Department of Health and Human Services

Office of Inspector General

Work Plan

FISCAL YEAR 2008

OIG Office of Inspector General

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General

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A Message From the Office of Inspector General

We are pleased to present the Office of Inspector General Work Plan for fiscal year (FY) 2008. This publication describes activities that the Office of Inspector General (OIG) plans to continue or initiate with respect to the programs and operations of the Department of Health and Human Services (HHS). To place our activities in context, I describe below the authority for our work and the work-planning process.

Our work is authorized by the Inspector General Act of 1978 (Public Law 95-452), as amended. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the Department Secretary or agency administrator and Congress informed about the necessity for corrective action.

OIG is frequently asked how we allocate our resources and select the areas to review. We generally direct our resources to reflect OIG's and the Department's budget and priorities and accommodate our specific budget mandates. Consequently, over the last several years, we have allocated about 80 percent of our resources to reviews and investigations of the Medicare and Medicaid programs and 20 percent to the Department's public health and human service programs.

On an annual basis, OIG conducts a comprehensive work-planning process to identify the areas most worthy of attention in the coming year. The various factors we take into account include the following:

- requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress and the Department's management;
- significant management and performance challenges facing the Department, which we identify as part of the Department's annual performance assessment review;
- work performed by the Department and other organizations, such as the Government Accountability Office and the Office of Management and Budget (OMB); and
- management's actions to implement OIG recommendations from previous reviews.

Prior to issuing our final plan, OIG provides a draft to the Department and OMB. Comments received assist us in refining our proposals and conceptualizing plans for future years.

OIG work planning does not end with the publication of this annual plan; rather, it is a dynamic process to ensure that we accommodate the changing nature of issues affecting the Department. We are continuously examining current events, emerging issues, and priority shifts in Congress and the Administration. As a result of this examination, we may add new activities and decide to delay or cancel lower priority work.

The need for OIG to remain flexible with respect to work planning is best illustrated by the Gulf Coast hurricanes. While we were finalizing our FY 2006 work plan, disastrous hurricanes hit the Gulf Coast and prompted the Department to carry out unprecedented response and recovery activities. Consistent with the Department's move to action, OIG immediately redirected resources from other planned assignments to initiate reviews and investigations focusing on the Department's hurricane activities. This quick reaction was crucial to our ability to contribute to the governmentwide efforts to assess the quality of hurricane response and recovery activities and account for the expenditures of funds for these activities. As with the unforeseen hurricanes, we will continue to examine the relevance of our work and ensure that we are reviewing the most important areas.

This edition, formulated as of September 2007, describes ongoing and planned assignments and provides for each assignment the review objective, criteria related to the program being reviewed, OIG identification codes, and year in which we expect the report to be issued. Generally, our ongoing work will result in FY 2008 reports; work slated to begin in FY 2008 will result in FY 2008 or FY 2009 reports, depending upon when the assignments are initiated during the year and the complexity and scope of the examinations.

Our ongoing and planned work is describes as follows:

- OIG Work Related to the Centers for Medicare & Medicaid Services features work related to such issues as integrity of Medicare and Medicaid payments, prescription drug costs, and quality of care in long term care settings.

- OIG Work Related to Public Health and Human Services Programs and Departmentwide Issues features work related to such agencies as the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health; human service programs of agencies such as the Administration for Children and Families and the Administration on Aging; and departmentwide issues, such as financial accounting, information systems management, and oversight of grants and contracts.

An online version of this document is located at http://oig.hhs.gov/publications.html. If you have questions about this publication, please contact OIG's Office of External Affairs at 202-619-1343.

To report potential instances of waste, fraud, or abuse related to HHS's programs, you may file a report with the OIG Hotline at 1-800-HHS-TIPS (1-800-447-8477) or HHSTips@oig.hhs.gov.

OIG Components

With more than 1,500 staff throughout the Nation, OIG plans and carries out audits, evaluations, investigations, and legal activities through the following four components:

Office of Audit Services

The Office of Audit Services (OAS) conducts financial and performance audits of departmental programs, operations, grantees, and contractors following Government Auditing Standards issued by the Government Accountability Office. Financial audits principally provide reasonable assurance about whether financial statements are presented fairly in all material respects; performance audits assess the achievement of objectives and identify the presence of systemic weaknesses giving rise to waste, fraud, or abuse. Recommendations address problems, such as improper payments and inefficient and ineffective use of resources. OAS performs audits or oversees the audit work of others through a nationwide network of auditors, information technology experts, and other professionals.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations, conducted by a nationwide staff of evaluators and other professionals, focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts and coordinates investigations of fraud and misconduct related to the Department's programs, operations, and beneficiaries. With investigators working in all 50 States, OI leverages its resources by actively coordinating with the Department of Justice and other law enforcement authorities. OI identifies systemic weaknesses that leave Department programs vulnerable to fraud and recovers damages and penalties through civil and administrative proceedings.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides legal advice and representation to OIG on matters relating to Medicare, Medicaid, and other HHS programs and operations, administrative law issues, criminal procedure, and internal OIG management. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. Finally, OCIG renders advisory opinions, issues fraud alerts, and provides other guidance to the health care industry concerning the Federal anti-kickback statute and OIG sanctions.

Acronyms and Abbreviations

The following is a list of acronyms and abbreviations used in this publication.

ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AMP	average manufacturer price
AoA	Administration on Aging
ASC	ambulatory surgical center
ASP	average sales price
ASPR	Office of the Assistant Secretary for Preparedness and Response
AWP	average wholesale price
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
BIPA	Benefits Improvement and Protection Act
BP	best price
CAH	critical access hospital
CDC	Centers for Disease Control and Prevention
CFO	Chief Financial Officers Act
CFR	Code of Federal Regulations
CIA	corporate integrity agreement
CMS	Centers for Medicare & Medicaid Services
CMP	civil monetary penalty
CWF	Common Working File
CY	calendar year
DEA	Drug Enforcement Administration
DME	durable medical equipment
DoD	Department of Defense
DOJ	Department of Justice
DRA	Deficit Reduction Act
DRG	diagnosis-related group
DSH	disproportionate share payment
EMS	emergency medical services
ENT	enteral nutrition therapy
ESRD	end stage renal disease
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FFP	Federal financial participation
FFS	fee-for-service
FI	fiscal intermediary
FISMA	Federal Information Security Management Act
FUL	Federal upper limit
FY	fiscal year
GAO	Government Accountability Office

GSA	General Services Administration
HCBS	home- and community-based services
HHA	home health agency
HHS	Department of Health and Human Services
HHSAR	HHS Acquisition Regulation
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IMD	institution for mental diseases
IT	information technology
LTCH	long term care hospital
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage Organization
MA-PDP	Medicare Advantage Prescription Drug Plan
MCO	managed care organization
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act
MMIS	Medicaid management information system
MSIS	Medicaid Statistical Information System
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
OMB	Office of Management and Budget
OS	Office of the Secretary
PDP	prescription drug plan
PPS	Prospective Payment System
PSC	Program Support Center
Pub. L.	Public Law
QIO	Quality Improvement Organization
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
SNF	skilled nursing facility
TrOOP	true out-of-pocket
UPL	upper payment limit
U.S.C.	United States Code
WAMP	widely available market price

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OIG Work Related to the Centers for Medicare & Medicaid Services

The Office of Inspector General (OIG) allocates about 80 percent of its resources to work related to the Centers for Medicare & Medicaid Services (CMS), which administers the following programs:

- Medicare, which provides health insurance for people 65 years old or older, people younger than 65 years old with certain disabilities, and people of any age with end-stage renal disease. In fiscal year (FY) 2006, Medicare served 43 million beneficiaries at a cost of $337 billion. Medicare has four parts: Hospital Insurance (Part A), which helps cover inpatient care in hospitals, including critical access hospitals (CAH), skilled nursing facilities (SNF), and hospice and certain home health care; Supplementary Medical Insurance (Part B), which helps pay for physician services and outpatient care; Medicare Advantage (MA), which offers a range of prepaid managed health care choices; and Medicare Prescription Drug Benefit (Part D), which provides an optional prescription drug benefit to individuals enrolled in Medicare, generally through private prescription drug plans.

- Medicaid, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. In FY 2006, the enrollment for Medicaid was estimated at 47 million people; total Federal and State outlays were $317 billion, of which the Federal share was $180 billion.

- The State Children's Health Insurance Program (SCHIP), established in 1997 under Title XXI of the Social Security Act, is a matching grant to provide health insurance for low-income children who do not qualify for Medicaid but whose families are not able to afford private coverage. In FY 2006, SCHIP served 6.6 million beneficiaries at a cost of $5.5 billion in Federal share.

OIG's emphasis on these health care programs reflects the spending of the Department of Health and Human Services (HHS): CMS expenditures have accounted for about 80 percent of the Department's budget over the last several years. This focus is also rooted in statutory mandates and funding sources, including the following:

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA, Public Law (Pub. L.) No. 104-191), which established the Health Care Fraud and Abuse Control program (HCFAC) under the direction of the Attorney General and the Secretary of HHS to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a major portion of OIG's annual operating budget and must be used for work related to Medicare and Medicaid.

