

OFFICE OF INSPECTOR GENERAL  
**WORK PLAN**



**FISCAL YEAR 2006**

# Introduction

The project areas described in this Office of Inspector General (OIG) Work Plan reflect what we believe at the beginning of each fiscal year best identifies vulnerabilities of Department of Health & Human Services' (HHS) programs and activities, and promotes improvement in their efficiency and effectiveness. But OIG work planning does not end with publication of the plan. This is a dynamic, year-round process, adjusting to new issues, new information, and shifts in the priorities of Congress, the President, and the Secretary.

To ensure that our studies do not duplicate existing work and to build on that work, we identify and evaluate the audits, inspections, and studies done by others, such as the Government Accountability Office (GAO), the Centers for Medicare & Medicaid Services (CMS), and the Office of Management & Budget Program Assessment and Rating Tool (PART) process. We also undertake projects designed to determine the effectiveness of management actions to correct deficiencies cited in prior studies.

This document is divided into four sections. The first three consist of the ongoing and proposed work relating to each of the major program operating divisions of HHS: (1) CMS; (2) the seven major public health agencies: Agency for Health Care Research & Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA); and (3) Administration for Children & Families (ACF) and Administration on Aging (AoA). The fourth section contains projects that cut across Department programs, including State and local government use of Federal funds, and the functional areas of the Office of the Secretary.

**Note:** In addition to the projects outlined in this work plan, OIG will continue in FY 2006 its oversight of HHS programs regarding their provision of relief to the areas and individuals affected by Hurricanes Katrina and Rita. Our planning in this area was in progress at the time this document was being finalized. As we begin to conduct these projects related to hurricane relief efforts, resources will need to be shifted away from some of the audits, evaluations, and other work described in this plan. As a result, some of the projects we originally contemplated performing this year will be delayed until the following year.

# OIG Mission Activities

The work is planned and performed by the four direct mission components of OIG: the offices of Audit Services (OAS), Evaluation and Inspections (OEI), Investigations (OI), and Counsel to the Inspector General (OCIG).

## Program Audits

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OAS conducts financial and performance audits of departmental programs and operations to determine whether objectives are being achieved, which aspects of programs need to be performed more efficiently, and to identify systemic weaknesses that give rise to fraud, waste, or abuse. OAS also provides leadership and direction in carrying out the mandates of the Chief Financial Officers Act of 1990 and the Government Management Reform Act of 1994 relating to financial statement audits.

## Program Inspections

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OEI seeks to improve HHS program effectiveness and efficiency by conducting 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, Congress, and the public. The inspections in this work plan focus on programs with significant expenditures of funds, and in which important management issues have surfaced. The results of these inspections should generate useful information on how well the programs are operating and offer specific recommendations to improve their overall efficiency and effectiveness.

## Investigative Focus Areas

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OI conducts investigations of fraud and misconduct to safeguard the Department's programs and protect its beneficiaries. OI concentrates its resources on criminal investigations, but its activities are also aimed at deterring fraud and abuse by identifying systemic weaknesses and vulnerabilities that can be mitigated through corrective management actions, regulation, or legislation; and by pursuing criminal convictions and recovering damages and penalties through civil and administrative proceedings.

## Legal Counsel Focus Areas

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OCIG coordinates OIG's role in the judicial and administrative 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. OCIG issues special fraud alerts to the public, 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.

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# Centers for Medicare & Medicaid Services

## Medicare Hospitals

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### Adjustments for Graduate Medical Education Payments

We will determine if audit adjustments for direct and indirect graduate medical education (GME) that fiscal intermediaries make while settling Medicare cost reports were properly reflected in the revised Medicare reimbursement.

*(OAS; W-00-06-35189; A-04-06-00000; expected issue date: FY 2006; new start)*

### Payments for Observation Services versus Inpatient Admissions for Dialysis Services

During a recent audit, we noted that hospitals admitted patients for dialysis treatment, which lasted from 24 to 48 hours. Medical reviewers indicated that the stays were for the purpose of observation rather than treatment. CMS Intermediary Manual Part 3, Chapter II, section 3112.8 requires the physician's order to clearly state the level of care the patient requires; e.g., "admission to inpatient status" or "admission to observation status." Observation services are outpatient services that are paid on an hourly basis and can last up to 48 hours. Inpatient services are paid under a diagnosis-related group (DRG) at a much higher rate. The objective of this audit will be to determine whether payments were made for inpatient admissions for dialysis services when the physicians' orders stated the level of care as admission to observation status.

*(OAS; W-00-06-35190; A-04-06-00000; 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 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; various reviews; expected issue date: FY 2006; work in progress)*

### Nursing and Allied Health Education Payments

We will determine the appropriateness of payments for provider-operated 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. OMB has expressed interest in this area.

*(OAS; W-00-05-35123; A-00-00-00000; expected issue date: FY 2006; work in progress)*

### 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-00-04-35142; various reviews; expected issue date: FY 2006; work in progress)*

### **Inpatient Rehabilitation Facilities Payments**

We will review payments to inpatient rehabilitation facilities (IRF) 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 IRFs 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 IRFs. In addition, we will review rural IRFs' patients' length of stay and cost of services to determine whether the Medicare payment increase is justified. We will also determine whether claims as a discharge should have been paid as a transfer.

*(OAS; W-00-04-35103, W-00-05-35103, W-00-05-35127, W-00-05-35178, W-00-05-35153, W-00-05-35183, W-00-05-35184; various reviews, expected issue date: FY 2006; work in progress)*

### **Inpatient Hospital Payments for New Technologies**

We will review payments made to hospitals for new services and technologies. We will examine the costs associated with the new devices and technologies to determine if the reimbursement is appropriate.

*(OAS; W-00-06-35191; A-04-06-00000; expected issue date: FY 2006; new start)*

### **Inpatient Psychiatric Hospitals**

We will review payments to psychiatric hospitals under the prospective payment system to determine the extent to which they were made in accordance with Medicare laws and regulations. We will review outlier payments made to psychiatric hospitals, as well as payments made for interrupted stays. We will also review rural psychiatric hospitals' patients' length of stay and cost of services to determine whether the Medicare payment is justified.

*(OAS; W-00-06-35192; various reviews; expected issued date: FY 2006; new start)*

### **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 2006; new start)*

### **Long Term Care Hospital 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, outlier payments, and payments made under arrangements to these hospitals.

*(OAS; W-00-04-35128, various reviews, expected issue date: FY 2006, 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 inpatient prospective payment system.

*(OAS; W-00-05-35101; A-06-00-00000; expected issue date: FY 2006; 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 post transplant 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 and will identify and review controls and cost containment practices used by organ procurement organizations to acquire organs for transplant.

*(OAS; W-00-05-35083/04-35083; various reviews; expected issue date: FY 2006, work in progress)*

### **Rebates Paid to Hospitals**

We 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 2006; work in progress)*

### **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; A-00-00-00000; expected issue date: FY 2006; 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 2006; work in progress)*

### **Outpatient Department Payments**

We will review payments to hospital outpatient departments under the prospective payment system to determine the extent to which they were made in accordance with Medicare laws and regulations. We will review the appropriateness of payments made for multiple procedures, repeat procedures, and global surgeries.

*(OAS; W-00-06-35193; various reviews; expected issued date: FY 2006; new start)*

### **Unbundling of Hospital Outpatient Services**

We will determine the extent to which hospitals and other providers are submitting claims for services that should be bundled into outpatient services. Sections 9342 (c) and (g) of the Omnibus Reconciliation Act of 1986 prohibits the unbundling of hospital services to include outpatient as well as inpatient services. The unbundling of services could lead to unnecessary Medicare expenditures.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **“Inpatient Only” Services Performed in an Outpatient Setting**

We will determine if Medicare payments are appropriately denied for “inpatient only” and related services performed in an outpatient setting and assess the extent to which Medicare beneficiaries are held liable for denied inpatient claims for these services. The BBA and the Balanced Budget Refinement Act of 1999 established and refined the Hospital Outpatient Prospective Payment System which went into effect August 1, 2000. We will also assess whether CMS computer edits required to implement the outpatient prospective payment system were implemented.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Diagnosis-Related Group Coding**

We will examine DRG codes to determine whether some acute care hospitals exhibit aberrant coding patterns. Under the prospective payment system, DRGs for inpatient acute care depend on accurate coding of diagnoses and procedures. Inaccurate coding by hospitals can lead to Medicare overpayments.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **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 2006; work in progress)*

## **Medicare Home Health**

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### **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 for which the 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 2006; 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; various reviews; expected issue date: FY 2006; work in progress)*

### **Medicare Home Health Agency Survey and Certification Deficiencies**

We will examine trends and patterns in home health agencies survey and certification deficiencies. The Social Security Act requires that CMS survey the quality of care and services furnished by home health agencies as measured by indicators of medical, nursing, and rehabilitative care every 36 months. We will also identify whether any home health agencies show patterns of cyclical noncompliance with certification standards.

*(OEI; 00-00-00000; various reviews; expected issue date: FY 2006; new start)*

### **Accuracy of Data on the Home Health Compare Web Site**

We will determine to what extent the Home Health Compare Web site includes accurate and complete information on Medicare-certified home health agencies. The CMS maintained Web site provides beneficiaries and



their families with information on all home health agencies certified by Medicare as of January 2003. We will also examine how CMS identifies and updates missing and incorrect information on the database.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Medicare Nursing Homes**

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### **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 (SNF) 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 2006; work in progress)*

### **Use of Additional Funds Provided to Skilled Nursing Facilities**

In July 2003, CMS published a 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 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 2006; new start)*

### **Skilled Nursing Facilities' Involvement in Consecutive Inpatient Stays**

We will determine whether SNF care provided to Medicare beneficiaries with consecutive inpatient stays was medically reasonable and necessary. An inpatient hospital stay must precede all SNF stays. This study will focus on beneficiaries who experience three or more consecutive stays, including at least one SNF facility stay. We will also examine the extent and nature of consecutive Medicare hospital inpatient stays.

*(OEI; 07-05-00340; expected issue date: FY 2007; new start)*

### **Skilled Nursing Facility Payments for Day of Discharge**

Medicare regulations state that the day of discharge is not a day of billable services for SNFs. We will determine if Medicare is inappropriately paying SNFs for services on the day of discharge.

*(OAS; W-00-06-35194; A-04-06-00000; expected issue date: FY 2006; new start)*

### **Skilled Nursing Facility Consolidated Billing**

We will determine whether controls are in place to preclude duplicate billings under Medicare Part B for services covered under the SNF prospective payment system (PPS) and assess the effectiveness of Common Working File edits established in 2002 to prevent and detect improper payments. Under the PPS, the SNF has the Medicare billing responsibility for virtually all of the Medicare-covered services that its residents receive. As a result, the outside supplier must receive payment from the SNF, rather than the Medicare Part B carrier. Prior OIG work identified millions of dollars in improper payments associated with outpatient hospital, ambulance, laboratory, and radiology services during 1999 and 2000. We will identify any additional improper payments for services during calendar years 2001, 2002, and 2003 and also determine whether the Common Working File edits are effective in detecting and preventing improper payments.

*(OAS; W-00-05-35185; A-01-06-00000; expected issue date: FY 2006; 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 quality of care-related deficiencies 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; various reviews; expected issue date: FY 2006; new start)*

### **Nursing Home Residents Minimum Data Set Assessments and Care Planning**

We will examine the type, frequency, and severity of nursing home deficiencies related to Minimum Data Set assessments and care planning. 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 also examine methods the State survey agencies use in identifying assessments and care plans that do not address individualized needs of residents.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Enforcement Actions Against Noncompliant Nursing Homes**

We will continue our work in examining 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, 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; OEI-06-03-00390, OEI-06-03-00400, OEI-06-03-00410; expected issue date: FY 2006; work in progress)*

### **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)*

### **State Compliance with Complaint Investigation Guidelines**

We will determine the extent to which States follow CMS guidelines 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 2006; work in progress)*

### **Prescription Drug Plan Formularies and Dually Eligible Nursing Home Residents**

We will determine whether dual eligible nursing home residents are able to maintain their preexisting drug regimens after implementation of the Medicare Part D drug benefit. We will review if drug regimens changed for residents that were auto-enrolled in a prescription drug plan (PDP) and those who elected a PDP. In addition, we will assess residents' awareness of their options to appeal PDP formulary decisions or change their PDP.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## Medicare Hospice

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### Oversight of Hospice Providers

We will determine to what extent CMS ensures that hospice providers meet Medicare quality of care standards. Medicare expenditures for hospice increased from \$3.5 billion in 2001 to almost \$6 billion in 2003. We will examine what hospice provider oversight activities are performed, what hospice performance information is maintained by CMS, and to what extent CMS utilizes oversight information to track hospice performance including quality of patient care.

*(OEI; 06-05-00260; expected issue date: FY 2006; work in progress)*

### Hospice Payments to Nursing Facilities

We will determine whether hospice payments for services for dually eligible patients/residents residing in nursing facilities are accurate. OIG's previous work in this area indicated that nursing home hospice patients received nearly 46 percent fewer nursing and aide services from hospice staff than hospice patients living at home. OIG also raised concerns about the appropriateness of the arrangements hospices have with nursing facilities to provide services. We will examine what services are provided by hospice, by nursing homes, whether there are any overlaps in these services, and if so, identify any duplication in reimbursement by Medicare hospice and Medicaid.

*(OEI; 00-00-0000, expected issue date: FY 2006; new start)*

## Medicare Physicians and Other Health Professionals

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### Billing Service Companies

We will identify and review the relationships between billing companies and the physicians and other Medicare providers who use their services. We will also identify the types of arrangements physicians and other Medicare providers have with billing services and determine the impact of these arrangements on physicians' billings.

*(OAS; W-00-05-35162; various reviews; expected issue date: FY 2006; 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 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 the beginning of January 2001 and the end of June 2003. Using time reporting and payroll documentation from VA, we will identify the services rendered while the physicians were reported on duty at VA hospitals and remunerated for such duty.

