine the impact of cost sharing on the participation of the low-income elderly in services authorized by Title III of the Older Americans Act. This review will follow up on our 1996 study, which was conducted in anticipation of legislation allowing States to charge older citizens for some Title III services. Such legislation was enacted in 2000. Our earlier study found that some States were better prepared to implement the cost sharing provisions of Title III.
(OEI; 02-04-00290; expected issue date: FY 2005; work in progress)

Departmentwide Issues

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Financial Statement Audits

The Government Management Reform Act of 1994 seeks to ensure that Federal managers have at their disposal the financial information and flexibility necessary to make sound policy decisions and manage scarce resources. This Act broadened the Chief Financial Officers Act of 1990 by requiring annual audited financial statements for all accounts and associated activities of HHS and other Federal agencies.

Audits of FY 2004 Financial Statements

The audited FY 2004 consolidated HHS financial statements are due to the Office of Management and Budget (OMB) by November 15, 2004. The following FY 2004 financial statement audits will be completed and reports will be issued during FY 2005:

- The **consolidated HHS** audit will be performed at all operating divisions, including those that will receive separate audit reports (listed below) and those that will not. Those that will not receive separate audit reports include ACF, HRSA, IHS, CDC, SAMHSA, AHRQ, NIH (excluding the Service and Supply Fund), AoA, and the Office of the Secretary.
  (*OAS; W-00-04-40009; A-17-04-00001)*

- **CMS**
  (OAS; W-00-04-40008; A-17-04-02004)

- **FDA**
  (OAS; W-00-04-40013; A-17-04-00003)

- **Program Support Center**
  (OAS; W-00-04-40003; A-17-43-00004)

- **NIH Service and Supply Fund**
  (OAS; W-00-04-40013; A-17-04-00005)

FY 2004 Statement on Auditing Standards 70 Examinations

A Statement on Auditing Standards (SAS) 70 examination reports on those controls of a service organization that may be relevant to the user organizations' internal control structures. The following SAS 70 examinations of HHS service organizations will support FY 2004 financial statement audits:

- **Center for Information Technology** (NIH Computer Center)
  (OAS; W-00-04-40012; A-17-03-00010)

- **Program Support Center—Major Administrative Support Services**

    - **Payment Management System**
      (OAS; W-00-04-40012; A-17-04-00009)

    - **Division of Financial Operations in conjunction with the Information Technology Service Center**
      (*OAS; W-00-04-40012; A-17-04-00011)*

    - **Human Resources Support in conjunction with the Information Technology Service Center**
      (OAS; W-00-04-40012; A-17-04-00012)

FY 2004 Financial-Related Reviews

- **Office of Personnel Management (OPM) Agreed-Upon Procedures** assist OPM in assessing the reasonableness of retirement, health benefits, and life insurance withholdings and contributions, as well as enrollment information.
  (OAS; W-00-04-40012; A-17-04-00008)

- **Payment Management System Agreed-Upon Procedures** focus on analyses of grant advances and expenditures, posting of expenditures, and recalculation of the estimated yearend grant accrual.
  (OAS; W-00-04-40012; A-17-04-00013)

- **Closing-Package Audit Reports for the Governmentwide Financial Report System** are intended to support the preparation of governmentwide financial statements and reports.
  (OAS; W-00-04-40012; A-17-04-00006)

- **Intragovernmental Agreed-Upon Procedures for the Closing Package** are intended to assist with accounting for and eliminating intragovernmental activity and balances in the preparation of governmentwide financial statements and reports.
  (OAS; W-00-04-40012; A-17-04-00007)

Audits of FY 2005 Financial Statements

The audited FY 2005 consolidated HHS financial statements are due to OMB by November 15, 2005. The following FY 2005 financial statement audits will be completed and reports issued during FY 2006:

- The **consolidated HHS** audit will be performed at all operating divisions, including those that will receive separate audit reports (listed below) and those that will not. Those that will not receive separate audit reports include ACF, HRSA, IHS, CDC, SAMHSA, AHRQ, NIH (excluding the Service and Supply Fund), AoA, and the Office of the Secretary.
  (*OAS; W-00-05-40009; A-17-00-00000)*