- The Deficit Reduction Act of 2005 (DRA, Pub. L. No. 109-171), which provides OIG annual funding of $25 million from FY 2006 through FY 2010 to undertake fraud and abuse control activities related to the Medicaid program.

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, which mandates that OIG:

    - compare average sales prices (ASP) to average manufacturer prices (AMP) and widely available market prices (WAMP) for drugs covered under Medicare Part B and notify the Secretary if the ASP for a drug exceeds the AMP or WAMP by more than 5 percent, and

    - report to Congress on annual evaluations of Medicare intermediaries' and carriers' information security programs.

Through our previous work, we have identified management and performance challenges facing the Medicare and Medicaid programs, most significantly oversight of Medicare Part D, integrity of Medicare payments, appropriateness of Medicaid payments, Medicaid and SCHIP administration, and quality of care in institutional and community-based settings. This chapter presents ongoing and proposed OIG work related to these challenges and other high-priority issues that we have identified during our work-planning process.

Medicare

Medicare Hospitals

Hospital Capital Payments

We will review Medicare inpatient capital payments. Capital payments are a hospital's expenditures for assets such as equipment and facilities. The basic methodology for determining capital prospective rates is found at 42 Code of Federal Regulations (CFR) § 412.308. We will determine whether capital payments to hospitals are appropriate. We will examine the methodology used to update capital rates and analyze the appropriateness of the payment level.
(OAS; W-00-08-35300; various reviews; expected issue date: FY 2009; new start)

Medicare-Dependent Hospital Program

We will review the appropriateness of FY 2002 base-year costs for a selected number of Medicare-dependent hospitals (MDH). Pursuant to section 5003(c) of the DRA, starting on October 1, 2006, payments to MDHs are based on 75 percent of its FY 2002 hospital-specific rates for discharges if that payment would result in higher Medicare payments than those under the Medicare Inpatient Prospective Payment System (IPPS). Payments to MDHs would be based on 75 percent of the FY 2002 adjusted hospital-specific costs. We will determine whether payments made to MDHs are correct and supported based on allowable costs from the FY 2002 cost reports.
(OAS; W-00-07-35301; various reviews; expected issue date: FY 2008; work in progress)

Adjustments for Graduate Medical Education Payments

We will review audit adjustments for direct and indirect graduate medical education that fiscal intermediaries (FI) make while settling Medicare cost reports. Regulations governing graduate medical education payments are found at 42 CFR §§ 412.105 and 413.78 through 413.83. We will determine whether the adjustments were appropriately reflected in the revised Medicare reimbursement.
(OAS; W-00-06-35189; various reviews; expected issue date: FY 2008; work in progress)

Nursing and Allied Health Education Payments

We will review 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 in accordance with Federal regulations at 42 CFR § 413.85. We will determine whether payments to providers for these costs were appropriate.
(OAS; W-00-05-35-35123; various reviews; expected issue date: FY 2008; work in progress)

Inpatient Prospective Payment System Wage Indices

We will review hospital and Medicare controls over the accuracy of the hospital wage data used to calculate wage indices for the IPPS. Hospitals must accurately report wage data for CMS to properly calculate the wage index in accordance with section 1886(d)(3) of the Social Security Act. Our prior work found hundreds of millions of dollars in misreported wage data. We will

determine whether hospitals have complied with Medicare requirements for reporting wage data and determine the effect on the Medicare program of incorrect diagnosis-related group (DRG) reimbursement caused by inaccurate wage data. We will also examine the appropriateness of using hospital wage indices for other provider types.
(OAS; W-00-04-35142; various reviews; expected issue date: FY 2008; work in progress)

Payments to Organ Procurement Organizations

We will review Medicare payments made to organ procurement organizations (OPO). An OPO coordinates the retrieval, preservation, and transportation of organs for transplant and maintains a system to allocate available organs to prospective recipients. Medicare reimburses OPOs under 42 CFR § 413.200 according to a cost basis method set out at 42 CFR § 413.24. We will determine whether payments made to OPOs are correct and supported.
(OAS; W-00-06-35152; various reviews; expected issue date: FY 2008; work in progress)

Inpatient Hospital Payments for New Technologies

We will review payments made to hospitals for new services and technologies. Pursuant to sections 1886(d)(5)(K) and (L) of the Social Security Act, Medicare's new technology payments consist of payments for new medical services and technologies that qualify as "new" under 42 CFR § 412.87 and are demonstrated to be otherwise inadequately paid under the DRG system. We will determine whether hospitals have submitted claims in accordance with the criteria and were appropriately reimbursed for costs associated with the new devices and technologies.
(OAS; W-00-08-35191; various reviews; expected issue date: FY 2008; new start)

Long Term Care Hospital Payments for Interrupted Stays

We will review certain payments made to long term care hospitals (LTCH). Pursuant to Federal regulations at 42 CFR § 412.531, special payment provisions apply to interrupted stays at LTCHs. As defined in 42 CFR § 412.531, an interrupted stay occurs when a beneficiary is discharged from an LTCH to certain kinds of facilities and then returns to the same LTCH within specified periods of time. We will determine whether payments for interrupted stays made to LTCHs were correct.
(OAS; W-00-06-35128; A-04-06-00024; expected issue date: FY 2008; work in progress)

Long Term Care Hospital Short Stay Outliers

We will review payments for cases discharged from LTCHs with lengths of stay well below the average for their DRGs, which are referred to as short stay outliers (SSO). Section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. No. 106-113, mandated the implementation of a Prospective Payment System (PPS) for LTCH facilities. Between 1995 and 2003, Medicare payments for LTCHs increased from $836 million to more than $2.7 billion. In 2002, Medicare began paying LTCHs under a PPS based on the same DRGs as those for inpatient acute-care hospitals. However, CMS applies a larger base payment to LTCHs. Our review will focus on the distribution of and payment amounts for SSO cases. We also will review cases that only marginally exceeded the SSO threshold.
(OEI; 01-07-00290; expected issue date: FY 2008; work in progress)

Special Payment Provisions for Patients Who Are Transferred to Onsite Providers and Readmitted to Long Term Care Hospitals

We will review the application of special payment provisions for patients who were transferred to onsite providers and readmitted to LTCHs. Pursuant to Federal regulations at 42 CFR § 412.532, if an LTCH discharges patients to specified colocated providers and directly readmits more than 5 percent of the total number of its Medicare inpatients discharged from that setting, special payment provisions apply. We will determine whether the special payment provisions were appropriately applied.
(OAS; W-00-08-35400; expected issue date: FY 2008; new start)

Special Payment Provisions for Long Term Care Hospitals Discharging Beneficiaries to Colocated or Satellite Providers

We will review the application of special payment provisions for LTCHs discharging beneficiaries to colocated hospitals or satellite providers. Pursuant to Federal regulations at 42 CFR § 412.534, special payment provisions apply if an LTCH's or LTCH satellite facility's discharged Medicare inpatient population that was admitted to the LTCH or satellite facility from the colocated hospital exceeds the applicable threshold outlined in the regulations. In these situations, payments to the LTCH may be reduced. We will determine whether the special payment provisions were appropriately applied.
(OAS; W-00-08-35401; expected issue date: FY 2008; new start)

Critical Access Hospitals

We will review payments made to CAHs. Pursuant to sections 1814(l)(1) and 1834(g) of the Social Security Act, CAHs are generally paid 101 percent of the reasonable costs of providing covered CAH services. Our objectives are to determine whether CAHs have met the CAH classification criteria set forth in section 1820(c)(2)(B) of the Social Security Act and conditions of participation set forth at 42 CFR 485 subpart F and whether payments made to CAHs were made in accordance with Medicare requirements.
(OAS; W-00-07-35101; expected issue date: FY 2008; work in progress)

Medicare Disproportionate Share Payments

We will review Medicare disproportionate share (DSH) payments made to hospitals. Under section 1886(d)(5)(F)(i)(I) of the Social Security Act, Medicare makes additional payments to acute care hospitals that serve a significantly disproportionate number of low-income Medicare and Medicaid patients. Medicare DSH payments have been steadily increasing, and previous OIG work has identified overpayments in this area. We will determine whether these payments were made in accordance with Medicare criteria set forth in section 1886(d)(5)(F)(vii) of the Social Security Act. We will review various components of the calculation methodology as set forth in section 1886(d)(5)(F)(v)-(vi) of the Social Security Act, determine whether the hospitals' classifications are appropriate, and examine the total amounts of uncompensated care costs that hospitals incur.
(OAS; W-00-08-35402; expected issue date: FY 2009; new start)

Inpatient Psychiatric Facility Emergency Department Adjustments

We will review payments made to inpatient psychiatric facilities to determine whether appropriate adjustments were made for facilities that operate emergency departments. Pursuant

to Federal regulations at 42 CFR § 412.424, some of these facilities receive an adjusted rate if they maintain a qualifying emergency department. We will determine whether appropriate rate adjustments were made.
(OAS; W-00-08-35403; expected issue date: FY 2008; new start)

Provider Bad Debts

We will review Medicare bad debts claimed by acute care inpatient hospitals, LTCHs, inpatient rehabilitation facilities, inpatient psychiatric facilities, and SNFs to determine whether they were reimbursable. Pursuant to Federal regulations at 42 CFR § 413.89, uncollectible debts related to unpaid deductible and coinsurance amounts may be claimed as Medicare bad debt if specific criteria are met. We will determine whether the bad debt payments were appropriate under Medicare regulations and whether recoveries of prior year writeoffs were properly used to reduce the cost of beneficiary services for the period in which the recoveries were made.
(OAS; W-00-08-35404; expected issue date: FY 2008; new start)