*(OAS; W-00-05-35155; A-00-00-0000; expected issue date: FY 2006; work in progress)*

### Care Plan Oversight

We will evaluate the efficacy of controls over Medicare payments for care plan oversight claims submitted by physicians. Care plan oversight exists where there is physician supervision of patients in hospice care that require complex or multidisciplinary modalities involving regular physician and/or revision of care plans. 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; various reviews; expected issue date: FY 2006; work in progress)*

### **Ordering Physicians Excluded From Medicare**

We 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. Federal regulation generally precludes physicians who are excluded from Federal health care programs from ordering or performing services for Medicare beneficiaries. In a current review, we identified a number of services that had been ordered by excluded physicians.

*(OAS; W-00-04-35116; various reviews; expected issue date: FY 2006; work in progress)*

### **Physician Pathology Services**

We will focus on pathology services performed in physicians' offices. We will determine if the billings for pathology laboratory services comply with Medicare Part B requirements. 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 2006; work in progress)*

### **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.

*(OAS; W-00-05-35165; various reviews; expected issue date: FY 2006; work in progress)*

### **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 2006; work in progress)*

### **Payment to Providers of Care for Initial Preventive Physical Examination**

Section 611 of the Medicare Modernization Act (MMA) provides for coverage under Part B of an initial preventive physical examination (IPPE), including a screening electrocardiogram (EKG) for new Medicare beneficiaries effective January 1, 2005. In addition to the screening EKG, the IPPE must include a measurement of height, weight, blood pressure, a review of medical and social history, assessment of the potential for depression, and evaluation of functioning ability. For new Medicare beneficiaries with established relationships, the physician is presented with the opportunity to claim a higher payment for IPPE under a new Healthcare Common Procedure Coding System (HCPCS) code, G0344, for services that may already have been performed in a past evaluation and management visit. We will evaluate the impact of IPPE on Medicare payments and physician billing practices.

*(OAS; W-00-06-35195; A-02-06-00000; expected issue date: FY 2006; new start)*

### **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 2006; 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)*

## **“Long Distance” Physician Claims**

We will review Medicare claims for face-to-face physician encounters where a significant distance separated the practice setting and the beneficiary’s location. 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)*

## **Potential Duplicate Physical Therapy Claims**

We will assess whether CMS’s systems are able to identify and prevent payment for potential duplicate claims for physical therapy submitted by providers. In May 2004, CMS issued a fraud alert regarding physical therapy suppliers switching their submission of claims between Part A and Part B. We will review the current Common Working File operations to determine whether edits are adequately identifying potential duplicate physical therapy claims submitted to Part A and Part B contractors.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start.)*

## **Medicare Medical Equipment and Supplies**

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### **Durable Medical Equipment Payments for Beneficiaries Receiving Home Health Services**

During recent audits of home health agency (HHA) services, beneficiaries have indicated during interviews that they receive numerous durable medical equipment (DME) items and supplies. We will review medical records for DME items and supplies furnished to beneficiaries receiving HHA services to determine whether the items and supplies were reasonable and necessary for the beneficiaries’ conditions.

*(OAS; W-00-06-35196; A-02-06-00000; expected issue date: FY 2006; new start)*

### **Medicare Payments for Therapeutic Footwear**

Under certain circumstances, Medicare covers therapeutic footwear for beneficiaries who have diabetes and at least one of several related conditions. Medicare payments for therapeutic footwear totaled over \$130 million in 2003. A previous OIG report indicated that a significant percentage of payments made for therapeutic footwear did not have adequate documentation to support the beneficiaries’ medical need for the footwear. The objective of this study will be to determine whether therapeutic footwear furnished by individual suppliers was reasonable and necessary for the beneficiaries to whom it was provided.

*(OAS; W-00-05-35187; A-04-05-05033; expected issue date: FY 2006; work in progress)*

### **Medical Necessity of Durable Medical Equipment**

We will determine the appropriateness of Medicare payments for certain items of durable medical equipment, such as power wheelchairs, wound care equipment and supplies, and glucose test strips. We will assess whether the suppliers’ documentation supports the claim, whether the item was medically necessary, and/or whether the beneficiary actually received the item.

*(OEI; various reviews; 00-00-00000; expected issue date: FY 2006; 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, parenteral nutrition, wound care equipment and supplies, and oxygen equipment and supplies.

*(OEI; various reviews; 00-00-00000; expected issue date: FY 2006; new start)*

## Home Blood Glucose Testing Supplies

We will assess the appropriateness of Medicare Part B payments made to a supplier for home blood glucose testing supplies, specifically test strips and lancets. Medicare covers the supplies based on the medical needs of the diabetic patients. The utilization guidelines issued by Medicare allow up to 100 test strips and 100 lancets every 3 months for noninsulin treated patients, and up to 100 test strips and 100 lancets every month for insulin treated patients. However, Medicare may cover supplies in quantities greater than the utilization guidelines if certain criteria are met.

*(OAS; W-00-05-35182; A-09-05-00000; expected issue date: FY 2006; work in progress)*

## Medicare Drug Reimbursement

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### 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 the MMA.

*(OAS; W-00-05-35174; various reviews; expected issue date: FY 2006; work in progress)*

### Collecting and Maintaining Average Sales Price Data

We will evaluate CMS's system for collecting and maintaining the 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 the MMA, Medicare will base payments for most of these drugs on the ASP. The MMA requires manufacturers to report accurate ASP information to CMS. We will also assess CMS's oversight of the ASP reporting.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### Effectiveness of Average Sales Price Cost Controls

We will examine why reported average sales prices are rising, how these increases reflect provider costs, and the extent to which these price changes have affected the expected cost reductions of the average sales price program. The MMA introduced drug reimbursements based on manufacturers' average sales prices. The intent of the MMA was both to control Medicare drug expenditures and also link Medicare reimbursement to costs incurred by providers. Emerging evidence, however, indicates that the reported average sales price for certain drugs have been rising, thereby increasing Medicare costs.

*(OAS; W-00-06-35197; various reviews; expected issue date: FY 2006; new start)*

### Medicare Payments for Oral Antiemetic Medications

Medicare covers certain oral antiemetic medications when they are used as a full therapeutic replacement for the intravenous antiemetic medication. The oral antiemetic must replace the intravenous antiemetic medication that would otherwise have been administered immediately before, or within 48 hours after, the time of the chemotherapy treatment. We will assess Medicare payments for oral antiemetic medications.

*(OAS; W-00-06-35198; A-04-06-00000; 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 generally pays for drugs based on the average sale price methodology. The MMA mandates that OIG conduct studies, which may include market surveys, to determine widely available market prices for Part B drugs. The market price will then be compared to average sales price. Also, as mandated by the MMA, we will compare reported average manufacturer prices to average sales price.

*(OEI; 03-04-00430; 03-04-00440; expected issue date: FY 2006; new start)*

### **Duplicate Payments for Part B Drugs Under the Competitive Acquisition Program**

We will determine if there are duplicate payments to physicians for Part B drugs purchased from vendors selected through a competitive bidding process and those directly reimbursed under the average sales price system. We will further evaluate what systems CMS has in place to prevent duplicate payments for Part B drugs.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Medicare Reimbursement for End Stage Renal Disease Drugs**

We will determine the difference between Medicare reimbursement for selected billable end stage renal disease (ESRD) drugs and the acquisition cost of these drugs to ESRD facilities. The MMA mandates that we conduct a study with respect to drugs furnished to ESRD patients under the Medicare program that are billable by the ESRD facilities. The study will also analyze the growth rate of facilities' expenditures for the ESRD drugs.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Adequacy of Reimbursement Rate for Drugs Under the Average Sales Price**

We 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 the ASP. The study will take into account practices of different sizes in determining the adequacy of Medicare reimbursement.

*(OAS; W-00-05-35167; various reviews, expected issue date: FY 2006; work in progress)*

## **Medicare Part D Administration**

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### **CMS Program Integrity Safeguards for Medicare Drug Plan Applicants**

We will assess the safeguards that CMS has implemented to identify if Medicare drug plan applicants qualify to provide drug benefits under Medicare Part D. We will also analyze to what extent CMS addresses program integrity concerns associated with the sponsors who apply to offer drug plan benefits. Additionally, we will review regulations and guidance associated with the application and approval process focusing on business integrity and required compliance.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Beneficiary Awareness of the Medicare Part D Low-Income Subsidy**

We will determine to what extent Medicare beneficiaries are aware of the low-income subsidy program available under Medicare Part D. The low-income subsidy benefit provides assistance to Medicare beneficiaries in receiving full or partial subsidies of premiums and reductions in cost sharing for the Medicare prescription drug benefit. We will also analyze the methods used to educate beneficiaries about the low-income subsidy.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Tracking Beneficiaries True Out-of-Pocket Costs for Part D Prescription Drug Coverage**

We will examine CMS's oversight of the calculation of beneficiaries' true out-of-pocket (TrOOP) expenses that qualify toward catastrophic coverage. The study will also analyze the accuracy of tracking beneficiaries' TrOOP expenses in the Coordination of Benefits system.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Prescription Drug Plan and Marketing Materials for Prescription Drug Benefits**

We will determine whether marketing materials for Medicare prescription drug plans are in compliance with CMS regulations and guidelines. We will also examine whether the prescription drug plans' marketing materials are clear and understandable to Medicare beneficiaries according to CMS guidelines.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Auto-Enrollment of Dual Eligibles into Medicare Part D Plans**

We will evaluate CMS's auto-enrollment of dually eligible beneficiaries into Medicare Part D drug coverage plans as the MMA shifts coverage of prescription drugs for dual eligibles from Medicaid into Part D plans. The study will also examine the proportion of dual eligible beneficiaries who selected their own Part D plans, rather than being automatically enrolled, as well as those not enrolled in any Part D plan.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Medicare Prescription Drug Benefit Pharmacy Access in Rural Areas**

We will measure beneficiary access to retail pharmacies that dispense Medicare Part D covered prescription drugs in rural areas. The study will also assess the extent to which drug plans comply with minimum pharmacy access requirements. The MMA mandates that beneficiaries must have convenient access to retail pharmacies and establishes minimum pharmacy access standards.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Monitoring Fluctuation in Drug Prices Under Prescription Drug Plans and Medicare Advantage Prescription Drug Plans**

We will examine price variation patterns for PDPs and Medicare Advantage Prescription Drug Plan (MA-PD). The Part D prescription drug benefit authorized in the MMA allows beneficiaries to enroll in drug coverage through a PDP or MA-PD. In general, beneficiaries are only allowed to change PDPs or MA-PDs during specific annual open enrollment periods, but plans can change the drugs available under their formularies and the cost-sharing status of the drugs. This study will monitor fluctuation in drug prices under the PDP and MA-PD plans.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Coordination and Oversight of Medicare Part B and D to Avoid Duplicate Payments**

We will determine whether there is sufficient coordination and oversight of Medicare B and Part D to prevent duplicate payments for drugs. Drugs for which payment is available under Medicare Part B will continue to be covered by Part B and should not also be reimbursed under Medicare Part D drug coverage. Proper coordination will be needed to prevent duplicate payments for the same prescription under Part D.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Enrollee Access To Negotiated Prices for Covered Part D Drugs**

We will examine compliance with the requirement that Prescription drug plans and Medicare Advantage drug plans must provide enrollees access to negotiated prices for covered Part D drugs including all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, regardless of whether the drug was paid for under the benefit.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*



### **Prescription Drug Plans' Use of Formularies**

We will evaluate whether prescription drug plans' use of formularies comply with Federal rules and regulations. More specifically, the study will focus on three broad areas: (1) the Pharmacy and Therapeutics committees that construct the formularies, (2) the breadth and depth of drugs included on the formularies, and (3) beneficiary management tools including beneficiaries' rights to formulary exceptions and appeals.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Coordination Between State Pharmaceutical Assistance Programs and Medicare Part D**

We will examine the coordination between State Pharmaceutical Assistance Programs (SPAP) and Medicare Part D to identify whether beneficiaries are able to obtain needed assistance and appropriate drug coverage. SPAPs provide funding for prescription drugs to eligible senior and disabled citizens in their States. A significant portion of individuals currently enrolled in SPAPs will become eligible for Medicare Part D drug coverage in January 2006. SPAPs may offer wrap-around benefits to beneficiaries with Medicare Part D coverage who experience a coverage gap.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Prescription Drug Plans' and Medicare Advantage Drug Plans' Implementation of Required Programs to Deter Fraud, Waste and Abuse**

We will evaluate the PDPs' and MA-PDs' implementation of required programs to deter fraud, waste, and abuse. We will also examine CMS programs' integrity systems to oversee PDPs' and MA-PDs' fraud, waste, and abuse programs. This study will follow up on the OIG inspection that will assess program integrity safeguards in the PDP and MA-PD application process, including applicants' descriptions of their plans for implementing such programs.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **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. The discount card program will end on January 1, 2006, and we will present the results of our review as "lessons learned" for use in the full prescription drug benefit.

*(OAS; W-00-05-35166; various reviews; expected issue date: FY 2006; work in progress)*

### **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; work in progress)*

## **Medicare Part D Drug Benefit Payments**

To implement the new Part D drug benefit established by MMA, CMS will establish new policies and procedures, as well as new computerized payment systems. To determine whether these policies, procedures, and payment systems are working as intended, we will sample Part D beneficiaries' claim files to determine whether controls have been implemented and are working to ensure that (1) benefits are paid on behalf of eligible beneficiaries and (2) Medicare, as well as the beneficiaries, paid appropriate amounts for drug coverage.

*(OAS; W-00-06-35199; various reviews; expected issue date: FY 2006; new start)*

## **State Contribution to Drug Benefit Costs Assumed by Medicare**

Under the MMA, Medicare will subsidize prescription drug costs for full benefit, dual eligible individuals. Beginning in January 2006, each of the 50 States and the District of Columbia will be responsible for making monthly payments to the Federal Government to defray a portion of the Medicare drug expenditures for these individuals. We will determine States' compliance with laws and regulations and include reviews of data used to calculate States' contribution payments, calculation of the States' contribution payments, the States' payment amounts, and CMS and States' controls related to contribution payments.