- **CMS**
  (OAS; W-00-05-40008; A-17-00-00000)

- **FDA**
  (OAS; W-00-05-40013; A-17-00-00000)

- **Program Support Center**
  (OAS; W-00-05-40003; A-17-00-00000)

- **NIH Service and Supply Fund**
  (OAS; W-00-05-40013; A-17-00-00000)

FY 2005 Statement on Auditing Standards 70 Examinations

A SAS 70 examination reports on those controls of a service organization that may be relevant to the user organizations' internal control structures. The following SAS 70 examinations of HHS service organizations will support FY 2005 financial statement audits:

- **Center for Information Technology** (NIH Computer Center)
  (OAS; W-00-05-40012; A-17-00-00000)

- **Information Technology Support Center** (Office of Secretary)
  (OAS; W-00-05-40012; A-17-00-00000)

- **Program Support Center—Major Administrative Support Services**

  - **Payment Management System**
    (OAS; W-00-05-40012; A-17-00-00000)

  - **Division of Financial Operations**
    (OAS; W-00-05-40012; A-17-00-00000)

  - **Human Resources Support**
    (OAS; W-00-05-40012; A-17-00-00000)

FY 2005 Financial-Related Reviews

- **OPM Agreed-Upon Procedures** assist OPM in assessing the reasonableness of retirement, health benefits, and life insurance withholdings and contributions, as well as enrollment information.
  (OAS; W-00-05-40012; A-17-00-00000)

- **Payment Management System Agreed-Upon Procedures** focus on analyses of grant advances and expenditures, posting of expenditures, and recalculation of the estimated

yearend grant accrual.
(OAS; W-00-05-40012; A-17-00-00000)

- **Closing-Package Audit Reports for the Governmentwide Financial Report System** are intended to support the preparation of Governmentwide financial statements and reports.
(OAS; W-00-05-40012; A-17-00-00000)

- **Intragovernmental Agreed-Upon Procedures for the Closing Package** are intended to assist with accounting for and eliminating intragovernmental activity and balances in the preparation of Governmentwide financial statements and reports.
(OAS; W-00-05-40012; A-17-00-00000)

Automated Information Systems

Information Systems Internal Controls—FY 2004

As part of our responsibilities under the Chief Financial Officers Act and the Federal Financial Management Improvement Act, we will oversee and conduct tests of internal controls over HHS information systems. The Acts require that OIG, or an independent public accountant chosen by OIG, understand the components of internal controls and conduct sufficient tests to reasonably assess control risk. This work will include nationwide reviews of internal controls in Medicare and Medicaid systems and in other HHS financial systems. The results of this effort will be included in our report on the consolidated HHS FY 2004 financial statements.
(OAS; W-00-04-40017; various reviews; no report)

Information Systems Internal Controls—FY 2005

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(OAS; W-00-05-40017/40019; various reviews; no report)

Federal Information Security Management Act of 2002 and Critical Infrastructure Protection

Our review will assess various operating divisions' compliance with the Federal Information Security Management Act (FISMA) of 2002 and critical infrastructure protection requirements. FISMA and OMB Circular A-130, Appendix III, require that agencies and

their contractors maintain programs that provide adequate security for all information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. As part of our review, we will follow up on the unresolved findings from other relevant audit reports on information systems controls.
(OAS; W-00-04/05-40016; various reviews; expected issue date: FY 2005; work in progress)

Security Planning for the Unified Financial Management System

We will determine whether the Department has adequately addressed information systems security requirements as it develops and implements the Unified Financial Management System. Federal law and departmental policy require that information security be practiced throughout the life cycle of all systems. We will determine whether security plans and related internal control deliverables for the new system conform to Federal guidelines and incorporate best practices from the public and private sectors.
(OAS; W-00-05-42001; A-17-00-00000; expected issue date: FY 2005; new start)