Compliance With Medicare's Transfer Policy

We will review coding of claims submitted by hospitals for erroneously coded discharges that should have been coded as transfers. Pursuant to Federal regulations at 42 CFR § 412.4 (e), a hospital discharging a beneficiary is paid the full DRG payment. In contrast, under 42 CFR § 412.4(f), a hospital that transfers a beneficiary to another facility is paid a graduated per diem rate, not to exceed the full DRG payment that would have been made if the beneficiary had been discharged without being transferred. We will determine whether claims were appropriately coded.
(OAS; W-00-07-35102; A-04-07-03035, expected issue date: FY 2008; work in progress)

Payments for Diagnostic X-Rays in Hospital Emergency Departments

We will review a sample of Medicare Part B paid claims and medical records for diagnostic x-rays performed in hospital emergency departments to determine the appropriateness of payments. Radiology services furnished by a physician are reimbursed by the Medicare Physician Fee Schedule provided the conditions for payment for radiology services at 42 CFR § 415.102 (a) and 42 CFR § 120 are met. The Medicare Payment Advisory Commission (MedPAC), in its March 2005 testimony before Congress, reported concerns regarding the increasing cost of imaging services for Medicare beneficiaries and potential overuse of diagnostic imaging services. In 2004, approximately 4.7 million diagnostic x-rays were performed in Medicare-certified hospitals with emergency departments, a 9.6-percent increase since 2001. Medicare spent approximately $48.3 million for these services in 2004. We will determine the appropriateness of payments for diagnostic x-rays and interpretations.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Patient Care and Safety in Physician-Owned Specialty Hospitals

We will review indicators of patient care and safety in physician-owned specialty hospitals. Hospitals are required to comply with the Federal requirements set forth in the Social Security Act at section 1861(e) to ensure that Medicare beneficiaries receive care and services pursuant to 42 CFR Part 482, Conditions for Participation for Hospitals. Concerns associated with the growth of specialty hospitals led Congress, as part of the MMA, to impose an 18-month moratorium on referrals to new physician-owned specialty hospitals. In June 2005, CMS issued

a memorandum suspending the processing of provider enrollment applications for new specialty hospitals by the Medicare FIs. As part of this review, we will also examine policies related to staffing requirements at these hospitals.
(OEI; 02-06-00310; expected issue date: FY 2008; work in progress)

Oversight of the Joint Commission Hospital Accreditation Process

We will review CMS's policies and procedures regarding the Joint Commission hospital accreditation process. Sections 1861(e) and 1865(a)) of the Social Security Act and the regulations at 42 CFR 488.5 allow institutions accredited as hospitals by the Joint Commission to be deemed to meet the Medicare Conditions of Participation for Hospitals. The Joint Commission accredits about 80 percent of the Nation's hospitals that participate in the Medicare program. In 2004, the Joint Commission revamped its hospital accreditation process, requiring hospitals to evaluate themselves, typically in the middle of the hospital's 18-month accreditation cycle, and develop action plans for performance improvement. This study will evaluate the extent and adequacy of CMS's policies and procedures regarding the Joint Commission hospital accreditation process.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Medicare Secondary Payer

We will review Medicare payments for beneficiaries who have other insurance. Pursuant to section 1862(b) of the Social Security Act, Medicare payments for such beneficiaries are required to be secondary to certain types of insurance coverage. We will assess the effectiveness of current procedures in preventing inappropriate Medicare payments for beneficiaries with other insurance coverage. For example, we will evaluate procedures for identifying and resolving credit balance situations, which occur when payments from Medicare and other insurers exceed the providers' charges or the allowed amount.
(OAS; W-00-08-35317; various reviews; expected issue date: FY 2008; new start)

Medicare Home Health

Cyclical Noncompliance in Medicare Home Health Agencies

We will review national data on home health agencies' (HHA) survey and certification deficiencies to identify whether there are trends and patterns of cyclical noncompliance with certification standards. Section 1891(c)(2)(A) of the Social Security Act requires that CMS survey at least every 36 months the quality of care and services furnished by each HHA, as measured by indicators of medical, nursing, and rehabilitative care. We will evaluate how cyclically noncompliant HHAs perform on these indicators as compared to HHAs without histories of noncompliance and identify whether CMS applies appropriate sanctions to noncompliant HHAs.
(OEI; 09-06-00040; expected issue date: FY 2008; work in progress)

Accuracy of Data on the Home Health Compare Web Site

We will review the extent to which the Home Health Compare Web site includes accurate and complete information on Medicare-certified HHAs. This CMS-maintained Web site provides beneficiaries and their families with information on all HHAs certified by Medicare as of

January 2003. We will also examine how CMS identifies and updates missing and incorrect information in the database.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Accuracy of Coding and Claims for Medicare Home Health Resource Groups

We will review Medicare claims submitted by HHAs to determine the extent to which the home health resource groups (HHRG) that are used in determining payments to HHAs are accurate and supported by documentation in the medical record. Section 1895 of the Social Security Act governs the payment basis and reimbursement for claims submitted by HHAs including a case-mix adjustment using HHRGs. Medicare pays for home health episodes based on a PPS that categorizes beneficiaries into groups, referred to as HHRGs. Each HHRG has an assigned weight that affects the payment rate. We will assess the accuracy of HHRG assignment and identify potential patterns of upcoding by HHAs.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Medicare Nursing Homes

Skilled Nursing Facility Consolidated Billing

We will review Medicare Part B claims submitted by suppliers for items, supplies, or services provided to beneficiaries during Part A Medicare-covered SNF stays. Pursuant to sections 1842(b)(6)(E) and 1862(a)(18) of the Social Security Act, the supplier must bill and receive payment from the SNF, rather than from Medicare, for these items or services. Prior work has identified significant improper claims submission and reimbursement in this area, and we are continuing our work to identify additional overpayments. We will also determine whether edits in CMS's main claims-processing system, the Common Working File (CWF), are effective in detecting and preventing improper payments.
(OAS; W-00-06-35185; various reviews; expected issue date: FY 2008; work in progress)

Oversight of Medicare Skilled Nursing Facility Cost Reports

We will review a sample of nursing facility cost reports and evaluate CMS's oversight of Medicare expenditures contained in those cost reports. Section 1888(e) of the Social Security Act established a PPS for skilled nursing facilities based on the submission of allowable cost data by SNFs. CMS has issued guidelines governing the reporting of cost data in its "Provider Reimbursement Manual." Nursing facility care accounted for 16 percent of Medicare expenditures in 2005. We will determine the extent to which CMS is monitoring Medicare nursing facility cost reports to ensure compliance with established requirements and whether submitted cost reports meet those requirements.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Accuracy of Coding for Medicare Skilled Nursing Facility Resource Utilization Groups' Claims

We will review a national sample of Medicare claims submitted by SNFs to determine the extent to which Resource Utilization Groups (RUG) included on SNF claims for Medicare reimbursement are accurate and supported by the residents' medical records. Section 1888(e) of the Social Security Act provides the basis for the establishment of the per diem Federal payment

rates applied under a PPS to SNFs effective July 1, 1998. Medicare pays for Part A-covered SNF stays based upon a PPS that includes a case-mix adjustment based upon groups, referred to as RUGs. A 2006 OIG report found that 22 percent of claims were upcoded, representing $542 million in potential overpayments for FY 2002. As part of our follow-up work, we will also identify areas to improve the accuracy of payments to SNFs.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Medicare Hospice Care

Medicare Hospice Care for Nursing Home Residents: Services and Appropriate Payments

We will review the nature and extent of hospice services that are provided to Medicare beneficiaries who reside in nursing facilities and assess the appropriateness of payments for hospice care for these services. Section 1861(dd) of the Social Security Act governs hospice care in the Medicare program. Medicare hospice spending doubled from $3.5 billion to $7 billion from 2001 to 2004, with the growth associated mostly with nursing home residents. A previous OIG review found that hospice beneficiaries in nursing facilities received nearly 46 percent fewer nursing and aid services than hospice beneficiaries residing at home. By conducting a medical record review of selected beneficiaries, we will assess beneficiaries' plans of care and determine whether the services they receive are consistent with their plans of care and whether payments are appropriate.
(OEI; 02-06-00221; expected issue date: FY 2008; work in progress)

Medicare Physicians and Other Health Professionals

Place of Service Errors

We will review physician coding of place of service on claims for services performed in ambulatory surgical centers (ASC) and hospital outpatient departments. Federal regulations at 42 CFR § 414.22(b)(5)(i)(B) provide for different levels of payments to physicians depending on where the services are performed. Medicare pays a physician a higher amount when a service is performed in a non-facility setting, such as a physician's office, than it does when the service is performed in a hospital outpatient department or, with certain exceptions, in an ASC. We will determine whether physicians properly coded the places of service on claims for services provided in ASCs and hospital outpatient departments.
(OAS; W-00-06-35113; various reviews; expected issue date: FY 2008; work in progress)