*(OAS; W-00-06-35186; various reviews; expected issue date: FY 2006; work in progress)*

## **Medicare Part D Risk-Sharing Payments and Recoveries**

Medicare will share a portion of a prescription drug plan's losses or profits resulting from expenses that fall either above or below an expected target level. CMS will calculate risk-sharing payments or recoveries based on information provided by the prescription drug plans. We will determine whether CMS and the prescription drug plans have established adequate controls over Medicare Part D risk sharing payments and recoveries to ensure that (1) the plans submit accurate and timely information to CMS; (2) CMS calculations are performed in accordance with applicable laws and regulations; and (3) payments and recoveries are made in accordance with applicable laws and regulations.

*(OAS; W-00-06-35200; various reviews; expected issue date: FY 2006; new start)*

## **Prescription Drug Benefit**

Under the MMA, effective January 2006, Medicare Advantage (MA) organizations offering a coordinated care plan must offer throughout that plan's service area at least one MA plan that includes prescription drug coverage under Part D. Many MA organizations currently offer a prescription drug benefit as a supplemental benefit when expected Medicare payments exceed Medicare costs. While any supplemental benefits (prescription drug benefit under Part D or as an additional benefit under an MA plan) offered by the plan may be viewed as a single package of supplemental benefits, the two types of supplemental benefits are considered separately for bidding purposes. We will examine the bidding of prescription drugs when these two scenarios are present. We will also examine the impact of the amount a beneficiary must spend on Part D covered drugs to reach catastrophic coverage of prescription drugs available under a MA sponsored plan and any drug benefit provided as an additional benefit.

*(OAS; W-00-06-35201; various reviews; expected issued date: FY 2007; new start)*

## **Other Medicare Services**

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### **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 the clinical diagnostic laboratory fee schedule. Preliminary work indicated that \$73 million of laboratory services were rendered in hospital settings 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 the percentage of these costs that are unallowable.

*(OAS; W-00-05-35168; various reviews; expected issue date: FY 2006; work in progress)*

### **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 2006; 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 was 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 2006; work in progress)*

### **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 Medicare Part B improperly paid a significant amount of calendar year 2001 ambulance services for periods when the beneficiary was an inpatient. This follow-up review will cover calendar years 2001 and 2002.

*(OAS; W-00-05-35085; A-01-05-00000; expected issue date: FY 2006; work in progress)*

### **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 Medicare Part B improperly paid a significant amount of calendar year 2001 radiology services for periods when the beneficiary was an inpatient. This follow-up review will cover calendar years 2001 and 2002.

*(OAS; W-00-05-35169; A-01-05-00000; expected issue date: FY 2006; work in progress)*

### **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 and other specified 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 2006; work in progress)*

### **Separately Billable Laboratory Services under the End Stage Renal Disease Program**

The MMA requires a report on a bundled prospective payment system (PPS) for ESRD services. This bundled PPS would include certain clinical laboratory tests that are currently separately billable. The current facility payment (composite rate) includes payments for certain automated multi-channel chemistry (AMCC) tests provided routinely at specified frequencies. Any AMCC tests performed in excess of specified frequencies or that are not included in the composite rate payment are billed separately provided that medical necessity is documented. Prior OIG reviews concluded that providers were paid separately for AMCC tests included in the composite rate. To ensure that the bundled PPS rate is based on valid data, we will review providers' current compliance with the current payment policies for AMCC tests furnished to ESRD beneficiaries.

*(OAS; W-00-06-35202; A-01-06-00000; expected issue date: FY 2006; new start)*

### **Ground Ambulance Services**

Section 1861(s)(7) of the Social Security Act provides coverage for ambulance services where the use of other means of transportation is contraindicated by the individual's condition. Federal regulation code 42 CFR § 410.40 requires that the ambulance service provided to the beneficiary be medically necessary, such that other means of transportation would endanger the beneficiary's health. Further, the ambulance services must be reasonable and Medicare payment should be for the lowest level of service necessary to meet the patient's medical need. The objective of this study will be to determine whether ambulance services furnished by individual providers were reasonable and necessary and furnished at the appropriate level.

*(OAS; W-00-06-35179; A-06-00-00000; expected issue date: FY 2006; work in progress)*

### **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 2006; new start)*

### **Medicare Pricing of Laboratory Services**

We will compare Medicare payment rates for certain laboratory tests with the rates of other Federal and State health programs and private payers. In 2003, Medicare-allowed charges for tests paid under the laboratory fee schedule totalled \$3.2 billion. This study will build upon prior OIG work in which we found that Medicare paid significantly higher prices than other payors for certain laboratory tests.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

### **Quality of Care in Dialysis Facilities**

We will examine the level of CMS oversight of the ESRD facilities. Previous reports showed that the length of time between the 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; 05-05-00300; expected issue date: FY 2006; new start)*

## **Preventive Care Services**

We will examine the access to and use of Medicare preventive screening services such as physical exams, cardiovascular screening tests, mammograms, and laboratory diagnostic tests. The MMA authorized coverage of certain screening examinations and tests, effective January 2005. We will also monitor whether appropriate controls are in place to identify inappropriate payments or utilization of these services.

*(OEI; 00-00-00000; expected issue date: FY 2007; new start)*

## **Medicare Managed Care**

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### **Regional Plan Stabilization Fund**

We will assess compliance with MMA requirements and CMS regulatory guidance pertaining to the establishment and management of the “Regional Plan Stabilization Fund for CYs 2004 and 2005.” It will also examine the adequacy, propriety and timeliness of CMS’s review processes for evaluating Managed Care Organization (MCO) proposals and the awarding of stabilization funds.

*(OAS; W-00-05-35171; various reviews, expected issue date: FY 2006; work in progress)*

### **Adjusted Community Rate Proposals**

We 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 2006; work in progress)*

### **Followup on Adjusted Community Rate Proposals**

We 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 2006; 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. 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 2006; work in progress)*

### **Managed Care Encounter Data**

We 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 comprised 10 percent of the rate in 2003. The risk-adjusted portion increased to 50 percent in 2005 and will become 75 percent in 2006. It will eventually be 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 2006; 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 2006; work in progress)*

### **Duplicate Medicare Fee-For-Service Payments**

We will determine if duplicate Medicare fee-for-service payments were made to providers for beneficiaries enrolled in MCO operating under a risk-based contract. MCOs paid under a risk-based model are paid a monthly per capita premium amount. The MCOs assume full financial risk for all care provided to Medicare beneficiaries and must provide all Medicare-covered services. Payments to providers for these beneficiaries are unallowable. Previous reviews have identified potential duplicate Medicare fee-for-service payments for services that should have been paid for by an MCO. We will identify whether CMS or its fiscal intermediaries have sufficient controls in place to prevent such duplicate payments from occurring.

*(OAS; W-00-05-35122; A-07-05-01016; expected issued date: FY 2006; work in progress)*

### **Marketing Practices of Managed Care Organizations**

We will determine whether Medicare MCOs market their plans to beneficiaries pursuant 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 to an MCO.

*(OEI; 01-05-00130; expected issue date: FY 2006; work in progress)*

### **Medicare Capitation Payments to Managed Care Plans After a Beneficiary's Death**

We will determine to what extent payments are made to MA plans for deceased beneficiaries. MA organizations are required to submit information to CMS about the status of their members and report specific beneficiary status changes such as death. We will examine processes and systems used by CMS to identify Medicare Advantage overpayments due to beneficiary deaths. Further, we will assess what proportion of payments are subsequently recovered by CMS.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Medicare Advantage Regional Plans: Availability, Physician Participation, and Beneficiary Enrollment in Rural Areas**

We will determine the availability of regional MA plans to beneficiaries residing in rural areas. We will also assess the extent to which Medicare beneficiaries residing in rural areas choose to enroll in Medicare Advantage plans and whether physician practices in rural areas participate in regional MA plans. Historically, Medicare

managed care plans have been concentrated in urban areas. The MMA supports introduction of Medicare Advantage regional plans beginning in 2006.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Dissemination of Beneficiary Information Materials by Medicare Advantage Prescription Drug Plans**

We will determine the extent to which MA-PD plans meet statutory and regulatory requirements regarding the content of their informational materials distributed to beneficiaries. We will also examine whether marketing materials for the MA-PD plans comply with CMS policy guidelines.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Medicare Contractor Operations**

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### **Pre-award 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 2006; work in progress)*

### **Contractors' Administrative Costs**

As requested by CMS, we will review administrative costs claimed by various contractors for their Medicare activities, paying 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 2006; 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 2006; 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 2006; work in progress)*

### **Unfunded Pension Costs**

In this review, which was requested by CMS, we 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 2006; 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 2006; 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 2006; work in progress)*

### **CMS Oversight of Contractor Performance**

We will assess CMS oversight of contractor performance. In prior work, we have 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; various reviews; expected issue date: FY 2007; 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; various reviews 03-04-00050; 00-00-00000; expected issue date: FY 2006; work in progress)*

### **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 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; 07-05-00100; expected issue date: FY 2006; 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 2006; work in progress)*

### **Handling of Beneficiary Inquiries**

We will assess Medicare beneficiaries' experience accessing information from Medicare-funded call centers. In July 2004, all calls to Medicare-funded call centers began routing through a single phone number: 1-800-Medicare. As changes occur in Medicare coverage and delivery options as a result of the MMA, beneficiary



calls are expected to increase. Prior OIG work found that some beneficiaries had difficulty obtaining needed information from Medicare-funded call centers.

*(OEI: 00-00-00000; expected issue date: FY 2007; new start)*

### **Provider Education and Training**

We will examine Medicare carriers' efforts to educate and train providers. The MMA created new incentives and enhanced resources for contractors to improve education and outreach. One of the primary goals of provider education is to improve billing practices and to reduce payment errors and Medicare program losses. We will assess the extent to which these goals are being met.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Medicare Appeals Process**

We will update prior work in which we identified significant problems in the Medicare appeals process which resulted in the system being backlogged and untimely. Several recommendations in these reports have subsequently been addressed by legislation, including the transfer of the Administrative Law Judge (ALJ) function from Social Security Administration (SSA) to HHS and modifying the timeframes for the various levels of appeals to provide adequate time for fair and effective processing while still ensuring timely and efficient resolution of appeals. In a series of reviews, we will examine the early implementation of these changes to the entire appeals process, including the transfer of ALJs to HHS. We will also evaluate the impact of these changes on the process including examining the timeliness and outcomes of appeal processing at the various levels.

*(OEI; various reviews; 00-00-00000; expected issue date: FYs 2006 and 2007; new start)*

## **Medicaid Hospitals**

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### **Medicaid Graduate Medical Education Payments**

We will examine Medicaid Graduate Medical Education (GME) payment programs. 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; and W-00-05-39022; various reviews; expected issue date: FY 2006; work in progress)*

### **Hospital Outlier Payments**

We will determine whether Medicaid State agencies' methods of computing inpatient hospital award cost outlier payments result in reasonable payments. 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 2006; work in progress)*

### **Medicaid Diagnosis-Related Group Payment Window**

We will determine whether PPS 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 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 a joint project with the Department of Justice, 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 2006; 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 and W-00-05-39023; various reviews; expected issue date: FY 2006; work in progress)*

## **Hospital Eligibility for Disproportionate Share Hospital Payments**

We 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; work in progress)*

## **Medicaid Long Term and Community Care**

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### **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; W-00-05-39040; various reviews; expected issue date: FY 2006; work in progress)*

### **Community Residence Claims**

We 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 2006; work in progress)*

### **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 2006; work in progress)*

### **Medicaid Home Health Care Services to Dually Eligible Recipients**

At the request of CMS, we will examine Medicaid home health services provided to recipients dually eligible for Medicare and Medicaid recipients. In one state we found that home health care providers were being paid under the Medicaid program for services provided to dually eligible recipients whose services were concurrently

covered under the Medicare home health prospective payment system. Our review will determine if the services paid by Medicaid duplicate the Medicare prospective payment made to the provider.

*(OAS; W-00-05-39008; A-01-04-00011; expected issue date: FY 2006; 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. Further, reimbursement is not available unless these services are separately billable under the Medicaid program.

*(OAS; W-00-04-39010; W-00-05-31082; various reviews; expected issue date: FY 2006; work in progress)*

### **Personal Care Services**

We 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.

*(OAS; W-00-05-31035; various reviews; expected issue date: FY 2006; work in progress)*

### **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.

*(OAS; W-00-03-39003; various reviews; expected issue date: FY 2006; work in progress)*

### **Additional Reimbursement for Distinct Part/Nursing Facilities of Public Hospitals**

At the request of CMS, we will determine whether one State established eligibility for additional reimbursement for the distinct part/nursing facilities of public hospitals and properly calculated the reimbursement amount pursuant to State regulations. For this State, a nursing facility is eligible for additional reimbursement if the facility provides services to Medicaid recipients, is a distinct part of an acute care hospital providing skilled nursing services, and is owned or operated by a county, city, or health care district. The additional reimbursement amount, when combined with all other Medicaid payments the facility received, should not exceed 100 percent of projected costs.

*(OAS; W-00-05-39038; A-09-05-00050; expected issue date: FY 2006; work in progress)*

### **Medicaid Eligibility and the Working Disabled**

We will evaluate how Federal and State agencies determine Medicaid eligibility for working disabled individuals. 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 that OIG ascertain how effectively the State and local offices are assuring eligibility for working disabled individuals.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## Medicaid Mental Health Services

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### 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 2006; 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 2006; 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; W-00-05-39035; W-00-05-31099; A-05-00-00000; expected issue date: FY 2006; work in progress)*

### Medicaid Supplemental Mental Health Payments to Prepaid Inpatient Health Plans

We will focus on States' Medicaid supplemental mental health payments to prepaid inpatient health plans. Federal law prohibits prepaid inpatient health plans from receiving a supplemental payment that is not part of the actuarially certified capitated rate and is not part of the contract between the State Medicaid Agency and the prepaid inpatient health plans. We will determine if the prepaid inpatient health plans were paid in accordance with Federal laws and regulations.