Payment Management System Controls

Our review will document and evaluate the existence and reliability of information systems controls over the electronic funds transfer function of the Payment Management System, which supports the Program Support Center's primary mission. As the largest grant payment and cash management system in the Federal Government, the Payment Management System disburses more than $200 billion of the over $300 billion in annual Federal grant funds and financial assistance awarded each year. The system services the grant programs of all HHS operating divisions and more than 40 other Federal agencies. The National Critical Infrastructure Assurance Office recognizes the system as one of the Department's most important national-level assets.
(OAS; W-00-05-42002; A-17-00-00000; expected issue date: FY 2005; new start)

Automated Information System Security Program

We will document and evaluate the existence and reliability of the Automated Information System Security Program at selected operating divisions. This program helps to protect information resources in compliance with the Computer Security Act of 1987 and the directives of OMB and the National Institute of Standards and Technology. To date, limited reviews have been conducted to determine compliance with HHS-mandated security program requirements. We will focus on defined areas in the HHS Automated Information System Security Program handbook and the new Information Technology Security Program being developed/sponsored by HHS.
(OAS; W-00-05-42003; various reviews; expected issue date: FY 2005; new start)

Use of Social Security Numbers in the Integrated Time and Attendance System

Our review will determine whether the Program Support Center provides adequate controls over employees' Social Security numbers, which are used as identifiers in the HHS Integrated Time and Attendance System. Federal agencies are responsible for limiting the risk of unauthorized disclosure of Social Security numbers and must safeguard the integrity of the numbers by reducing opportunities for external entities to improperly obtain and misuse them. We will perform an application assessment of the Time and Attendance System's security, including its use of encryption.
(OAS; W-00-05-42004; A-17-00-00000; expected issue date: FY 2005; new start)

Grants and Contracts

Requested Audit Services

Throughout the year Members of Congress and officials from the Department and other Federal departments request that we perform a variety of audit services. Requested audit services include:

- recipient capability audits
- contract and grant closeouts
- indirect cost audits
- bid proposal audits
- other reviews designated to provide specific information requested by management

We will evaluate these requests as we receive them, considering such factors as why the audit is being requested, how the results will be used, when the results are needed, and whether the work is cost beneficial.
(OAS; W-00-05-12345; various reviews, expected issue date: FY 2005; new start)

Incurred Cost Contracts

We will initiate audits of certain contracts awarded by public health agencies, ACF, AoA, and/or the Office of the Secretary. Selection will be based on the materiality of the contract; the significance of contract modifications since the original award; and input from the operating divisions and the Assistant Secretary for Budget, Technology and Finance.
(OAS; W-00-05-58055; A-00-00-00000; expected issue date: FY 2005; new start)

State Issues

State Contracted Services

This review will examine States' increasing use and oversight of contractors that perform administrative and program functions in such areas as foster care, child support, and Statewide systems. Our prior work in the individual ACF program areas, as well as single audit reports, identified abuses in contract performance, service delivery, and costs claimed. We plan to expand that work to determine whether these are isolated incidents or indicators of systemic problems that should be addressed through improved control systems.
(OAS; W-00-05-58056; A-06-00-00000; expected issue date: FY 2005; new start)

State Pension Funds

These reviews will determine whether the Federal Government received an appropriate allocation when State pension funds were withdrawn, transferred to other State funds, or used to cover State expenses. We have identified pension transactions in two States that warrant review.
(OAS; W-00-05-58050; A-00-00-00000; expected issue date: FY 2005; new start)

State Trust Funds

We will determine whether a State appropriately charged the Federal Government for fees assessed on selected State trust funds. The State assessed fees as a way to transfer assets from some State trust funds to its general fund in order to balance its budget for State FY 2004.
(OAS; W-00-04-58051; A-04-05-03500; expected issue date: FY 2005; work in progress)

Excess Fund Reserves

We will determine whether internal service, self-insurance, or other State funds that receive Federal Government contributions have accumulated excess reserves. Previous reviews found that some States built excess reserves and transferred these reserves to their general funds without refunding the Federal share.
(OAS; W-00-05-58052; A-00-00-00000; expected issue date: FY 2005; new start)