Evaluation and Management Services During Global Surgery Periods

We will review industry practices related to the number of evaluation and management (E&M) services provided by physicians and reimbursed as part of the global surgery fee. CMS's "Medicare Claims Processing Manual," Chapter 12, section 40, contains the criteria for the global surgery policy. Under the global surgery fee concept, physicians bill a single fee for all of their services usually associated with a surgical procedure and related E&M services provided during the global surgery period. The global surgery fee includes payment for a certain number of E&M services provided during the global surgery period. We will determine whether industry

practices related to the number of E&M services provided during the global surgery period have changed since the global surgery fee concept was developed in 1992.
(OAS; W-00-06-35207; A-05-06-00040; expected issue date: FY 2008; work in progress)

Medicare Payments for Psychiatric Services

We will review Medicare payments for psychiatric services. Section 1862 (a)(1)(A) of the Social Security Act provides that Medicare will pay for items or services only if they are reasonable and medically necessary. We will determine whether claims submitted for psychiatric services were supported and billed in accordance with Medicare requirements.
(OAS; W-00-07-35304; expected issue date: FY 2009; new start)

Services Performed by Clinical Social Workers

We will review services furnished by clinical social workers (CSW) to inpatients of Medicare participating hospitals or SNFs to determine whether the services were separately billed to Medicare Part B. Federal regulations at 42 CFR § 410.73 (b)(2) describe services performed by a CSW that cannot be billed as CSW services under Medicare Part B when provided to inpatients of certain facilities. We will examine Medicare Part A and Part B claims with overlapping dates of service to determine whether services performed by CSWs in inpatient facilities were separately billed to Medicare Part B.
(OAS; W-00-08-35405; expected issue date: FY 2009; new start)

Medicare Payments for Selected Physician Services

We will review the appropriateness of Medicare Part B payments for selected physician services. Section 1861(q) of the Social Security Act describes physician services as professional services performed by physicians, including surgery; consultation; and home, office, and institutional calls. Medicare reimbursement for physician services is made on the basis of a fee schedule, which is a predetermined payment amount set forth by law. Section 1833(e) of the Social Security Act precludes payments to any provider of services unless the provider has furnished the information necessary to determine the amounts due such provider. We will review the appropriateness of Medicare payments for various types of physician services to determine whether these services were paid in accordance with Medicare requirements.
(OAS; W-00-08-35406; expected issue date: FY 2009; new start)

Medicare "Incident to" Services

We will review Medicare claims for services furnished "incident to" the professional services of selected physicians. Medicare Part B generally pays for services "incident to" a physician's professional service; such services are typically performed by a nonphysician staff member in the physician's office. Federal regulations at 42 CFR § 410.26(b) specify criteria for "incident to" services. We will examine the Medicare services that selected physicians bill "incident to" their professional services and the qualifications and appropriateness of the staff who perform them. This study will review medical necessity, documentation, and quality of care for "incident to" services.
(OEI; 09-06-00430; 09-06-00431; expected issue date: FY 2008; work in progress)

Appropriateness of Medicare Payments for Polysomnography

We will examine the appropriateness of payments for polysomnography services. Polysomnography, which typically occurs at a specialized sleep clinic or center, is a type of diagnostic test in which a number of the patient's physical parameters, such as heart rate and brain activity, are measured during sleep. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare will pay for services only if they are medically necessary. Medicare covers polysomnography for the diagnosis of a limited number of conditions when the testing meets particular criteria. Sleep studies are reimbursable for patients with symptoms consistent with sleep apnea, narcolepsy, impotence (the diagnosis of which can benefit from polysomnography), or parasomnia in accordance with the "Medicare Benefit Policy Manual," Pub. No. 100-02, Chapter 15, section 70. Medicare payments for polysomnography increased from $62 million in 2001 to $170 million in 2004. We will also examine the factors contributing to the rise in Medicare payments for polysomnography.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Long Distance Physician Claims Associated With Home Health Agency and Skilled Nursing Facility Services

We will review the appropriateness of payments for physician services paid under Medicare Part B for beneficiaries either receiving care from Medicare HHAs or residing in SNFs while living significant distances from the physicians billing for services. Section 1861(m) of the Social Security Act defines home health services provided to Medicare beneficiaries under the Hospital Insurance (Part A) and the Supplemental Medical Insurance (Part B) benefits of the Medicare program. We will determine whether Medicare Part B physician services have been inappropriately claimed for beneficiaries receiving HHA and SNF services.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Assignment Rules by Medicare Providers

We will review whether Medicare providers are adhering to assignment rules in billing Medicare beneficiaries. Section 1866(2)(A) of the Social Security Act precludes participating physicians/suppliers from charging Medicare beneficiaries more than the deductible and coinsurance based upon the approved Medicare payment amount determination. Providers who accept assignment must accept Medicare's payment and beneficiary copayment, referred to as the Medicare allowed amount, as payment in full for all covered services. Providers cannot "balance bill" beneficiaries for amounts in excess of the Medicare allowed amounts. We will determine the extent to which providers may be billing beneficiaries in excess of amounts allowed by Medicare requirements and assess beneficiary awareness of the potential violations.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Business Relationships and the Use of Magnetic Resonance Imaging Under the Medicare Physician Fee Schedule

We will review the arrangements under which magnetic resonance imaging (MRI) is provided under the Medicare Physician Fee Schedule. Section 1848 (a) (1) of the Social Security Act establishes the physician fee schedule as the basis for Medicare reimbursement for all physician services. We will describe relationships among physicians, billing providers, and others who work together to provide imaging services and determine whether these relationships affect levels of utilization. We will pay particular attention to financial relationships among the parties

involved in providing services and identify whether such relationships are associated with high use of services.
(OEI; 01-06-00261; expected issue date: FY 2008; work in progress)

Medicare Payments for Interventional Pain Management Procedures

We will review Medicare payments for interventional pain management procedures. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare will pay for services only if they are medically necessary. Interventional pain management procedures consist of minimally invasive procedures, such as needle placement of drugs in targeted areas, ablation of targeted nerves, and some surgical techniques. Many clinicians believe that these procedures are useful in diagnosing and treating chronic, localized pain that does not respond well to other treatments. Interventional pain management is a relatively new and growing medical specialty. In 2005, Medicare paid nearly $2 billion for these procedures. We will determine the appropriateness of Medicare payments for interventional pain management procedures and assess the oversight of these procedures.
(OEI; 05-07-00200; expected issue date: FY 2008; work in progress)

Geographic Areas With High Utilization of Ultrasound Services

We will review services and billing patterns in geographic areas with high utilization of ultrasound services paid under the Medicare Physician Fee Schedule. Our review will examine disproportionately high Medicare allowed charges and services per beneficiary and disproportionately high percentages of beneficiaries receiving ultrasound services relative to the rest of the country. Section 1848(a)(1) of the Social Security Act establishes the physician fee schedule as the basis for Medicare reimbursement for all physician services, and section 1862(a)(1)(A) provides that Medicare will pay for services only if they are medically necessary. In areas of high utilization of ultrasound services, we will examine service profiles, provider profiles, and beneficiary profiles.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Geographic Areas With a High Density of Independent Diagnostic Testing Facilities

We will review services and billing patterns in geographic areas with high concentrations of independent diagnostic testing facilities (IDTF). An IDTF is a facility that performs diagnostic procedures and that is independent of a physician's office or hospital. It may have a fixed location or be a mobile entity, and the practioner performing the procedures may be a nonphysician. IDTFs must meet performance requirements at 42 CFR § 410.33 to obtain and maintain Medicare billing privileges. A 2006 OIG review found numerous problems with IDTFs, including noncompliance with Medicare standards and potential improper payments of $71.5 million. In areas with a high density of IDTFs, we will examine service profiles, provider profiles, beneficiary profiles, and billing patterns.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Payments for High Frequency Chiropractic Treatments

We will review chiropractor billings for high frequency treatments to determine whether they comply with Medicare coverage criteria and documentation requirements. High frequency refers to a potentially excessive number of treatments or outliers to guidelines or standards of care.