*(OAS; W-00-06-31101; A-07-06-00000; expected issue date: FY 2006; new start)*

### Nursing Home Residents with Mental Illness and Mental Retardation

We will 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 2001 report, we found that the PASRRs were not in compliance with Federal requirements. We will update this previous work. The review will evaluate CMS's oversight of States' PASRR programs, State Medicaid agencies' oversight of the process, and the extent to which nursing facilities comply with the PASRR requirements.

*(OEI; 05-05-00220, 07-05-00230; expected issue date: FY 2006; work in progress)*

### Restraint and Seclusion in Children's Psychiatric Residential Treatment Facilities

We 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 onsite inspections of 20 percent of their residential treatment facilities. We will review CMS's 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**

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### **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 2006; work in progress)*

### **Detecting and Investigating Fraud and Abuse in State Children's Health Insurance Programs**

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) require 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; 06-04-00380; expected issue date: FY 2006; work in progress)*

### **Accuracy of State Children's Health Insurance Program Enrollment Data**

We will (1) assess States' efforts to ensure the accuracy of the SCHIP enrollment data reported in the Statistical Enrollment Data System, (2) determine whether inaccuracies in enrollment data could cause incorrect claims for Federal reimbursement, and (3) assess CMS's oversight of these activities. States are required to submit enrollment data that distinguish separate and Medicaid-expansion SCHIP children from children who would be eligible for traditional Medicaid. States receive an enhanced Federal match rate for children eligible for the SCHIP. Prior OIG work found that some States had difficulty accurately identifying and enrolling children in the SCHIP. This study will assess States accuracy in reporting enrollment data to CMS.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **State Children's Health Insurance Program Use of the National Correct Coding Initiative**

We will determine (1) the extent to which separate SCHIP programs use the National Correct Coding Initiative (CCI) edits or similar prepayment edits, and (2) the extent to which separate SCHIP programs paid for services that would otherwise be denied if they had used the CCI edits. To identify improper payments, CMS requires Medicare carriers to utilize the CCI edits; however, no similar mandate exists for Medicaid or separate SCHIP programs. A prior OIG study, "Applying the National Correct Coding Initiative to Medicaid Services," found that State Medicaid agencies paid \$54 million in 2001 for services that would have been denied based on CCI edits. If CCI edits could identify services that should not have been paid in both Medicare and Medicaid, applying these edits to SCHIP could produce similar results.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## Medicaid Drug Reimbursement

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### Average Manufacturer Price and Average Wholesale Price

We will examine the relationship between average manufacturer price (AMP) and average wholesale price (AWP). The AMP is used for Medicaid drug rebate purposes and is based on actual sales data for drug manufacturers. The AWP is a published catalogue price that most States have elected to use as a basis for Medicaid drug reimbursement. The AWP has been the subject of numerous reviews and its shortcomings as a basis for reimbursement have been widely documented. We 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 2006; work in progress)*

### Medicaid Drug Rebates—Computation of Average Manufacturer Price 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 2006; OEI new start, OAS work in progress)*

### 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 2006; 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 2006; new start)*

### Overprescribing of OxyContin and Other Prescription 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 2006; work in progress)*

### **Effect of Nominal Pricing on Medicaid Drug Rebates**

We will examine how drug manufacturers are complying with the nominal price provision of the Medicaid Drug Rebate law. The Medicaid Drug Rebate legislation excluded drugs sold at nominal prices from consideration in determining a manufacturer's best price. The rebate agreement between CMS and drug manufacturers defines nominal prices as any price less than 10 percent of the average manufacturer price. The concern is that manufacturers may be selling a significant volume of drugs at nominal prices to certain customers, such as hospitals, that can improve the drugs' market share. If a manufacturer can start a patient on a drug while hospitalized, the patient could be more likely to continue using that drug when discharged from the hospital. Since nominal prices are excluded from best price, there is no rebate consequence to the manufacturers from selling at the nominal price.

*(OAS; W-00-06-31102; various reviews; expected issue date: FY 2006; new start)*

### **Medicaid Reimbursement of Drugs for Long Term Care Pharmacies**

We will examine Medicaid reimbursement for long term care pharmacies. Previous OIG reviews of the acquisition cost for prescription drugs found that long term care pharmacies purchase drugs at significantly lower prices than traditional retail pharmacies. One State recognized this difference and now reimburses long term care pharmacies at a lower rate than other pharmacies. Therefore, the objective of this study will be to compare State reimbursement rates with the acquisition cost of drugs for long term care pharmacies. We will select several States for review. We will estimate the savings available to individual states from lowering reimbursement rates to amounts more in line with the actual cost of drugs for long term care pharmacies.

*(OAS; W-00-06-31103; various reviews; expected issue date: FY 2006; new start)*

### **Effect of Authorized Generic Drugs on Medicaid Drug Rebates**

Congressional interest was recently shown in authorized generic drugs and their effect on Medicaid drug rebates. As a drug is ending its patent life, the brand name manufacturer can attempt to save market share from being lost to multiple generic producers by making a deal with a generic manufacturer to have the generic manufacturer produce the drug as an authorized generic. The authorized generic is marketed under the brand manufacturer's original drug application rather than under its own separate application. As a result, the authorized generic should be paying the higher rebates associated with brand name drugs and not the lower rebates for generic drugs. Another more complicated issue is whether the sales to the generic manufacturer should be included in the average manufacturer price and best price calculations for the brand manufacturer. We will examine authorized generic drugs and determine their effect on the Medicaid drug rebate program.

*(OAS; W-00-06-31104; various reviews; expected issue date: FY 2006; new start)*

### **Medicaid Payments for HIV Drugs**

There have been reports in one State about potential abuses in the Medicaid drug program related to the high-cost drugs used to treat Human Immunodeficiency Virus (HIV). These reports indicate the pharmacies have been soliciting referrals from current HIV patients through gifts and other cash incentives. These reports also appear to indicate that Medicaid is paying far too much for HIV drugs. We intend to examine the HIV drugs to determine whether abusive conditions are occurring and whether one State is paying too much for these drugs.

*(OAS; W-00-06-31105; various reviews; expected issue date: FY 2006; new start)*

## **Zero Dollar Unit Rebate Amounts**

We will determine whether States are properly collecting drug rebates for drugs with \$0 unit rebate amounts (URA). CMS provides the URA information quarterly to the States; however, this information may contain a \$0 URA if a drug labeler (e.g., a manufacturer) did not provide timely information, or if the pricing information significantly varies from the previous quarter. The State agency is instructed to invoice the units at \$0 and the manufacturer is required to calculate the URA and remit the proper amount with their quarterly payment. Our review will determine whether the rebates for these drugs were properly billed and collected.

*(OAS; W-00-06-31106; various reviews; expected issue date: FY 2006; new start)*

## **Dispute Resolution in the Medicaid Prescription Drug Rebate Program**

We will assess the extent to which CMS's Dispute Resolution Program has helped to resolve disputes between State Medicaid programs and drug manufacturers. 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 of not receiving drug rebates. We will review the dispute process and how the program facilitates resolution between the States and the manufacturers.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Medicaid Generic Drug Utilization Among States**

We will determine to what extent State Medicaid programs have policies to encourage generic drug use in Medicaid. In prior work, we found that the use of generic drugs is one of the primary mechanism States use to control prescription drug costs in the Medicaid program. We will also examine the potential cost savings associated with greater reliance on generic drugs.

*(OEI; 05-05-00360; expected issue date: FY 2006; new start)*

## **States Compliance With Federal Upper Limit Requirements**

We will evaluate if States are meeting Federal upper limit requirements for drugs covered under the Medicaid program. In 1987, CMS regulations created upper limit standards to limit the amount that Medicaid could reimburse for certain generic drugs. We will examine whether States are meeting aggregate pricing requirements for drugs subject to the Federal upper limit program.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Medicaid Drug Pricing in State Maximum Allowable Cost Programs**

We will determine how criteria differ among States for including drugs in maximum allowable cost (MAC) programs and how MAC amounts vary among States. The study will also examine how the methodology for establishing MAC reimbursement amounts differs among States and will compare State MAC list to the Federal upper limit list.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Other Medicaid Services**

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### **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 2006; work in progress)*



### **School-Based Health Services**

We will determine whether Medicaid payments for school-based health services were in accordance with Federal 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; and W-00-05-39024; W-00-05-39041; various reviews; expected issue date: FY 2006; work in progress)*

### **Adult Rehabilitative Services**

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 2006; 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 2006; work in progress)*

### **Freestanding Inpatient Alcoholism Providers**

We will determine whether States have improperly claimed Federal Medicaid reimbursement for inpatient alcoholism services provided in freestanding facilities. These services are not covered under the Federal Medicaid program. Prior reviews in one State identified improper claims totaling about \$3.8 million in Federal reimbursement.

*(OAS; W-00-06-31107; A-02-06-00000; expected issue date: FY 2006; new start)*

### **Medical Services for Undocumented Aliens**

We will review Medicaid payments for medical services rendered to undocumented aliens to determine whether States appropriately claimed Federal funds for allowable medical services. States may claim Federal funds for medical services provided to undocumented aliens only when those services are necessary to treat an emergency condition. Prior OIG survey work revealed that six States claimed more than \$1.8 billion annually for Medical services rendered to undocumented aliens. We have indications from work in one State and discussions with CMS officials that at least three of the six States have claimed Federal funds for nonemergency medical services.

*(OAS; W-00-06-31108; various reviews, expected issued date: FY 2006; new start)*

### **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 Control Units (MFCU). 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 2006; work in progress)*

## Medicaid Administration

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### 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 2006; 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) which is 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; W-00-05-39032; various reviews; expected issue date: FY 2006; work in progress)*

### 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 2006; 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 and W-00-05-39030; various reviews; expected issue date: FY 2006; 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; W-00-05-39036; various reviews; expected issue date: FY 2006; 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. Survey work in one State showed that, 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 2006; work in progress)*

### **Medicaid Claims for Excluded Providers**

We 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 2006; work in progress)*

### **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 2006; work in progress)*

### **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 or "not recovered overpayments" without reporting these amounts to CMS. In such cases, the State may have failed to repay the Federal share of overpayments.

*(OAS; W-00-03-31047 and W-00-05-39029, W-00-05-39034; various reviews; OEI; 00-00-00000; expected issue date: FY 2006; 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 2006; work in progress)*

### **Duplicate Payments for Medicaid Services**

We will determine if States have effective controls in place to preclude duplicate payments. Public Law 92-603 was enacted to provide Federal reimbursement for design, development, installation, and operation of State mechanized Medicaid claims processing and information retrieval systems. Federal regulations at 42 CFR § 447.45(f) require that the State must conduct prepayment claims review to ". . . verify that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed." A prior review disclosed that duplicate payments were made as a result of ineffective claims resolution.

*(OAS; W-00-06-31109; various reviews; expected issue date: FY 2006; new start)*

### **Impact on the Medicaid Program of Certified Public Expenditures**

We will determine whether State's are complying with Federal regulations for claiming certified public expenditures (CPE). The CPEs are normally generated by local governments as part of their contributing to the coverage of Medicare services. States may claim CPEs to provide the State's share in claiming Federal reimbursement as long as the CPEs comply with Federal regulations (42 CFR § 433.51) and are being used for the stated purposes.

*(OAS; W-00-06-31110; various reviews; expected issue date: FY 2006; new start)*

### **Edits on Medicaid Payment**

We will determine whether States have turned off or overridden edits in Medicaid claims payment systems. Specifically, we will identify for selected States their most critical payment edits and determine State procedures to control the override or turn-off of these payment edits. We will also review paid claims to determine the effect on the Federal Government of any overridden payment edits.

*(OAS; W-00-06-31111; various reviews; expected issue date: FY 2006; new start)*

### **Administrative Costs for Medicaid Included in Temporary Assistance for Needy Families Grants**

We will determine the amount of common administrative costs included in the Temporary Assistance for Needy Families (TANF) block grants and reported on the Medicaid 64 expenditure report. The Personal Responsibility and Work Opportunity Reconciliation Act replaced Aid for Families with Dependent Children with the TANF block-grant program. The block grants that States receive are based on historical Federal welfare expenditures including administrative costs. Although the welfare reform act is silent about the cost allocation process, States are required to charge part of the common administrative cost of Medicaid and TANF to Medicaid, even if those costs are already included in the States' TANF block grants. The Congressional Budget Office estimated a saving of \$3.6 billion over the period 2002-2011 if the Federal reimbursement for Medicaid administrative cost is reduced to reflect the share of those costs that are covered by the TANF block grant.

*(OAS; W-00-06-31112; various reviews; expected issue date: FY 2006; new start)*

### **Medicaid Asset Transfers and Estate Recovery Provision for Nursing Home Care**

We will determine whether States have adequate procedures for determining the appropriateness of beneficiary eligibility for Medicaid nursing home care. States are required to impose penalties on individuals who transfer assets at less than fair market value within 3 years of applying for Medicaid benefits. States are also required by Federal law to seek recovery of amounts correctly paid by the State for certain Medicaid beneficiaries. We will also review State procedures for recovery of payment from individual estates to determine whether States are complying with applicable Federal laws and requirements.

*(OAS; W-00-06-31113; various reviews; expected issue date: FY 2006; new start)*

### **Medicaid Payments for County Administrative Services**

At CMS's request, we will review selected State's claims for county administrative services. Our reviews will determine if Medicaid expenditures for county administrative services were allowable, allocable, and in accordance with applicable Federal laws, regulations, and guidelines and the State plan.