Internal Service Funds

We will determine if a State has appropriately credited the Federal Government for its share of refunds (or redirections of revenues) from the State's internal service fund for information technology services. This service fund provides centrally managed computing services to all of the State agencies and to county and city governments within the State. The fund receives almost all of its revenue income through a fee-for-service arrangement.
(OAS; W-00-04-58052; A-04-04-03503; expected issue date: FY 2005; work in progress)

Statewide Cost Allocation Plan

We will examine the equitableness of a State's allocation of indirect costs to Federal programs. One State has been cited in at least three recent statewide audits for significant inequities in its cost allocation plan. The inequitable allocation methods or other errors may have resulted in overcharges or undercharges to the Federal Government.
(OAS; W-00-05-58053; A-00-00-00000; expected issue date: FY 2005; new start)

Joint Work With Other Federal and State Agencies

To efficiently use audit resources, we will continue our efforts to provide broader coverage of HHS programs by partnering with State auditors, State departmental internal auditors and inspectors general, State agencies, and departmental financial managers. Since 1994, active partnerships have been developed with States on such Medicaid issues as prescription drugs, clinical laboratory services, the drug rebate program, and durable medical equipment. Future joint initiatives will cover managed care issues, hospital transfers, prescription drugs, outpatient therapy services, and transportation services.

We will also expand our partnerships to cover ACF State-administered programs. Our Partnership Plan will highlight opportunities for joint reviews in critical areas, such as licensing and monitoring child care facilities and foster homes and assessing safeguards for the elderly and people with disabilities. We will also identify areas in which State auditors can help States avoid disallowances and financial penalties due to unallowable costs claimed or noncompliance with Federal program requirements. Based on current OIG work, our planned expansion could also cover such issues as increasing child support collections and reducing undistributed collections; expanding enrollment in the State Children's Health Insurance Program; and improving oversight of State contracting for services, providers, and systems.
(OAS; W-00-05-27002; various reviews; expected issue date: FY 2005; new start)

Other Issues

Annual Accounting of Drug Control Funds

We will determine whether HHS agencies are in compliance with the Office of National Drug Control Policy requirements for annual accounting of drug control funds. Each year, agencies that participate in the National Drug Control Program are required to submit to the Office of National Drug Control Policy a detailed accounting of all prior-year drug control funds, along with an accompanying OIG "authentication." We will make this authentication to express a conclusion on the reliability of the HHS assertions regarding FY 2004 drug control funds.
(OAS; W-00-05-58001; A-03-00-00000; expected issue date: FY 2005; new start)

Non-Federal Audits

Under OMB Circular A-133, State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards are required to have an annual organizationwide audit of all Federal money they receive. We will continue to review the quality of these audits by non-Federal auditors, such as public accounting firms and State auditors, in accordance with the circular. The objectives of our reviews are to ensure that the audits and reports meet applicable standards, identify any followup work needed, and identify issues that may require management attention.

We also provide up-front technical assistance to non-Federal auditors to ensure that they understand Federal audit requirements and to promote effective audit work. In addition, we analyze and record electronically the audit findings reported by non-Federal auditors for use by Department managers. Our reviews provide Department managers with assurance about the management of Federal programs and identify significant areas of internal control weaknesses, noncompliance with laws and regulations, and questioned costs that require formal resolution by Federal officials.

Reimbursable Audits

We will conduct a series of audits as part of the Department's cognizant responsibility under OMB Circular A-133. To ensure a coordinated Federal approach to audits of colleges, universities, and States, OMB Circular A-133 establishes audit cognizance—that is, which Federal agency has lead responsibility for audit of all Federal funds the entity receives. HHS OIG has audit cognizance for all State governments and most major research colleges and universities. Agreements have been reached among many OIG offices to reimburse the cognizant agency for audits performed at their request or the request of their program offices. *(OAS; W-00-05-50012; various reviews; expected issue date: FY 2005; new start)*

Internet Address

The FY 2005 OIG Work Plan and other OIG materials, including final reports issued and OIG program exclusions, may be accessed on the Internet at the following address:

http://oig.hhs.gov