Section 1861(r)(5) of the Social Security Act defines physicians as including chiropractors, but only for treatment by manual manipulation of the spine to correct subluxations of the spine. Federal regulations at 42 CFR § 410.21(b) further limit Medicare payment to treatment of subluxations that result in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. Sections 1862(a)(1)(A) and 1833(e) of the Social Security Act provide that Medicare pay for services only if they are medically necessary and supported by documentation. Prior OIG work found that 40 percent of chiropractic services were for maintenance therapy and thus did not meet Medicare coverage criteria, potentially costing the program and its beneficiaries approximately $186 million in improper payments. We will determine the appropriateness of Medicare payments for high frequency chiropractic claims.
(OEI; 07-07-00390; expected issue date: FY 2008; work in progress)

Physician Reassignment of Benefits

We will review the extent to which Medicare physicians reassign their benefits to other entities. Section 1842(b)(6) of the Social Security Act prohibits physicians who provide services for Medicare beneficiaries from reassigning their right to Medicare payments to other entities, unless a specific exception applies. For example, physicians are permitted to reassign to other entities enrolled in Medicare when contractual arrangements exist between the physicians and the entities that meet certain program integrity safeguards or when payments are being made to the physicians' employers. Investigations in South Florida have revealed schemes in which fraudulent providers obtain identifying information about legitimate physicians and request reassignments on their behalf. Having a large number of reassignments may be indicative of fraudulent or abusive activity. We will examine a national sample of Medicare physicians to determine the extent to which they reassign their benefits to other entities and the extent to which the physicians are aware of reassignments requested on their behalf.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Medical Equipment and Supplies

Durable Medical Equipment Payments for Beneficiaries Receiving Home Health Services

We will review Medicare claims for durable medical equipment (DME), prosthetics, orthotics, and supplies furnished to beneficiaries receiving HHA services. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare pay for items and supplies only if they are medically necessary. CMS's "Medicare Benefit Policy Manual," Pub. L. No. 100-02, Chapter 15, section 110.1.C, provides additional guidance on application of the medical necessity requirement for DME. Based on OIG interviews with home health patients, there were indications of unnecessary DME being ordered for beneficiaries receiving home health services. We will determine whether DME claims paid by Medicare on behalf of beneficiaries receiving home health services were allowable.
(OAS; W-00-07-35196; expected issue date: FY 2008; work in progress)

Medicare Payments for Durable Medical Equipment Claims With Modifiers

We will review the appropriateness of Medicare payments to DME suppliers that submitted claims with modifiers. Section 1833(e) of the Social Security Act precludes payments to any

service provider unless the provider has furnished the information necessary to determine the amounts due such provider. For certain items to be covered under the Medicare program, a DME supplier must use modifiers to indicate that it has the appropriate documentation on file; upon request, the supplier is required to provide the documentation to support its claim for payment. Reviews of suppliers conducted by several of CMS's DME regional carriers found that suppliers had little or no documentation to support their claims. This suggests that many of the claims submitted may have been invalid and should not have been paid by Medicare. We will determine whether payments to DME suppliers were made in accordance with Medicare requirements.
(OAS; W-00-07-35305; expected issue date: FY 2009; new start)

Medicare Part B Payments for Home Blood Glucose Testing Supplies

We will review Medicare Part B payments made for home blood glucose test strips and lancet supplies. Section 1862(a)(1)(A) of the Social Security Act requires that a service or an item be reasonable and medically necessary for the diagnosis or treatment of illness or injury to be covered by Medicare. The Local Medical Review Policies (LMRP) or local coverage determinations, whichever is applicable, issued by the four DME Medicare administrative contractors, require that the physician's order for each item billed to Medicare include certain elements and be retained by the supplier to support billing for those services. Further, the LMRP requires that suppliers add a modifier to identify when the patient is insulin-treated or non-insulin treated. The amount of supplies allowable for Medicare reimbursement differs depending on the applicable modifier. We will determine the appropriateness of Medicare Part B payments to DME suppliers for home blood glucose test strips and lancet supplies.
(OAS; W-00-08-35407; various reviews; expected issue date: FY 2009; new start)

Durable Medical Equipment Payments in South Florida

We will review Medicare claims submitted by South Florida providers for DME items and supplies. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare pay for items and services only if they are medically necessary. CMS's "Medicare Benefit Policy Manual," Pub. L. No. 100-02, Chapter 15, section 110.1.C, provides additional guidance on the application of the medical necessity requirement for DME. In a recent review of DME suppliers in three South Florida counties, we found that 31 percent of suppliers did not meet selected Medicare supplier standards requiring suppliers to maintain a physical facility and to be open and staffed during reasonable business hours. We will determine whether DME claims paid by Medicare to suppliers in South Florida were allowable.
(OAS; W-00-07-35213; various reviews; expected issue date: FY 2008; work in progress)

Comparison of Prices for the Negative Pressure Wound Therapy Pump

We will compare suppliers' acquisition costs and prices of certain negative pressure wound therapy pumps (pump) to Medicare reimbursement. Section 1861(s)(4) provides for Medicare Part B coverage of medically necessary durable medical equipment, including the pump. Between 2001 and 2006, Medicare payment for the pump rose 624 percent, and a recent OIG study found that 24 percent of pump claims did not meet Medicare coverage criteria. We will assess the range of supplier purchase prices for the pump to determine how Medicare reimbursement compares to the median supplier purchase price.
(OEI; 02-07-00000; expected issue date: FY 2008; work in progress)

Payment Suspensions for Medical Equipment Suppliers

We will review whether CMS has inappropriately made payments to suspended or excluded DME suppliers. Regulations at 42 CFR § 405.371 authorize the suspension of payments to providers and suppliers if reliable information exists indicating overpayment, fraud, willful misrepresentation, or aberrant billing practices. We will assess the adequacy of CMS's safeguards to prevent payment to providers and suppliers that have been suspended or excluded.
(OEI; 06-07-00080; expected issue date: FY 2008; work in progress)

Durable Medical Equipment Claims Review in Comprehensive Error Rate Testing

We will review Medicare payments for DME to determine the adequacy of medical records and other supporting documentation used by the Comprehensive Error Rate Testing program to support CMS's FY 2006 DME error rate. We will determine whether payments for items such as power wheelchairs, orthotics, and other medical supplies were appropriate; whether the suppliers' and physicians' documentation support the claims; and whether the items were medically necessary and/or whether the beneficiaries actually received the items.
(OAS; W-00-07-40026; A-01-07-00508; expected issue date: FY 2008; new start)

Appropriateness of Medicare Reimbursement for Pressure-Reducing Support Surfaces

We will review the appropriateness of payments for pressure-reducing support surfaces. Pressure-reducing support surfaces are a kind of durable medical equipment used for the care of pressure sores. Sections 1862(a)(1)(A) and 1861(s)(4) of the Social Security Act provide for coverage of medically necessary DME, including pressure-reducing support surfaces under Medicare. In 2006, Medicare-allowed charges for support surfaces reached $164 million. We will conduct a medical review of claims to determine the appropriateness of payments for support surfaces.
(OEI; 02-07-00420; expected issue date: FY 2009; work in progress)

Medicare Payments for Power Wheelchairs

We will review documentation supporting claims for power wheelchairs paid for by Medicare and determine whether Medicare beneficiaries received the required face-to-face examinations from the referring practitioners prior to receipt of power wheelchairs, in accordance with sections 1862(a)(1)(A) and 1834(a) of the Social Security Act. Section 1861(n) of the Social Security Act defines DME as including power-operated wheelchairs. In 2003, Medicare payments for power wheelchairs peaked at $1.2 billion. In 2004, as a result of expanded CMS program integrity initiatives, power wheelchair spending decreased to $850 million. However, Medicare payments for power wheelchairs increased again in 2005 to approximately $920 million. We will determine the appropriateness of Medicare payments for power wheelchairs.
(OEI; 04-07-00410; expected issue date: FY 2008; work in progress)

Supplier Purchase Prices for Power Wheelchairs in the Medicare Program

We will review invoice prices for power wheelchairs and compare those prices to the Medicare fee schedule to assess pricing variations. In 2004, we found that the reimbursement rate paid by Medicare for power wheelchairs exceeded the prices suppliers paid by 242 percent. Section

1861(n) of the Social Security Act defines DME as including power-operated wheelchairs. On November 15, 2006, CMS implemented a revised Medicare fee schedule for power wheelchairs as part of a strategy to curb fraud and abuse and address the significant growth in expenditures for power wheelchairs and similar items under the Medicare program. We will determine the difference between the Medicare fee schedule for power wheelchairs and suppliers' invoice prices.
(OEI; 04-07-00400; expected issue date: FY 2008; work in progress)

Part B Services in Nursing Homes: An Overview

We will review the extent of Part B services provided to nursing home residents whose stays are not paid for under Medicare's Part A SNF benefit. Unlike services provided during a Part A SNF stay, which are billed to Medicare directly by the SNF according to consolidated billing requirements, Part B services are provided and billed directly by suppliers and other providers. In repealing consolidated billing provisions that would have applied to non-Part A SNF stays, Congress directed OIG in section 313 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. No. 106-554) to monitor these services for abuse. This review will determine the extent of Part B services provided to nursing home residents during 2006 and assess patterns of billing among nursing homes and providers. We also plan a number of indepth reviews on specific Part B services, such as DME and enteral nutrition therapy (ENT).
(OEI; 06-07-00580; expected issue date: FY 2008; work in progress)

Part B Services in Nursing Homes: Durable Medical Equipment

We will review Medicare Part B DME payments allowed for items or supplies provided to beneficiaries in nursing homes. Section 1834(a) of the Social Security Act authorizes Medicare payments for DME claims. Pursuant to section 1861(n) of the Social Security Act, a nursing home is specifically excluded from qualifying as a beneficiary's home for DME payment purposes when the nursing home is engaged primarily in providing skilled nursing care or rehabilitation services. A previous OIG report found that $210 million was potentially inappropriately paid for DME for beneficiaries residing in nursing homes. We will review 2006 Medicare claims data to determine the appropriateness of Medicare Part B DME services allowed for beneficiaries during nursing home stays not covered by Medicare Part A. We will also assess the efforts of Medicare suppliers and contractors to detect and prevent inappropriate Part B DME payments.
(OEI; 06-07-00100; expected issue date: FY 2008; work in progress)