*(OAS; W-00-05-39025, W-00-05-39026, W-00-05-39037; various reviews; expected issue date: FY 2006; work in progress)*

### **Medicaid Buy-In**

At the request of CMS, we will review one State's Medicaid buy-in program of Medicare Parts A and B. Our review will determine whether this State had adequate controls to ensure that only Medicare premiums are paid for individuals eligible for State buy-in coverage of Medicaid services.

*(OAS; W-00-05-39027; A-04-05-00000; expected issue date: FY 2006; work in progress)*

### **Medicaid Eligibility in Multiple States**

We will determine the appropriateness of Medicaid payments for beneficiaries with Medicaid eligibility in multiple States. Federal regulation code 42 CFR § 435.403 states that the agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. We have determined that individual beneficiaries are eligible in more than one State during a specific period of time. Initial survey work has confirmed that payments are made to providers in different States, for a specific beneficiary, for identical or overlapping dates of service.

*(OAS; W-00-06-31114; various reviews; expected issue date: FY 2006; work in progress)*

### **Medicaid Administrative Costs**

At the request of CMS, we will determine whether the administrative costs claimed by one State were properly allocated or directly charged to the Medicaid program and claimed in accordance with applicable Federal and State requirements. The Federal share of Medicaid administrative costs is typically 50 percent, with enhanced rates for specific types of costs. Prior reviews in one State noted problems in this area.

*(OAS; W-00-05-39031; A-06-05-00045; expected issue date: FY 2006; work in progress)*

### **Medicaid Management Information Systems Costs**

At CMS's request, we will determine whether the Medicaid Management Information System operational costs claimed by one State were allowable and adequately supported pursuant to Federal laws and regulations and the State Medicaid Manual. Federal reimbursement is available at the 75 percent matching rate for quarterly expenditures related to systems operations (whether such systems are operated directly by the State or by another person under contract with the State).

*(OAS; W-00-05-39039; A-09-05-00052; expected issue date: FY 2006; work in progress)*

### **Appropriateness of Medicaid Payments**

We will identify Medicaid expenditures for services such as home health, dental, personal care services, outpatient mental health, and personal care services 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; various reviews; 04-04-00210; 00-00-00000; expected issue date: FY 2006; work in progress)*

### **Medicaid Provider Enrollment Controls**

We will examine Medicaid provider enrollment controls for various services such as personal care, home health, and mental health. We will also assess potential vulnerabilities for enrollment controls and whether Federal and State guidelines are met pertaining to provisions of practice.

*(OEI; various reviews; 04-05-00180; 00-00-00000; expected issue date: FY 2006; work in progress)*

### **Medicaid Payment Safeguards**

We will assess payment safeguards used by State Medicaid programs for a range of services such as dental, home health, and mental health. Our reviews will examine prepayment edits for certain Medicaid services. In addition, we will analyze State practices to detect and prevent improper Medicaid payments.

*(OEI; various reviews; 00-00-00000; expected issue date: FY 2006; work in progress)*

### **Medicaid Pricing Comparisons**

We will compare Medicaid payment rates for certain medical equipment and supplies among State Medicaid programs. Our review will cover durable medical equipment, prosthetics, orthotics, and supplies and primarily examine payment variation among States.

*(OEI; 04-05-00290; expected issue date: FY 2006; new start)*

### **Medicaid Fee-for-Service Payments for Beneficiaries Enrolled in Managed Care**

We will assess to what extent Medicaid fee-for-service payments are made for beneficiaries who are enrolled in capitated Medicaid managed care health plans. We will also analyze what controls States have in place to detect if improper fee-for-service payments are being made for beneficiaries enrolled in Medicaid capitated health plans.

*(OEI; 07-05-00320; expected issue date: FY 2006; new start)*

### **CMS Oversight of Home- and Community-Based Waivers**

We will evaluate CMS regional office oversight of Medicaid Home- and Community-Based Services 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)*

### **Effect of State Medicaid Financing Arrangements on the Federal Share of Program Expenditures**

Many States have taken advantage of loopholes in the Medicaid regulations to devise various financing schemes to generate additional Federal revenues for their Medicaid programs without an associated increase in State payments. We will focus on several States to determine the overall effect of various Medicaid financing arrangements on the Federal share of actual program expenditures. We will determine the benefit of each financial mechanism employed to maximize the Federal share of Medicaid expenditure.

*(OAS; W-00-06-31115; various reviews; expected issue date: FY 2006; new start)*

### **Medicaid and SCHIP Eligibility Determinations**

We will conduct pilot reviews in three States to determine whether statistically valid error rates can be developed to project the number of beneficiaries who were not eligible for SCHIP benefits during the period selected for review. If appropriate, the dollar value of Federal monies associated with the number of ineligible beneficiaries will also be estimated. The review will further assess the States' policies, procedures, and controls for verifying and re-determining eligibility.

*(OAS; W-00-05-31100; various reviews; expected issue date: FY 2006; work in progress)*

## **Information Systems Controls**

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### **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 2006; work in progress)*

### **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 2006; work in progress)*

### **CMS's Drug Data Processing System**

In 2003, Congress passed the MMA, which, among other things, provides for a Medicare beneficiary drug benefit. CMS must develop and implement a drug data processing system capable of supporting CMS' implementation of the new prescription drug benefit program to begin processing live data on January 1, 2006. We will conduct on-going assessment of the status of the analysis phase, design phase, and testing/implementation phase of the system development life cycle. The fact that no system(s) exist to perform the necessary tasks required by the prescription drug program, coupled with the extremely tight deadlines, raises concerns that a formal structured analysis to design the system and essential internal controls will not occur.

*(OAS; W-00-05-40017; expected issued date: FY 2006; work in progress)*

### **Plan Readiness and Sufficiency of Information Systems Controls Supporting MMA Titles I and II**

With contractor support, we will assess the sufficiency of project planning and monitoring by CMS in the development and implementation of information systems to support the MMA Title I (Prescription Drug) and Title II (Medicare Advantage). These new parts of the Medicare program entail development and implementation of many new and/or enhanced information systems to be deployed not only at CMS, but also at Prescription Drug Plans (PDP), Medicare Advantage (MA) plans, and other locations (e.g., existing Medicare data centers) where MMA-related Medicare data may be processed. We have been advised by CMS that the normal systems development life cycle for MMA has been compressed to about one quarter of the normally expected timeframe, and the agency is relying on its external business partners (PDPs and MA/PDPs) as covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to certify the adequacy of their internal controls for security and privacy. Problems in timely and effective implementation of HIPAA privacy and security requirements nationwide have been reported in the press. Thus, project risk is high, and there is the strong possibility of gaps in internal controls.

*(OAS; W-00-05-41010; various reviews; expected issue date: FY2006; work in progress)*

### **IT Planning to Support Medicare FFS Contractor Reform**

With contractor support, we will assess how CMS is addressing internal controls issues in its plans for Medicare contractor reform. Section 911 of the MMA called for the phased replacement of the 33 corporate entities that serve as fiscal intermediaries (FIs) (including regional home health intermediaries, (RHHI) and/or carriers (including durable medical equipment regional carriers, DMERC) with new Medicare administrative contractors (MAC) by 2011. Section 911 also required the Secretary to submit to Congress a plan for accomplishing the transition. The HHS plan, being implemented by CMS, calls for consolidation of all existing FI/carrier/DMERC contracts into 15 regional A/B MACs, 4 regional DMERCs, and 4 regional RHHIs. The HHS plan further calls for the consolidation of the existing 16 Medicare data centers where claims are processed down to 4, and the streamlining of current fee-for-service (FFS) processing information systems (shared systems, common working file, national claims history) into a single, integrated claims processing system. Based on

results of previous reviews of internal controls at the current Medicare contractors, we are especially interested in determining the nature and extent of requirements for internal controls that CMS will be establishing in its new MAC/data center contracts. Also, based on prior reviews of CMS Medicare systems initiatives, we are especially interested in CMS's plans for consolidating data centers and integrating current Medicare FFS systems. (OAS; W-00-05-41011; various reviews; expected issue date: FY 2006; work in progress)

### **IG Report to Congress on Medicare Contractor Information Systems Security Programs-2005 (MMA Section 912)**

We will review independent evaluations of information systems security programs of Medicare fiscal intermediaries (FI), carriers, and administrative contractors (MAC). We will assess the scope and sufficiency of these evaluations and provide a report to Congress on the results of our assessment. The requirements for annual independent evaluation of FI, carrier, and MAC security programs and for subsequent assessment of these evaluations and reporting to Congress by OIG are mandated by section 912 of the MMA. The independent evaluations that FIs, carriers, and MACs must undergo annually are virtually the same in focus and content as the annual evaluations of agency information security programs that the Inspectors General perform pursuant to the Federal Information Security Management Act (FISMA). For 2005, it is anticipated that CMS will contract with an independent public accountant (IPA) to perform the independent evaluations of the Medicare contractor security programs, using agreed-upon procedures similar to those that OIG concurred with in 2004. We will review the IPA's work in accordance with both Government Auditing Standards and applicable guidance from the American Institute of Certified Public Accountants. Our report to Congress will reflect our assessment of the scope and sufficiency of the IPA's work and our summary of the results of independent evaluation of security programs across Medicare fee for service.

(OAS; W-00-06-41008; expected issue date: FY 2006, new start)

### **Medicaid Fiscal Agent Information Security Controls**

We will assess information security controls at one or more large Medicaid fiscal agents. Typically, these organizations contract with multiple states to perform any or all of the following: design, develop, implement, and operate Medicaid Management Information Systems; pay providers and plans; and administer specialized parts of a State's Medicaid program (e.g., outpatient prescription drugs). By addressing the information security controls, a higher level of security awareness and a more comprehensive view of risk can be obtained. Furthermore, as business associates of the States—covered entities under HIPAA—their contracts must call for assurance of reasonable and appropriate security safeguards and notification to the States should a security incident occur. We will use criteria established by the National Institutes of Standards and Technology, which provides guidance in evaluating controls over integrity, confidentiality and availability of data maintained in computerized systems.

(OAS; W-00-06-41012; A-18-00-00000; expected issue date: FY 2006; ongoing)

### **State-Based Controls over Medicaid Payments and Program Eligibility**

We will evaluate State-based information systems controls over Medicaid claim processing and program eligibility. At selected states, we will review: (1) entity-wide 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 2006; work in progress)

### **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 2006; work in progress)*

### **Compliance with the Health Insurance Portability and Accountability Act – University Hospital**

Our review will assess a university hospital's implementation of the HIPAA with respect to safeguarding Medicare beneficiaries' protected health information. The HIPAA mandates national standards for the protection of health information (Privacy Rule) and the integrity, availability and confidentiality of this information in electronic form (Security Rule). We intend to review the university hospital's environment and operations, including computer information systems and security systems, to determine if they meet the HIPAA standards and have controls to protect Medicare beneficiary information.

*(OAS; W-00-06-41006; A-05-06-00000; expected issue date: FY 2006; new start)*

### **Information Systems Controls in the Health Care Quality Improvement System**

We will assess the security controls in the Health Care Quality Improvement (HCQI) System to ensure confidentiality, integrity, and availability within the Department's information technology infrastructure and operations. Under the direction of CMS, the Quality Improvement Organization (QIO) program consists of a national network of 53 QIOs responsible for each U.S. State, territory, and the District of Columbia. The program safeguards the integrity of the Medicare trust fund by ensuring payment is made only for medically necessary services, and investigates beneficiary complaints about quality of care. The HCQI is used to monitor and improve utilization and quality of care for Medicare and Medicaid beneficiaries. The HCQI consists of three major applications that collect information and operate within the QualityNet network infrastructure: (1) Standard Data Processing System, (2) the Consolidated Renal Operations in a Web-Enabled Environment, and (3) Quality Improvement Evaluation System. We will review these computer systems, associated policies and procedures, and security systems to determine the safety of Medicare beneficiary data. We will review information and other systems, as necessary, to follow the process for recording, transmitting, and storing Medicare data. Sampling may be used to review beneficiary data in specific systems.

*(OAS; W-00-05-41013; various reviews; expected issue date: FY 2006; 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 2006; new start)*

## **General Administration**

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### **Fiscal Year 2005 Medicare Error Rate Estimate**

In this annual review, we will determine whether CMS has produced a valid and reliable Medicare fee-for-service paid claims error rate estimate for fiscal year 2005. Fiscal Year 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 Comprehensive Error Rate Testing

program (CERT) 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-00-05-40011; A-17-00-00000; expected issue date: FY 2006; work in progress)*

### **FY 2006 Medicare Error Rate Estimate**

In this annual review, we will determine whether CMS has produced a valid and reliable Medicare fee-for-service paid claims error rate estimate for FY 2006. FY 2006 will be the fourth year that CMS has developed the error rate, and the third 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-00-06-40011; A-17-00-00000; expected issue date: FY 2006; new start)*

### **Group Purchasing Organizations**

We will continue to determine how group purchasing organizations (GPO) 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 2006; 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 2006; work in progress)*

### **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)*

### **Payments for Services to Dually Eligible Beneficiaries**

We 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)*

### **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)*

## **CMS's Oversight Mechanisms to Evaluate the State Health Insurance Assistance Programs**

We will determine the extent to which CMS is able to assess the performance of the State Health Insurance Assistance Programs (SHIP) that provide counseling to their clients regarding Medicare and other health insurance issues. The study will also assess whether SHIP performance expectations in outreach, counseling and enrolling Medicare beneficiaries in the Prescription Drug Card and Benefit are being met.

*(OEI; 05-05-00190; expected issue date: FY 2006; work in progress)*

## **Investigations**

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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.

With the initiation of the Part D drug benefit, OI has invested effort in thoroughly understanding the various aspects of the laws and regulations, preparing for the conduct of future investigations related to drug benefit fraud and assisting the CMS in identifying program vulnerabilities. OI is providing training to Special Agents on the intricacies of the Part D benefit so that focused investigations can be conducted once the benefit becomes available on January 1, 2006. Because of the business relationships that will be formed under Part D, OI is anticipating violations such as kickbacks, billing for services not rendered, false statements, prescription shorting in institutional settings, and telephone scams that may be encountered under the Part D program. Separate and apart from this new program, OI will continue to devote resources to Medicare Part A and B and Medicaid fraud investigations.

Investigative focus areas include pharmaceutical fraud. Working jointly with other law enforcement partners at the Federal, State and local levels, OI will continue to identify and investigate illegal schemes to market, obtain, use, and distribute prescription drugs. By investigating these schemes, OI will address the problem of inflation 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.

OIG 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.

OIG does not investigate individuals, facilities, or entities that merely commit errors or mistakes on claims submitted to the Medicare or Medicaid program. CMS and CMS contractors address claims errors and mistakes. OIG 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**

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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 2006 includes the following:

### **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 2006, 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

## Agency for Health Care Research & Quality

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### Grants Management Activities

We will evaluate the Agency for Healthcare Research and Quality (AHRQ) monitoring and oversight of its patient safety grant program. In an effort to reduce medical errors, the Health Care Research and Quality Act of 1999 (Public Law 106-129) provided the authority for AHRQ to use \$50 million annually for patient safety related grants. AHRQ awarded 120 such grants in fiscal years 2001- 2003; these awards ranged from \$5,000 to \$2.8 million annually. We will evaluate AHRQ's compliance with Federal laws and policies in the monitoring of patient safety grants and the extent to which AHRQ evaluates required grantee reports, initiates actions in response to these reports, and ensures grantee responsiveness to action requests.

*(OEI; 07-04-00180; expected issue date: FY 2006; work in progress)*

## Centers for Disease Control and Prevention

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### 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-04-04-01005; expected issue date: FY 2006; work in progress)*

### 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; multiple reviews; expected issue date: FY 2006; new start and work in progress)*

### Management of the Select Agent Program

We will follow up on our earlier work that showed CDC had inspected less than one-fourth of registered facilities, conducted inspections without written procedures, and maintained inaccurate records of select agent transfers. The followup will have two broad objectives: (1) evaluate CDC's actions in response to the findings of our earlier review, and (2) evaluate CDC's actions to implement the expanded and detailed select agent regulation, 42 CFR 73, in four broad areas of management oversight, security planning and implementation, accountability, and access.

*(OAS; W-00-06-52005; A-00-00-00000; expected issue date: FY 2006; new start)*

### **Bioterrorism Preparedness: Distribution of CHEMPACK**

We 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, 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 SNS CHEMPACK is a pilot project in a limited number of States and localities for the forward placement of nerve gas antidotes as a response to chemical disasters. 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; 04-05-00040; expected issue date: FY 2006; work in progress)*

### **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. Begun in 1999 with \$40 million, the Program 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, 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 2006; new start)*

### **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. 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 to assist them in building 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 2006; new start)*

### **Early Implementation of Biowatch: An Interagency Review**

As part of an interagency effort with the Inspectors General at Department of Homeland Security (DHS) and Environmental Protection Agency, we will review the early implementation of CDC's portion of the Biowatch Program. DHS provides the funding, management, and policy oversight for Biowatch. CDC's role is to provide separate laboratories within the Laboratory Response Network to analyze sample collected by state or local agencies. In addition, CDC provides guidance as well as direct technical assistance in the event of a positive signal, to State and local health departments on planning for public health emergencies which might arise after detection of a biological pathogen.

*(OEI; 02-04-00230; expected issue date: FY 2006; work in progress)*

### **Monitoring Subrecipients of CDC's Investigations and Technical Assistance Grants**

We will determine the extent to which CDC monitors grantees' oversight of sub recipients of Investigations and Technical Assistance grants and the extent to which grantees monitor subrecipients of Investigations and

Technical Assistance grants. CDC awards Investigations and Technical Assistance grants to assist States, local health authorities, and other health related organizations in controlling chronic diseases and disorders as well as preventable diseases. In some cases grantees make awards to sub recipients. This inspection would focus on compliance with grants oversight requirements for recipients and sub recipients.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Coordination Between Grants Officers and Project Officers in CDC Grant Programs**

We will determine the extent to which grants officers and project officers in CDC coordinate their grant monitoring activities. Grant monitoring activities are shared between grants officers and project officers. Grants officers monitor a grantee's financial activities while project officers monitor a grantee's programmatic performance. As specified in departmental grants policies, these roles can be carried out in a responsible manner only when there is effective interaction between the grants officer and project officer.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Deemed Exports At CDC Laboratories**

We will determine whether CDC has established adequate security over its research laboratories to ensure compliance with export control regulations before allowing foreign nationals access to covered materials and technologies. Under authority of the Export Administration Act of 1979 and other laws, the United States controls the export of certain goods and technologies for reasons of national security. For example, certain biological materials, primarily select agents, are subject to controls governing shipments to locations outside the United States. Any release of covered goods and technologies to a foreign national within the United States is deemed to be an export to the home country of that foreign national. Accordingly, these "deemed exports" are subject to the same export controls as if the goods and technologies were being shipped to another country.

*(OASW-00-06-52010, A-04-06-00000; expected issue date: FY 2006; new start)*

## **Food and Drug Administration**

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### **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 2006; 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 had submitted 750 protocols for clinical trials that were recruiting patients. We will assess FDA's efforts and identify reasons that submissions are below FDA's expectation.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*



### **FDA Monitoring of Postmarketing Commitments**

We will determine to what extent FDA monitors postmarketing study commitments agreed to by drug applicants (pharmaceutical companies), and whether applicants complete postmarked study commitments in a timely manner. FDA requires that 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 trials 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; 01-04-00390; expected issue date: FY 2006; work in progress)*

### **FDA National Drug Code Directory**

We will identify and examine discrepancies between the National Drug Code (NDC) Directory and a frequently used private industry drug product database. We will determine how and to what extent FDA and drug firms contribute to any drug product omissions or outdated drug listings at FDA. 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 a 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 if additional efforts are needed by FDA to ensure that the NDC Directory is current and complete.

*(OEI; 06-05-00060; expected issue date: FY 2006; work in progress)*

### **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 2006; 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. FDA's Office of Regulatory Affairs conducts these inspections 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; 04-05-00120; expected issue date: FY 2006; work in progress)*

### **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 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 2006; new start)*

### **Adverse Event Reporting for Medical Devices**

We will determine how and to what extent 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. 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 2006; new start)*

### **FDA 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 2006; new start)*

### **Outside Activities of FDA Employees**

We will describe the nature of outside activities for which FDA employees received approval; the extent to which FDA senior-level employees provided required information on their outside activity request forms and financial disclosure statements; and FDA's process for reviewing outside activity requests. FDA employees, as well as all Federal employees, must adhere to governmentwide and program-specific ethical standards, which include provisions on conflict of interest. The provisions typically require employees to disclose outside activities, which are then screened for potential conflicts of interest and should be dealt with by agency officials.

*(OEI; 01-04-00400; expected issue date: FY 2006; work in progress)*

### **FDA Enforcement of Food Facility Registration**

We will determine how and to what extent FDA has enforced food facility compliance with registration, as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The Act authorizes FDA to protect the nation's food supply against actual or threatened terrorist acts and other food-related emergencies. New regulations in 2003 require certain domestic and foreign food facilities to register with FDA so that authorities could quickly identify and locate affected food processors and other appropriate facilities in the event of a food-borne outbreak or potential bioterrorist incident. This study will assess FDA's enforcement through its outreach efforts and through its oversight activities.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **FDA Processes to Address Serious Deficiencies in Foreign Drug and Medical Device Manufacturing**

We will review how FDA determines enforcement actions after it has detected serious deficiencies during an inspection of a foreign drug or medical device firm. We will also review to what extent FDA ensures that foreign firms comply with enforcement actions. Over the past decade, the number of FDA-regulated imports

has grown from 2 million to over 11 million. Drugs and medical devices comprise approximately one quarter of these products. In 1998, the Government Accountability Office found that FDA verified foreign drug firms' corrective actions in only half of those found to have deficiencies.

*(OEI-00-00-0000; expected issue date: FY 2006; new start)*

### **Conflicts of Interest in the FDA Product Specific Advisory Committees and Panels**

We will review to what extent FDA screens potential members of its product specific advisory committees and panels for conflicts of interest, and to what extent the Agency waives conflict of interest restrictions. FDA routinely consults with experts from outside of the Agency in making decisions on the safety and effectiveness of products, and these experts often serve on FDA advisory committees and panels. Federal law allows FDA to waive conflict of interest restrictions for committee and panel members if the need for the individual's services outweighs the potential conflict.

*(OEI-00-00-0000; expected issue date: FY 2006; new start)*

### **FDA Domestic Compliance Inspections**

We will review the extent to which FDA conducts compliance inspections of drug manufacturers who have been cited for manufacturing deficiencies. The Food, Drug and Cosmetic Act requires FDA to conduct comprehensive inspections of all aspects of the production and distribution of drugs and drug products and FDA has established Current Good Manufacturing Practices (CGMP) to ensure that drug manufacturers meet all mandated safety requirements. If FDA identifies a major deficiency in the manufacturing process during a routine CGMP inspection, the Agency must conduct a follow-up survey, or "compliance inspection" to verify that the firm has taken corrective action.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Health Resources and Services Administration**

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### **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 2006; new start)*

### **Ryan White CARE Act—Analysis of the Use of Funding**

We 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 Health Resources and Services Administration (HRSA) has adequate authority over the distribution and allocation of funds.

*(OAS; W-00-05-54250; A-02-00-00000; expected issue date: FY 2006; work in progress)*

### **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 2006; new start)*

### **Review of the 340B Drug Pricing Program**

We will examine whether entities participating in the Health Resources and Services Administration's 340B Drug Pricing Program pay at or below the ceiling price discount to which they are entitled pursuant to Section 340B of the Public Health Service Act. The 340B Drug Discount Program offers significant discounts on drug prices to nearly 12,000 entities, including community health centers, public hospitals, and other Federal grantees. HRSA's Pharmacy Affairs Branch administers the program for the enrolled entities, and spent an estimated of \$3.4 billion on drugs in 2003. If 340B participating entities do not receive the discount to which they are entitled, we will evaluate potential reasons through in-depth case studies.

*(OEI; 05-02-00073; expected issue date: FY 2006; work in progress)*

### **HRSA Oversight of Community Health Centers**

We will evaluate HRSA's monitoring of grants to community health centers. The FY 2006 President's Budget calls for \$2.0 billion for Health Centers, an increase of \$304 million above FY 2005. These additional funds will support the development of 275 new access points (new sites administered by new grantee organizations and satellites of existing grantees) and 303 expanded existing sites to serve an additional 2.39 million patients. Our review will examine the nature and extent of HRSA's review of grantee reports. We will also look at what actions HRSA takes as a result of these reviews and the responsiveness of grantees to HRSA's actions.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **Indian Health Service**

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### **Pharmacy Inventory Controls**

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; multiple reviews; expected issue date: FY 2006; work in progress)*

### **Accounting for Health Insurance Collections**

We will determine the adequacy of IHS's accounting procedures for health insurance collections. IHS collects nearly \$600 million annually from third party insurers, including Medicare and Medicaid. Each IHS area office has responsibility to use appropriate accounting internal controls for processing third party payments and managing the resulting revenue. We will examine these procedures in selected area offices.

*(OAS; W-00-06-55001; A-00-00-00000; expected issue date: FY 2006; new start)*

### **Tribal Governments Third Party Collections in Emergency Medical Services Programs**

We will evaluate the effectiveness of tribal governments' efforts to collect third party payments for their Emergency Medical Services Programs (EMS). Under statutory requirements, the IHS is a payor of last resort.

Third party collections are important to IHS and tribal governments because the money augments congressional appropriations and collected funds can be used for such activities as enhancing infrastructure and expanding services. In the IHS budget, there is no specific line item for EMS at either the IHS and tribal or tribal level. An IHS study in 2001 found that there is wide variation in tribal collection capabilities.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## **National Institutes of Health**

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### **Pharmacy Inventory Controls**

We will evaluate inventory control procedures for pharmaceuticals used in National Institutes of Health (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 2006; work in progress)*

### **Superfund Financial Activities for Fiscal Year 2005**

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 2005, agency obligations and disbursements of Superfund resources amounted to \$78.3 million and \$80.2 million, respectively.

*(OAS; W-00-05-56001; A-04-00-00000; expected issue date: FY 2006; new start)*

### **NIH Monitoring of Extramural Conflicts of Interest**

We will examine how NIH monitors extramural grantees for potential conflicts of interest. Under 42 CFR Part 50, institutions must certify that they maintain a "written, enforced policy" on conflicting interests. Under the regulations, institutions must also report to NIH the existence of any conflicting interests and assure that the interest has been "managed, reduced, or eliminated." The inspection will focus on the effectiveness of NIH's oversight, whether conflicts of interest have affected Federal and public interests, and whether the definition of "significant financial interest" effectively protects researchers from perceived conflicts of interest. Conflicts of interest in the scientific community pose especially serious risks to clinical trial subjects and consumers, where a risk of bias can affect the quality of treatment decisions.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Level of Commitment**

We will determine whether major research universities committed more than 100 percent of principal investigator's effort when applying for NIH grants and, if so, whether the resulting grant awards were inflated. 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-00-06-56014; A--00-00-00000; expected issue date: FY 2006; work in progress and new start)*

### **Subrecipient Costs and Monitoring**

We will determine whether college and universities are complying with applicable Federal regulations to monitor subrecipient costs. OMB Circulars A-110 and A-133 require that grantees monitor subawards and ensure subrecipients have met audit requirements. Grantee monitoring should take place during and after the award, and should include site visits, review of performance and financial reports, and development of risk assessments based on relevant factors to ensure a proper level of monitoring. Our reviews at three institutions show that grantees are not adequately complying with Federal requirements.