Part B Services in Nursing Homes: Enteral Nutrition Therapy

We will review Part B ENT, commonly called tube feeding, to determine the appropriateness of payments for associated services. This review will specifically assess the medical necessity, adequacy of documentation, and coding accuracy of claims submitted for Medicare beneficiaries during a nursing home stay that is not covered under the Part A SNF benefit. (ENT provided during a Part A SNF stay is the subject of another OIG review focusing on consolidated billing for SNFs and will address ENT provided during a Part A SNF stay). Section 1861(s)(8) of the Social Security Act authorizes Medicare Part B coverage of ENT under a prosthetic device

benefit provision for beneficiaries residing at home or in nursing facilities when the stays are not covered by Medicare Part A. We will assess the appropriateness of payments for claims for ENT.
(OEI; 06-07-00090; expected issue date: FY 2008; work in progress)

Part B Pricing of Enteral Nutrition Therapy

We will review Part B pricing of ENT. Medicare covers ENT for beneficiaries who cannot swallow because of permanent or severe medical problems. Section 1861(s)(8) of the Social Security Act authorizes Medicare Part B coverage of ENT under the prosthetic device benefit provision for beneficiaries residing at home or in nursing facilities when the stays are not covered by Medicare Part A. Past OIG work suggests that Medicare reimbursement for ENT substantially exceeds prices commonly available to purchasers, such as nursing homes or HHAs. We will compare Medicare's fee schedule for ENT to prices available to nursing homes, individuals, and other purchasers.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Part B Drug Reimbursement

Computation of Average Sales Price

We will review drug manufacturers' methodologies for computing the ASP and assess manufacturers' compliance with the requirements under section 1847A of the Social Security Act. The ASP is used for determining the Medicare Part B reimbursement for certain classes of drugs. The calculation of ASP by manufacturers is a requirement enacted as part of the MMA. This review will provide policymakers with information on whether manufacturers' calculations of the ASP complied with the requirements of the MMA.
(OAS; W-00-05-35174; various reviews; expected issue date: FY 2008; work in progress)

Payments to Dialysis Facilities for Epogen

We will review the appropriateness of Medicare claims submitted by dialysis facilities for Epogen administration. Epogen is a biologically engineered protein that is used to treat anemia associated with chronic renal failure. Federal regulations at 42 CFR § 405.2139 require that end-stage renal disease (ESRD) facilities maintain complete medical records on all patients in accordance with accepted professional standards and practices. The records must be completely and accurately documented and contain sufficient information to identify the patient, justify the diagnosis and treatment, and document the treatment results accurately. We will determine whether claims submitted for Epogen administered at dialysis facilities were supported and billed in accordance with Medicare requirements. We will also assess CMS's and the FIs' claim oversight function for Epogen administration.
(OAS; W-00-07-35306; A-03-07-00002; expected issue date: FY 2008; work in progress)

Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Widely Available Market Prices

We will periodically review WAMPs for selected prescription drugs covered by Part B and compare them to ASPs. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Section 1874A(d) of the Social Security Act, enacted by section

303(c)(1) of the MMA, mandates that OIG compare ASPs to WAMPs (if any) for Part B drugs and notify the Secretary of HHS, at such times as the Secretary may specify, if the ASP for a selected drug exceeds the WAMP by a threshold of 5 percent. We will compare ASPs to WAMPs and identify drug prices that exceed the threshold.
(OEI; 03-07-00190; 00-00-00000; various studies; expected issue date: FY 2008; work in progress)

Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Average Manufacturer Prices

We will periodically review Medicare Part B drug prices by comparing ASPs to AMPs. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Section 1847A(d) of the Social Security Act, enacted by section 303(c)(1) of the MMA, mandates that OIG compare ASPs to AMPs for Part B drugs and notify the Secretary of HHS if the ASP for a selected drug exceeds the AMP by a threshold of 5 percent. We will compare ASPs to AMPs for Part B drugs and identify drug prices that exceed the threshold.
(OEI; 03-07-00530; various studies; expected issue date: FY 2008; work in progress)

Changes in Average Sales Price for Part B Drugs

We will review the extent to which ASPs for Medicare Part B drugs fluctuate from quarter to quarter. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP as mandated by Section 1847A(c) of the Social Security Act, enacted by section 303(c)(1) of the MMA. We will identify the ASPs with the greatest quarterly variations.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Payment for Chemotherapy Drug Administration Services

We will review Medicare payment for chemotherapy drug administration services, as governed by Section 1832 of the Social Security Act, that occur without corresponding chemotherapy administration drug claims. MedPAC found that Medicare payments for chemotherapy drug administration services increased 217 percent between 2003 and 2004, while payments for chemotherapy drugs increased only 4 percent. We will select a sample of claims for chemotherapy administration services and determine whether drugs for chemotherapy services were also billed.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Billing for Excessive Dosages of Prescription Drugs in Medicare Part B

We will review Medicare Part B drug claims to determine whether certain drugs are billed at aberrantly high dosages. Section 1861(b)(2) of the Social Security Act provides for Part B coverage of certain drugs and biologicals. Many drugs covered under Part B have very high Medicare reimbursement levels. Therefore, billing for excessively high dosages (i.e., those greater than the established therapeutic ranges) could lead to substantial overpayments. We will examine provider prescribing patterns using a sample of claims for selected Part B drugs and compare the amounts of drugs billed to generally accepted dosages.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Upselling of Inhalation Drugs by Suppliers

We will review how often inhalation drug suppliers switch Medicare beneficiaries from less expensive generic inhalation drugs to more expensive brand-name inhalation drugs. Prior to January 1, 2005, Medicare reimbursed for both generic and brand-name drugs based on the average wholesale price (AWP). Section 305 of the MMA mandated that, effective in 2005, both multisource and brand-name drugs be reimbursed at the amount provided under section 1847(a) of the Social Security Act. In general, section 1847(a) specifies that payment is at 106 percent of the ASP. The ASP of generic inhalation drugs is generally less than that of similar brand-name drugs; therefore, Medicare pays more for the latter than for the former. We will assess the frequency and financial impact of switching Medicare beneficiaries from less expensive generic inhalation drugs to more expensive brand-name products.
(OEI; 03-07-00440; expected issue date: FY 2008; work in progress)

Medicare Part D Administration

Part D Dual-Eligible Demonstration Project

We will review CMS's system to reimburse States participating in the Part D Dual-Eligible Demonstration Project. As part of the transition of beneficiaries into the Part D program, CMS has initiated a demonstration project pursuant to section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. No. 90-248) to reimburse States for their efforts in assisting their dual-eligible and low-income subsidy-entitled populations in obtaining Medicare Part D coverage and paying for prescriptions for beneficiaries lacking coverage. Medicare will reimburse States for the difference between the drug plan reimbursement and Medicaid cost, as well as certain State administrative costs. We will determine whether payments made to States for the Part D Dual-Eligible Demonstration Project are correct and supported. We will also review the States' submission of data to determine accuracy of payments.
(OAS; W-00-06-31122; A-03-06-00203; expected issue date: FY 2009; work in progress)

Duplicate Drug Claims for Hospice Beneficiaries

We will review the propriety of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D. Per the "Medicare Claims Processing Manual," Chapter 11, "Processing Hospice Claims," subsection 30.2, CMS publishes the hospice payment rates, which include prescription drugs (used for pain relief and symptom control) related to the beneficiary's terminal illness. Hospice providers are paid daily per diem amounts, which include drugs related to a hospice beneficiary's terminal illness. Medicare Part D, which was implemented in January 2006, covers prescription drugs for Medicare beneficiaries enrolled in this voluntary benefit. Because the hospice program continues to cover prescription drugs related to a hospice beneficiary's terminal illness, Medicare Part D drug plans may unknowingly duplicate payments for such drugs. We will determine whether payments made under Part D are correct, supported, and not duplicated in hospice daily per diem amounts. We will identify the extent of duplication and the controls to prevent duplicate drug payments.
(OAS; W-00-07-35307; various reviews; expected issue date: FY 2009; new start)

Medicare Part D Duplicate Claims

We will review CMS's controls to prevent duplicate Part D claims for the same beneficiary, particularly when a beneficiary changes plans, tries to enroll in more than one plan, or tries to enroll in a plan and a retiree-subsidy covered plan. As of January 2007, there were more than 6 million beneficiaries dually eligible for Medicare and Medicaid assigned to Part D plans. These beneficiaries are allowed to change their enrollments in prescription drug plans monthly. We will determine whether payments made to plans are correct, supported, and not duplicated.
(OAS; W-00-08-35408; various reviews; expected issue date: FY 2009; new start)

Duplicate Medicare Part A and Part B Claims Included With Part D Claims

We will determine whether claims submitted under Medicare Part D are also not submitted under Medicare Part A or Part B. Pursuant to section 1860D-2(e)(2)(B) of the Social Security Act, a drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. Medicare Part A covers drugs for people with Medicare who are receiving treatments as inpatients of hospitals. Drugs covered under Medicare Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with DME, and some vaccines. Medicare Part A and Part B do not cover most outpatient prescription drugs that may be covered under Part D. We will determine whether payments made to Part D are correct, supported, and not duplicated in Part A and Part B.
(OAS; W-00-08-35409; various reviews; expected issue date: FY 2009; new start)

Coordination and Oversight of Medicare Parts B and D To Avoid Duplicate Payments

We will review CMS's oversight of Medicare Parts B and D to determine whether there is sufficient coordination to prevent duplicate payments for prescription drugs. Pursuant to Section 1860D-2(e)(2)(B) of the Social Security Act, drugs for which payment is available under Medicare Part B should not be covered under Medicare Part D. We will review CMS's oversight of the coordination processes and determine whether the processes are effective in preventing duplicate payments for the same prescription.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Payments for Drugs Under Medicare Part D During Part A Skilled Nursing Stays

We will review the extent to which payments are being made by Medicare Part D for drugs already paid for by Medicare Part A. Section 1860D-2(e)(2)(B) of the Social Security Act requires that Medicare Part D exclude coverage for all drugs prescribed, dispensed, or administered to individuals receiving coverage for those drugs under Medicare Part A. We will determine the extent to which drugs are being paid for under Part D while Medicare beneficiaries are covered under Part A SNF stays and identify the patterns, if any, associated with these drugs.
(OEI; 02-07-00230; expected issue date: FY 2008; work in progress)

Allocation of Employer Premiums Under the Retirement Drug Subsidy Program

We will review selected employers' controls to track actual "allowable retiree costs," as defined in section 1860D-22(a)(3)(C)(i) of the Social Security Act, under the Part D retirement drug

subsidy (RDS) program. We will also determine whether RDS reported costs are accurate and supportable, determine how closely the interim subsidy payments (based on allocated premium costs) approximate the actual allowable costs, and assess the impact of the difference between the interim payments and final payments to the Medicare program. Pursuant to section 1860D-22 of the Social Security Act, the Secretary of HHS must provide a special subsidy payment to the sponsor (a private or governmental employer, labor union, etc.) of a qualified plan for each qualified covered retiree in the plan. For employers with fully insured plans that pay premiums based on expected costs, the Medicare interim subsidy payments may be based on actuarial estimates. However, final cost data must reflect the actual allowable retiree costs attributable to gross retiree plan-related prescription drug costs within the cost limit and the cost threshold.
(OAS; W-00-07-35309; various reviews; expected issue date: FY 2008; work in progress)

Allowable Costs Under the Retirement Drug Subsidy Program

We will review employer controls to ensure that only drugs covered under Medicare Part D and related allowable costs are included in the employer interim drug cost submissions. Pursuant to section 1860D-2(a)(3)(C)(ii) of the Social Security Act, for employer Part D prescription drug plans, "gross retiree plan-related prescription drug costs" include nonadministrative costs and costs directly related to the dispensing of the covered Part D drugs. Under section 1860D-2(e) of the Social Security Act, Part D coverage excludes certain drugs (i.e., weight-loss drugs, cosmetic drugs, nonprescription drugs, and drugs covered under Medicare Part A and Part B). Also, pursuant to 42 CFR § 423.100, dispensing fees include only costs for mixing drugs, delivery, and overhead. We will determine whether employers' reported costs include only Medicare Part D drugs and related allowable costs.
(OAS; W-00-07-35310; various reviews; expected issue date: FY 2008; work in progress)

Actuarial Value of Retiree Prescription Drug Coverage

We will review selected employers' RDS plans to identify any material changes to the actuarial value of the plans since their initial approvals, which preceded the implementation of the Medicare drug program on January 1, 2006. We will also assess whether any changes affected subsidy payments to the employer and whether, pursuant to section 1860D-22(a)(2)(A) of the Social Security Act, the employer provided CMS with the required certification that the actuarial value of the prescription drug coverage under the plan was at least actuarially equivalent to the value of the standard prescription drug coverage under Medicare Part D.
(OAS; W-00-07-35311; various reviews; expected issue date: FY 2008; work in progress)

Rebates in the Retiree Drug Subsidy Program

We will review employers' controls for developing estimates of expected rebates and other price concessions used for determining interim subsidy payments to determine whether these estimates are reasonable, supported, and consistently applied pursuant to Federal regulations at 42 CFR § 423.888. An employer participating in the RDS program must provide an estimate of the expected rebates and other price concessions attributable to the plan (based on historical data) upon submission of data for payment. Employers are required to provide annual reconciliations that include actual rebates, discounts, or other price concessions received. The reconciliations must take place within 15 months following the end of the plan year. As a result of the reconciliation, employers will repay any subsidy overpayments or be paid any subsidy underpayments. We will determine whether payments made to employers or recoveries by CMS

are correct and supported by information provided by the employers for the yearend reconciliations.
(OAS; W-00-07-35312; various reviews; expected issue date: FY 2008; work in progress)

State Contribution to Drug Benefit Costs Assumed by Medicare

We will review States' compliance with section 1935(c)(1)(A) of the Social Security Act related to States' contribution payments toward Medicare Part D. Under section 1935(d)(1), full-benefit, dual-eligible individuals now receive drug coverage under Medicare Part D rather than Medicaid. As of January 2006, States are responsible for making monthly payments to the Federal Government to defray a portion of the Medicare drug expenditures for these individuals. We will determine whether payments made by the States to the Federal Government are correct and supported. We will review data used to calculate States' contribution payments, the States' calculation of contribution payments and the States' payment amounts, and CMS's and States' controls related to contribution payments.
(OAS; W-00-06-35186; various reviews; expected issue date: FY 2008; work in progress)

Medicare Part D Reconciliations

We will review whether CMS, the prescription drug plans (PDP), and Medicare Advantage Prescription Drug Plans (MA-PD) have established adequate controls over the Medicare Part D reconciliation process. We will determine whether the PDPs and MA-PDs submitted accurate and timely information to CMS pursuant to Federal regulations at 42 CFR § 423.343(c)(1) and (d)(1)), whether CMS's calculations are performed in accordance with 42 CFR § 423.343(b), and whether payments and recoveries are made in accordance with 42 CFR § 423.343(c)(2) and (d)(2). In addition, Medicare shares a portion of a PDP's or an MA-PD's losses or profits resulting from expenses that fall either above or below an expected target level. CMS calculates risk-sharing payments or recoveries based on information provided by the PDPs and MA-PDs. We will determine whether payments made to PDPs and MA-PDs or recoveries made by CMS are correct and supported by the information provided by PDPs and MA-PDs for the yearend reconciliation.
(OAS; W-00-06-35200; various reviews; expected issue date: FY 2008; work in progress)

Medication Therapy Management Program

We will review whether PDPs and MA-PDs enrolled qualified beneficiaries into a medication therapy management program (MTMP) and submitted administrative costs that were supported, reasonable, and allowable. MTMP is a program developed to ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use and to help reduce the risk of adverse events. Pursuant to Federal regulations at 42 CFR § 423.153(d)(2), sponsors must establish an MTMP targeted at Part D beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and/or are likely to incur annual costs of at least $4,000 for all covered Part D drugs.
(OAS; W-00-08-35410; various reviews; expected issue date: FY 2009; new start)

Aberrant Part D Claims

We will review Medicare Part D claims to identify aberrant claims, which are those that deviate from the usual patterns of claims, and determine how these claims relate to pharmacies, physicians, and/or beneficiaries. For example, we will determine whether PDPs are

appropriately processing Medicare Part D claims for Schedule II (street value) drugs. Pursuant to section 1860(D)-15(f)(1), PDPs must submit the information necessary for the Secretary to determine payments to the plan and HHS has the right to inspect and audit the PDPs' records pertaining to this information.
(OAS; W-00-08-35411; various reviews; expected issue date: FY 2008; new start)

Part D Catastrophic Coverage

We will review whether the drugs charged to Medicare enrollees' accounts were appropriate for those enrollees who reached the Part D catastrophic coverage limit. Section 1860D of the Social Security Act established the Medicare Prescription Drug Benefit, known as Medicare Part D. Section 1860D-2 (b)(4)(B) of the Social Security Act, "Annual Out-of-Pocket Threshold," states that, for 2006, once an enrollee has reached $3,600 in annual true out-of-pocket (TrOOP) costs (or $5,100 in total drug spending), the enrollee has met the annual out-of-pocket threshold and enters the catastrophic coverage phase. Pursuant to section 1860D-2 (b)(4)(A)(i) of the Social Security Act, under catastrophic coverage, the enrollee pays the greater of $2 (for generic or preferred multisource drugs) and $5 (for other drugs) copays or 5-percent coinsurance. Pursuant to section 1860D-15(b)(1) of the Social Security Act, Medicare pays 80 percent of the drug costs. The PDP pays the remaining 15 percent. We will determine whether payments made by enrollees during the catastrophic coverage phase are correct and supported.
(OAS; W-00-08-35412; various reviews; expected issue date: FY 2009; new start)

Bid Submission by Part D Sponsors

We will review the methodology that CMS uses to review and approve bids submitted by the Part D sponsors (PDPs and MA-PDs) to assess the adequacy of the process. As provided in section 1860D-11(b) of the Social Security Act, to become a PDP sponsor or an MA organization, each applicant is required to submit a bid for prescription drug coverage for each plan it intends to offer. The bid represents the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage in the applicable area for a Part D eligible individual with a national average risk profile. The Secretary of HHS determines payment amounts by adjusting the bid based on risk factors as described in section 1860D-15(c)(1)(A) of the Social Security Act. We will determine the adequacy of these risk factors. This review will also determine whether negotiated prices have been passed on to the Medicare beneficiaries and will be coordinated with the reviews related to "Part D Negotiated Drug Prices and Price Concessions," below.
(OAS; W-00-08-35413; various reviews; expected issue date: FY 2009; new start)