*(OAS; W-00-06-56011; A--00-00-00000; expected issue date: FY 2006; work in progress and new start)*

### **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-04-00-00000; expected issue date: FY 2006; work in progress)*

### **Cost Transfers**

We will determine the allowability of cost transfers at NIH grantees. We will assess if the transfers are supported by documentation that fully explains how errors occurred and if responsible grantee officials certify the correctness of the new charges. On-site visits by NIH during fiscal years 2000 through 2002 found that cost transfer policies and procedures tend to be nonexistent, incorrect, or confusing. Prior OIG work also found that cost transfers were unallowable and/or not appropriately documented. The potential effect of unreasonable, unallocable, or unallowable cost transfers is substantial considering the value of NIH grant funds awarded each year is approaching \$20 billion and increasing.

*(OAS; W-00-05-56012; various reviews; expected issue date: FY 2006; work in progress and new start)*

## **Substance Abuse and Mental Health Services Administration**

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### **Mental Health and Substance Abuse Disorders**

We will determine whether expenditures under the block grant for prevention and treatment of substance abuse incurred by the Puerto Rico Administration of Mental Health and Anti-Addiction Services (AMHAS) were reasonable, allowable, and allocable in accordance with the Federal requirements. In recent news, numerous concerns as to the misuse of program funds by the AMHAS management have been made public by patients and community activists.

*(OAS; W-00-06-57001, A-00-00-00000, expected issue date: FY 2006, new start)*

## Cross-Cutting Public Health Activities

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### 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-00-06-58004; various reviews; expected issue date: FY 2006; new start)*

### State and Local Government Progress Toward Meeting Bioterrorism Incident Management Requirements

We will assess State and local reporting of progress and actual achievements toward meeting the Incident Management benchmark, the first of six benchmarks, common to the bioterrorism cooperative agreements through which CDC and HRSA support bioterrorism preparedness efforts in 62 jurisdictions. Coordination of both preparedness and response efforts to an actual bioterrorism event are essential to successfully protect citizens. In fiscal years 2004 and 2005, HHS allocated more than \$2 billion to CDC and HRSA for these cooperative agreements, which are focused on improving the public health infrastructure and hospital preparedness. Because of the overlapping nature of the two cooperative agreements, CDC and HRSA identified six cross-cutting benchmarks. The incident management benchmark is intended to help States and local governments achieve participation in the National Incident Management System (NIMS). Beginning in FY 2005, NIMS participation is required for awardees receiving Federal preparedness assistance through grants, contracts, or other activities.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

## Investigations

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### Violations of Select Agent Regulations

OIG continues to receive requests for information and investigations of terrorist and bio-terrorist 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 continuing to work with CDC, the Federal Bureau Investigation, and the Department of Agriculture under the established protocols to investigate potential criminal violations of the statute governing the registration, storage, and transfer of select agents and toxins.

## Legal Counsel

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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 2006 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 final guidance in FY 2006.

### **Resolution of False Claims Act Cases**

We will continue to work closely with OIG investigators and auditors and with prosecutors from the Department of Justice 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.



# Administration for Children and Families; Administration on Aging

## Child Support

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### Review and Adjustment of Child Support Orders

At the request of the Office of Child Support Enforcement, 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. Federal law requires States to have in place and use a process to review and adjust child support orders.

*(OAS; W-00-05-23001; A-01-05-00000; expected issue date: FY 2006; work in progress)*

### Undistributable Child Support Collections

We will examine undistributable 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-00-06-23080; A-02-06-00000; A-05-06-00000; expected issue date: FY 2006; work in progress and new start)*

### States' Ability to Collect from the Self-Employed

We will determine whether States are effectively using available information to fully collect the amount of child support due from self-employed noncustodial parents. While Federal laws have expanded States' authority to enforce child support orders by providing States with information on wages or other income, recent OIG child support reviews have shown that States may not be collecting the full amount of support due from the self-employed. As a result, children may not be receiving the full amount of child support; or, for families receiving public assistance, States may not be collecting the full amount to offset related costs.

*(OAS; W-00-06-23101; A-01-06-00000; expected issue date: FY 2006; new start)*

### Child Support Enforcement Program Costs

We will determine whether Federal reimbursement for State administrative and program costs claimed for child support enforcement activities were allowable and appropriately allocated to the Child Support Enforcement Program. The Federal Government reimburses States for 66 percent of all expenditures for the administration and operation of the States' Child Support Enforcement Programs. Prior OIG work in various States has identified 30- to 70-percent increases in costs claimed over the past 5 years.

*(OAS; W-00-06-23104; A-05-06-00000; expected issue date: FY 2006; new start)*

### Debt Compromise

We will examine State compliance with regulations governing debt compromise practices and the effectiveness of debt compromise in increasing collections. Our review will include determining the extent of debt forgiveness among States, evaluating the regulatory appropriateness of State methods, identifying the role of State courts in the debt compromise process, and determining the effect of reducing child support debt on payment of ongoing support.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Costs and Benefits of Electronic Payments**

We will evaluate State's use of electronic payments. Our review will include: determining the extent of State use of electronic payments, identifying any barriers to full utilization, and quantifying the costs and benefits of electronic payments to parents, employers, and State child support enforcement agencies. We will review electronic payment programs from a diverse sample of States, document their implementation, and identify barriers and costs.

*(OEI; 00-00-00000; expected issue date: FY 2006; new start)*

### **Use of Financial Institution Data Match**

We will determine how effectively States are using the Financial Institution Data Match to collect payments of arrears and ongoing support obligations. Since its inception in 1999, the Financial Institution Data Match (FIDM) has led to collection of billions of dollars in past-due and current support. As an enforcement tool, FIDM is targeted primarily at increasing the collection of arrears, a performance indicator in Office of Child Support Enforcement (OCSE) FY2005-2009 Strategic Plan. However, stakeholders speculate that payments of arrears through FIDM may also reestablish contact between States and non-custodial parents and result in increases in ongoing support. An evaluation of FIDM would provide a means of identifying factors inhibiting its maximum effectiveness in increasing collections and reducing arrears.

*(OEI; 00-00-00000; expected issue date: FY 2006; 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 program now known as Project Save Our Children grew to 10 task forces covering all 50 States and the District of Columbia. These task forces bring together OI, the U.S. Marshals Service, Department of Justice, 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 2004, the most recent year with complete statistics, OI reported 169 criminal convictions and \$8,284,376 in court ordered fines, penalties and restitution. For FY 2006, we plan to continue our efforts to encourage and coordinate the efforts in the States, particularly in States that have not pursued prosecutions of individuals who failed to meet their child support obligations.

## **Child Welfare**

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### **Foster Care and Adoption Assistance Training and Administrative Costs**

Reviews of foster care and adoption assistance training and other administrative costs claimed under Title IV-E will focus on determining whether (1) current and retroactive claims allowable, reasonable, and supported in accordance with laws and regulations; and (2) costs are properly allocated between Federal and State programs. Title IV-E training and other administrative costs have risen dramatically in relation to maintenance payments in recent years. Prior OIG reviews have identified unallowable costs were claimed, costs were improperly allocated, and/or costs were otherwise unsupported.

*(OAS; W-00-06-20008; various reviews; expected issue date: FY 2006; new start)*

### **Foster Care Level-of-Care Classification**

We will determine whether the level-of-care needs of foster children are (1) periodically reassessed and appropriate reclassifications made to assure children are receiving the required services, and (2) indicated at a higher level than necessary by providers to obtain a higher foster care payment. If the level-of-care needs are not

appropriately set and periodically reassessed, States may be providing and paying for more or less services than a child requires, resulting in an improper payment. Foster children may also be impacted by not receiving needed services or having a reduced chance of adoption.

*(OAS; W-00-06-24006; various reviews; expected issue date: FY 2006; new start)*

### **Costs Billed by Child Placing Agencies**

We will determine whether State Title IV-E agencies properly excluded child placing agencies' administrative costs when they requested Federal reimbursement for maintenance payments. By statute, foster care maintenance payments cover a child's basic needs, such as food, clothing, shelter, and personal incidentals, but not administrative costs. Preliminary work in one State identified administrative costs included in the State's maintenance payment claims. We will review the State's procedures for reimbursing child-placing agencies' maintenance payments and determine whether administrative costs were paid.

*(OAS; W-00-06-24007; A-01-06-00000; expected issue date: FY 2006; new start)*

### **Group Home and Foster Family Agency Rate Classification**

We will determine if foster care payment rates made for group homes and/or foster family agency treatment programs are accurate. The foster care payment amount correlates to the rate classification level. The rate classification level is based on factors such as the number of weighted eligible hours per child per month of childcare services, social work activities, and mental health treatment services. Payments are initially established at a provisional rate. The State subsequently conducts an audit to establish the actual rate classification level. There have been changes in State regulations regarding rate renewal applications and rate application documentation requirements. Also, a reduction of State personnel and redirection of resources in the State foster care audits branch may lessen timely changes to the actual rate classification levels resulting in overcharges to the Federal Government.

*(OAS; W-00-06-24008; A-09-06-00000; expected issue date: FY 2006; new start)*

### **Adoption Assistance Subsidies**

We will determine whether claims for Federal reimbursement of adoption assistance subsidies complied with eligibility requirements. A Federal subsidy payment is provided to families to ensure that they have the necessary services and financial resources to meet the special needs of some adopted children. An OIG review of adoption assistance subsidies in one State identified payments to families that did not meet eligibility requirements.

*(OAS; W-00-06-24009; A-01-05-00000 and A-01-06-00000, expected issued date: FY 2006; new start)*

### **Accountability over Child Welfare Funds**

At the request, of Administration for Children and Families (ACF) we will determine whether a State agency is properly accounting for child welfare funds. ACF has long-standing concerns because of unreliable data on financial reports and funds returned unspent. We will review the State agency's cash management, internal controls, use of Federal funds and compliance with Federal regulations.

*(OAS; W-00-06-24010; A-06-06-00000; expected issue date: FY 2006; new start)*

### **Case Management/Case Supervision Claims**

We will determine if Title IV-E Case Management/Case Supervision claims filed by a State were accurate, adequately supported, and complied with Federal eligibility requirements. A previous OIG review found that the State required contractors to submit claims monthly for case management and case supervision services for each client in foster care, but only minimally reviewed any documentation of provision for these services. We will also determine whether the case manager was also involved in the direct provision of services.

*(OAS; W-00-06-24011; A-07-06-00000; expected issue date: FY 2006; new start)*

### **Foster Care Candidate Costs**

We will review several States with high ratios of foster care candidate costs to total Title IV-E administrative costs to determine whether candidates were properly documented and their costs were properly claimed. A candidate for foster care is a child who is at serious risk of removal from his/her home. Costs of some preplacement activities on behalf of children meeting Federal requirements for candidates of foster care can be claimed as Title IV-E administrative costs.

*(OAS; W-00-06-24012, various reviews; expected issue date: FY 2006; new start)*

### **Foster Children over 19 Years Old**

We will determine whether foster care maintenance payments were made on behalf of ineligible children over the age of 19. With few exceptions, foster care payments cease when a child reaches his/her 18th birthday. The ACF Adoption and Foster Care Analysis and Reporting System database listed over 10,000 of 532,000 children that were over 19 years as of September 30, 2002.

*(OAS; W-00-06-24013, A-03-06-00000; expected issue date: FY 2006; new start)*

### **State Standards and Capacity to Track Frequency of Caseworker Visits with Children in Foster Care**

We will determine the standards States have implemented for frequency of caseworker visits with children in foster care; the extent to which States could provide statewide automated reports reflecting caseworker visits; and the extent to which statewide reports indicate children were visited. It is estimated that in 2005, 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. This inspection will provide an overview of State Standards to track the frequency of caseworker visits, and States' ability to meet these standards.

*(OEI; 04-03-00350; OEI-04-03-00351; expected issue date: FY 2006; work in progress)*

### **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 of incidents occurring after the child had been placed in foster care. We will consider whether the investigations included factors such as the previous history of the alleged abuser, whether a background check was performed on members of the foster care household or provider, and how well caseworkers monitored the child and family/provider. We will be looking for root causes that have contributed to any identified weaknesses.

*(OAS; W-00-06-24004; A-09-06-00000; expected issue date: FY 2006; new start)*

### **Background Checks on Foster Families and Adoptive Parents**

We 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-00-06-24001; A-09-06-00000; expected issue date: FY 2006; new start)*

### **Kinship Placements in One State**

We will determine (1) whether a State used different standards for approving foster care placements in relatives' homes versus nonrelatives' homes and (2) whether it used Federal funds for approved relative foster homes that did not meet the State's licensing standards. ACF requested an audit of the process the State used for approving homes wherein a relative serves as the foster parent. Section 472 (c) of the Social Security Act requires that the same standards be used in the approval process for foster homes of relatives as are used in the licensing process for foster homes of nonrelatives.

*(OAS; W-00-04-24005; A-09-06-00000; expected issue date: FY 2006; work in progress)*

### **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 intent for comprehensive statewide systems is to provide effective automated capability to support the administration of services under child welfare programs.

*(OAS; W-00-06-24050; A-09-06-00000; expected issue date: FY 2006; 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 these systems are implemented, the Federal matching rate will drop 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 2006; new start)*

### **Administration for Children and Families' Public Assistance and Reporting Information System**

We will compare States' use and outcomes of the Public Assistance Reporting Information System (PARIS) to identify and address programmatic vulnerabilities to help prevent fraud, waste, and abuse. PARIS is designed to detect duplicate benefit payments by allowing States to share eligibility data through a confidentiality agreement. To date, States use PARIS primarily as a management tool to identify program savings. Little is known about how States use PARIS to identify program vulnerabilities. We will focus on the effectiveness of PARIS to identify program vulnerabilities other than improper payments. The information from this study could help prevent future cases of fraud, waste, and abuse and improve the accuracy and integrity of Federal payments which is the goal of the Improper Payments Information Act of 2002.

*(OEI-00-00-0000; expected issue date: FY 2006; new start)*

## **Family Assistance**

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### **Followup Aid to Families with Dependent Children Overpayments**

We will determine whether States have reimbursed the Federal Government for their share of Aid to Families with Dependent Children (AFDC) overpayment recoveries. Although the AFDC program has been repealed and replaced with the Temporary Assistance for Needy Families (TANF), States must return the Federal share of

AFDC overpayment recoveries. Prior OIG reviews identified large recoveries that should have been returned to the Federal Government. Survey work indicated that some States are still collecting AFDC overpayment recoveries. We will determine whether the Federal Government has been reimbursed for its share of these recoveries. (OAS; W-00-06-24004; A-01-06-00000; expected issue date: FY 2006; work in progress)

### **Aid to Families with Dependent Children Overpayment Recovery Rate Methodology**

At ACF's request we will determine the reasonableness of a State's proposed rate methodology for determining the Federal share of AFDC overpayment recoveries in counties that were not previously audited by OIG. Additionally, we will evaluate the AFDC overpayment recovery results calculated under the proposed methodology. OIG had previously audited the AFDC overpayment recoveries for three counties in the State. Based on the results of those audits, the State refunded about \$34.5 million to the Federal Government.

(OAS; W-00-06-21005; A-09-06-00000; expected issue date: FY 2006; new start)

## **Head Start/Child Care**

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### **Financial Abuses in the Child Care and Development Block Grant Program**

We will determine whether Child Care and Development Block Grant funds were used for childcare services to eligible children and families. Program funds could be improperly used for children who were not actually present to receive the services or for services that are not delivered. To be eligible for childcare assistance, a child must be less than 13 years old and the family's income must fall below a specified threshold. Additionally, States must use at least 70 percent of their total entitlement for childcare services for families that are trying to become independent of TANF, and for families that are at risk of becoming dependent on public assistance.

(OAS; W-00-06-25007; A-09-06-00000; expected issue date: FY 2006; 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 under enrollment. 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 2006; work in progress)

### **Head Start Facilities' Procurement and Construction Practices**

We will assess management controls and procedures ACF has in place to ensure that facilities purchased, constructed, or renovated with Head Start funds were acquired in accordance with applicable Federal requirements and whether Federal interests were 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 2006; work in progress)

### **Head Start Grantees**

We will determine if certain classes of Head Start costs are improperly claimed on a consistent basis and quantify any overpayments. Conversations with Regional ACF officials indicated that Head Start grantees are not receiving adequate audit coverage through the triennial reviews or the A-133 single audits. We will perform detailed cost audits at a limited number of grantees selected in coordination with Regional officials.

(OAS; W-00-06-25008; A-05-06-00000; expected issue date: FY 2006; new start)

### **Head Start Matching Costs**

We will determine whether grantees are providing the 20-percent match required for Federal Head Start funding. The matching share of 20 percent must be from non-Federal sources and may be in the form of cash or in-kind contributions. The change brought about by welfare reform may have affected grantees' ability to meet matching requirements. Regional ACF officials have indicated that grantees may not be meeting the matching requirements. (OAS; W-00-06-25003; A-05-06-00000; expected issue date: FY 2006; new start)

### **Head Start Enrollment of Disabled Children**

We will determine Head Start grantees' compliance with the Head Start regulatory requirement that at least 10 percent of each grantee's enrollment include disabled children. Head Start regulations and performance standards define "disabilities" to include mental retardation/developmental disabilities, orthopedic impairments, blindness, deafness, traumatic brain injury, and autism. Head Start data indicate that about 84 percent of the 123,000 children with disabilities in Head Start have speech and/or language problems with only 16 percent of disabled children having more severe disabilities such as autism, developmental disabilities and physical impairments.

(OEI-00-00-0000; New Start; Expected Issue Date: FY 2006)

### **Health and Safety Standards at Child Care Facilities**

We will determine compliance with health and safety standards at selected childcare facilities that received Federal funding from the State's Child Care Development Fund Block Grant. A 1994 audit identified numerous instances in which childcare facilities did not comply with States' health and safety standards. It also showed the need for greater Federal oversight to improve the health and safety conditions in childcare facilities.

(OAS; W-00-06-25005; A-04-06-00000; expected issue date: FY 2006; new start)

## **Other Issues**

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### **Cash and Medical Assistance Payments to Refugees**

We will determine if a State has controls in place to prevent the payment of cash and medical assistance benefits after a refugee's period of eligibility has expired. Currently, Federal regulations allow for Federal funds to be used to provide cash and medical assistance for up to 8 months after a refugee's entry into the United States. Over the years, refugees' eligibility for cash and medical assistance was as long as 36 months. In FY 2004 and prior years, nonfederal audits identified material noncompliance and reportable conditions in the State's administration of the program.

(OAS; W-00-06-27006 A-04-06-00000; expected issue date: FY 2006; new start)

### **Undocumented Alien Children released to Certain Sponsors**

At ACF's request, we will examine the release of Undocumented Alien Children to certain sponsors. We will examine (1) the procedures necessary to ensure the safety and most appropriate release to a sponsor in a timely manner, and (2) the time taken to initially place the undocumented alien child into Office of Refugee Resettlement's facilities once a placement designation is made. We will examine the effectiveness of this process.

(OEI; 00-00-00000; expected issue date: FY 2006: new start)

### **Monitoring States' Fiscal Year Preplanning Goals for Services Funded by Social Services Block Grant Program**

At ACF's request, we will examine fiscal year preplanning by States as required for services funded by the Social Services Block Grant program (SSBG). According to section 2004 of Title XX of the Social Security Act, in order for a State to receive its SSBG allotment, it is required to develop and submit an annual preexpenditure

report that describes how it plans to administer its SSBG funds for the coming year. Additionally, a public discussion of the plan of administration is required and the public should be allotted time to comment. A standardized format for these reports is not required. ACF collects these reports as well as expenditure and recipient data for the SSBG program, which leads primarily to output measures.

*(OEI 00-00-00000; expected issue date: FY 2006; new start)*

## **Administration on Aging**

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### **Aging Programs in One State**

We will determine whether aging program grants in a State comply with Federal requirements. HHS, under the Older American Act of 1965, Title III, awards funds to States to develop or strengthen preventive health service and health promotion systems through designated State agencies. These grants also have the objective to maximize informal support to enable senior citizens to remain in their homes and communities and to support nutrition services that nonfederal audits have identified problems in accounting for funds, unspent funds, and inadequately documented matching contributions.

*(OAS; W-00-06-26001 A-04-06-00000; expected issue date: FY 2006; new start)*

### **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. We 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 2006; work in progress)*



# Departmentwide Audits and Other Departmentwide Studies

## Financial Statement Audits

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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 2005 Financial Statements

The audited FY 2005 consolidated HHS financial statements are due to the Office of Management and Budget (OMB) by November 15, 2005. The following FY 2005 financial statement audits will be completed and reports will be 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-17-05-00001*)
- **CMS** - (*OAS; W-00-05-40008; A-17-05-02005*)
- **FDA** - (*OAS; W-00-05-40013; A-17-05-00003*)
- **Program Support Center** - (*OAS; W-00-05-40003; A-17-05-00004*)
- **NIH Service and Supply Fund** - (*OAS; W-00-05-40013; A-17-05-00005*)

### FY 2005 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 2005 financial statement audits:

- **Center for Information Technology** (NIH Computer Center)  
(*OAS; W-00-05-40012; A-17-05-00010*)
- **Program Support Center—Major Administrative Support Services**
  - **Payment Management System** (*OAS; W-00-05-40012; A-17-05-00009*)
  - **Division of Financial Operations** (*OAS; W-00-05-40012; A-17-05-00011*)
  - **Human Resources Support** (*OAS; W-00-05-40012; A-17-05-00012*)

## FY 2005 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-00-05-40012; A-17-05-00008)
- **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-00-05-40012; A-17-05-00013)
- **Closing-Package Audit Reports for the Governmentwide Financial Report System** are intended to support the preparation of governmentwide financial statements and reports.  
(OAS; W-00-05-40009; A-17-05-00006)
- **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-00-05-40009; A-17-05-00007)

## Audits of FY 2006 Financial Statements

The audited FY 2006 consolidated HHS financial statements are due to OMB by November 15, 2006. The following FY 2006 financial statement audits will be completed and reports issued during FY 2007:

- 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-00-06-40009; A-17-00-00000)
- **CMS** (OAS; W-00-06-40008; A-17-00-00000)
- **FDA** (OAS; W-00-06-40013; A-17-00-00000)
- **Program Support Center** (OAS; W-00-06-40003; A-17-00-00000)
- **NIH Service and Supply Fund** (OAS; W-00-06-40013; A-17-00-00000)

## FY 2006 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 2006 financial statement audits:

- **Center for Information Technology** (NIH Computer Center)  
(OAS; W-00-06-40012; A-17-00-00000)
- **Information Technology Support Center** (Office of Secretary)  
(OAS; W-00-06-40012; A-17-00-00000)

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

- **Payment Management System** (OAS; W-00-06-40012; A-17-00-00000)
- **Division of Financial Operations** (OAS; W-00-06-40012; A-17-00-00000)
- **Human Resources Support** (OAS; W-00-06-40012; A-17-00-00000)

## **FY 2006 Financial-Related Reviews**

- **Payment Management System Agreed-Upon Procedures** focus on analyses of grant advances and expenditures, posting of expenditures, and recalculation of the estimated year-end grant accrual.  
(OAS; W-00-06-40012; 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-00-06-40009; 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-00-06-40009; A-17-00-00000)

## **Automated Information Systems**

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### **Information Systems Internal Controls—FY 2005**

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 2005 financial statements.

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

### **Information Systems Internal Controls—FY 2006**

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 2006 financial statements.

*(OAS; W-00-06-40017/40019; various reviews; no report)*

### **Information System Security Program**

We will document and evaluate the existence and reliability of the Information System Security Program at selected operating divisions. This program helps to protect information resources in compliance with the

Federal Information Security Management Act 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.

*(OAS; W-00-06-42003; A-18-00-00000; expected issue date: FY 2006; new start)*

### **Federal Information Security Management Act of 2002 and Critical Infrastructure Protection**

We will assess various operating divisions' compliance with the Federal Information Security Management Act (FISMA) of 2002 and critical infrastructure protection requirements. The 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-00-06-40016; various reviews; expected issue date: FY 2006/07; work in progress and new start)*

### **Post Implementation Review for the Unified Financial Management System**

We will determine whether the Department has adequately addressed information systems security requirements as it 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-00-06-42006; A-18-00-00000; expected issue date: FY 2006; new start)*

### **Payment Management System Controls**

We 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-00-06-42002; A-18-00-00000; expected issue date: FY 2006; new start)*

## **Grants and Contracts**

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### **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-00-06-12345; various reviews, expected issue date: FY 2006; new start)*

## **Incurring Cost Contracts**

We will audit selected departmental contracts. Selection will be based on the dollar value of the contract; the significance of contract modifications since the original award; and input from the operating divisions and the offices of the Assistant Secretary for Budget, Technology and Finance and the Assistant Secretary for Administration and Management.

*(OAS; W-00-06-58055; A-00-00-00000; expected issue date: FY 2006; new start)*

## **State Issues**

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### **Direct Charges to Federal Programs for Unused Leave**

We will determine if a State is complying with OMB Circular A-87 in its treatment of unused leave that is charged to Federal programs. The State Auditor identified material noncompliance with OMB Circular A-87 by a State agency because unallowable payments for unused leave were charged as a direct cost to Medicaid. We will determine whether the State Auditor identified all inappropriate unused leave charges to Medicaid and whether other State agencies may be directly charging unused leave to Federal programs.

*(OAS; W-00-06-58057; A-04-06-00000; expected issue date: FY 2006; new start)*

### **Vendors' Rebates Collected**

We will determine if a State is using vendors' rebates received by the State as a result of purchases to reduce Federally claimed expenditures as required by OMB Circular A-87. The agency responsible for administering the State's cost allocation plan did not provide information regarding rebates received by the State to the various other State agencies so that they could be used to reduce Federal reimbursement claims. We will review the State's policies, procedures, controls, and practices to determine whether vendors' rebates were used to reduce federally claimed costs.

*(OAS; W-00-06-58058; A-04-06-00000; expected issue date: FY 2006; 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 2006; new start)*

### **State Funds**

The Office of Management and Budget Circular A-87, Cost Principles for State, Local and Indian Tribal Governments, establishes principles for determining the allowable costs incurred by State and Local governments

under Federal awards. Federal cost principles are designed to provide that Federal awards bear their fair share of cost but do not allow governmental entities to receive reimbursement for charges in excess of cost or to make a profit. From time-to-time OIG conducts reviews in the following areas:

- **Pensions**

These reviews will determine whether the Federal Government received equitable benefit when State pension funds were withdrawn, transferred to other State funds, or used to cover State expenses. (OAS; W-00-06-58050)

- **Excess Fund Reserves**

We will determine whether internal service, self-insurance, or other State funds that receive Federal Government contributions, have accumulated excess reserves. (OAS; W-00-06-58052)

- **Uncashed, Canceled Checks**

We will determine whether States with a large percentage of unclaimed, uncashed checks (escheated warrants) are promptly crediting Federal programs for the checks. Federal regulations require that States refund the Federal portion of unclaimed, uncashed checks. (OAS; W-00-06-58054)

## Other Issues

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### 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 2005 drug control funds. (OAS; W-00-06-58001; A-03-00-00000; expected issue date: FY 2006; 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 organization wide 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 follow-up 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-00-06-50012; various reviews; expected issue date: FY 2006; new start)*

### **Resolution of Audit Findings**

We will examine the Department's audit resolution process. Our review will focus on the monetary audit findings that have not been resolved within six months and the timeliness of final action taken on monetary recommendations. Each operating and staff division will be reviewed. We will also review the overall audit resolution process, staffing, training, and systems controls.