Part D Negotiated Drug Prices and Price Concessions

We will review Part D sponsors' implementation of and compliance with provisions associated with passing on negotiated drug prices to the Medicare program and/or its beneficiaries. We will also review CMS's oversight of sponsors' disclosure and pass-through of negotiated price concessions. Section 1860D-2(d)(1)(A) of the Social Security Act requires a Part D sponsor to provide its enrollees with access to negotiated prices for covered Part D drugs included in its formulary. Regulations at 42 CFR § 423.100 define negotiated prices as prices for covered Part D drugs that are available to beneficiaries at the point of sale at network pharmacies; are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D

enrollees at the point of sale; and include pharmacy dispensing fees. Pursuant to 42 CFR § 423.104(g)(3), Part D sponsors are also required to disclose to CMS data on aggregate negotiated price concessions. This OIG initiative will incorporate multiple specific reviews related to Part D negotiated prices and price concessions.
(OAS; W-00-08-35414; OEI-02-07-00460; OEI-03-07-00070; OEI-05-07-00560; various reviews; expected issue date: FY 2008; work in progress)

Disenrollment of Deceased Beneficiaries

We will review whether Part D plans carry deceased beneficiaries as current enrollees. Pursuant to Federal regulations at 42 CFR § 423.44(b)(2)(iii), "Required Involuntary Disenrollment," a PDP sponsor must disenroll individuals from PDPs upon their deaths. We will determine whether payments made to PDPs are for deceased beneficiaries. We performed similar reviews in Medicaid and found several instances in which States reimbursed claims for deceased beneficiaries.
(OAS; W-00-08-35415; various reviews; expected issue date: FY 2009; new start)

Implementation of Medicare Part D in Nursing Facilities

We will review the implementation of Medicare Part D for dual-eligible residents in a sample of nursing homes. Prior to the implementation of Part D, prescription drugs for dual-eligible nursing home residents were covered by Medicaid. Section 1860D-24(a) of the Social Security Act establishes requirements for plan coordination with respect to beneficiaries eligible for prescription drug coverage under both Medicaid and Medicare Part D. This review will assess whether dual-eligible residents are receiving medically necessary drugs and the factors contributing to the drugs they receive. We will also identify concerns of nursing home and long term care pharmacy staff regarding the implementation of Part D in nursing homes.
(OEI; 02-06-00190; expected issue date: FY 2008; work in progress)

Prescription Drug Plan Marketing Materials

We will review CMS's oversight of marketing materials for Medicare Part D PDPs. Previous OIG reviews have highlighted shortcomings with marketing materials for Medicare Advantage plans and temporary Medicare drug discount cards. We will also review the extent to which PDP marketing materials comply with CMS regulations and guidelines as specified in 42 CFR §§ 423.50 and CMS's Medicare Marketing Guidelines.
(OEI; 01-06-00050; expected issue date: FY 2008; work in progress)

Comparing Drug Prices: Medicare Part D to Medicaid

We will review Medicare Part D drug prices and compare them with amounts reimbursed by Medicaid. Section 1860D of the Social Security Act governs coverage and payment of prescription drugs under Medicare Part D. Section 1927 of the Social Security Act and 42 CFR §§ 447.331 to 447.334 govern payment for prescription drugs under Medicaid. Many beneficiaries covered under the Part D program previously received drug coverage under Medicaid. We will compare the prices for a sample of drugs paid under Part D to amounts reimbursed by the Medicaid program.
(OEI; 03-07-00350; expected issue date: FY 2008; work in progress)

Comparing Drug Prices: Medicare Part D to Medicare Part B Average Sales Prices

We will review Medicare Part D drug prices and compare them to Medicare Part B prices for drugs covered under both programs. Section 1860D of the Social Security Act governs coverage and payment for prescription drugs under Medicare Part D. Medicare Part B bases reimbursement for most drugs on ASPs. Some drugs may be covered under Medicare Part D for some uses and under Medicare Part B for other uses. We will compare the ASPs for a sample of drugs paid under Part B to the prices paid by Medicare Part D.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Part D Coordination of Benefits With Other Prescription Drug Coverage

We will review the coordination of benefits structure under the Medicare Part D program. Pursuant to 42 CFR § 423.464, Medicare Part D plans must coordinate benefits with other providers of prescription drug coverage. We will assess the systems used by Medicare Part D prescription drug plans to ensure that they coordinate benefits with other prescription drug insurers serving Part D beneficiaries.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Potential Fraudulent Drug Overutilization by Dual-Eligible Beneficiaries Under Medicare Part D

We will review Medicare Part D utilization for potentially inappropriate drug overutilization by dual eligible beneficiaries. Regulations at 42 CFR § 423.38(c) allow full benefit dual-eligible beneficiaries to enroll in a PDPs or disenroll from PDPs and enroll in other PDPs or MA-PDs at any time. Previous OIG work on Medicare Part D safeguards uncovered concerns regarding dual eligibles switching plans to fraudulently obtain prescription drugs. We will identify Part D program vulnerabilities that may lead to potentially inappropriate overutilization and assess utilization patterns and plan-switching by dual-eligible beneficiaries in the Part D program.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Drug Prices on the Medicare Prescription Drug Plan Finder

We will review the integrity of prices listed on the Medicare Prescription Drug Plan Finder (Plan Finder). The Plan Finder is a CMS-initiated interactive Web-based tool that enables beneficiaries to search for a Medicare prescription drug plan. We will determine whether prices listed on the Plan Finder are current, are regularly updated, and accurately reflect pharmacy prices.
(OEI; 03-07-00600; expected issue date: FY 2008; work in progress)

Drug Utilization During the Medicare Part D Coverage Gap

We will review prescription drug utilization when Medicare Part D beneficiaries reach the coverage gap after exceeding the initial coverage limit. Under standard Part D prescription drug coverage, while in the coverage gap, beneficiaries pay a 100-percent coinsurance rate for their prescription drug benefits until they reach the out-of-pocket threshold, as set forth at 42 CFR § 423.104(d) and, as a result, may alter their drug utilization because of the increased financial burden. We will compare prescription drug utilization rates for Part D beneficiaries

who have reached the coverage gap to their drug utilization rates during their initial and catastrophic coverage periods.
(OEI; 05-07-00610; expected issue date: FY 2009; work in progress)

Medicare Part D Explanation of Benefits Forms

We will review the adequacy of explanation of benefits (EOB) forms furnished to beneficiaries of Medicare Part D sponsors. Pursuant to 42 CFR § 423.128(e), Part D PDPs and MA-PDPs are required to provide beneficiaries with EOB notices during the months in which members utilize prescription drug benefits. In the EOB forms, which are not standardized, Part D sponsors must include information pertaining to beneficiary rights, benefits, and payments. We will assess whether Part D sponsors include these required elements and examine the format and clarity of their EOB forms for Part D.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Beneficiary Complaints About Medicare Prescription Drug Plans

We will review CMS's beneficiary complaint-monitoring systems for Medicare PDPs. Beneficiary complaints provide information about potential fraud and abuse in Part D. Complaints also provide insight into the effectiveness of the Medicare drug benefit. We will assess CMS's process to monitor and investigate beneficiary complaints received about Medicare PDPs.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Prescription Drug Plan Sponsors' Detection and Reporting of Fraud and Abuse

We will review the extent to which PDP sponsors detect and report Medicare Part D fraud and abuse to CMS. Pursuant to 42 CFR § 423.504(b)(4)(vi), PDP sponsors are required to institute comprehensive compliance plans to detect, correct, and prevent Part D fraud and abuse. A previous OIG report found that some PDP sponsors' compliance plans did not address all required elements regarding fraud. This review will determine the amount and types of fraud and abuse that PDP sponsors have identified since the inception of the Medicare Part D program.
(OEI; 03-07-00380; expected issue date: FY 2008; work in progress)

Other Medicare Services

Medicare Payments for Observation Services Versus Inpatient Admission for Dialysis Services

We will review Medicare payments to hospitals for admissions for observation status versus an inpatient stay for dialysis services. CMS's "Medicare Benefit Policy Manual," Pub. No. 100-02, Chapter 1, section 10, states that renal dialysis treatments are usually covered only as outpatient services but may, under certain circumstances, be covered as inpatient services depending on the patient's condition. When a hospital places a patient under observation but has not formally admitted the individual as an inpatient, the patient initially is treated as an outpatient. According to CMS's "Intermediary Manual Part 3," Chapter II, section 3112.8, observation services are covered only when provided by the order of a physician or another individual authorized by State licensure laws and hospital staff bylaws to admit patients to the hospital or to order outpatient

tests. 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 DRG at a much higher rate. This review will determine whether Medicare payments to hospitals for renal dialysis services were appropriate. *(OAS; W-00-06-35190; A-04-06-07001; expected issue date: FY 2008; work in progress)*

Laboratory Services Rendered During an Inpatient Stay

We will review Medicare Part B payments for laboratory services rendered during an inpatient stay. Pursuant to CMS's "Medicare Claims Processing Manual," Chapter 3, section 10.4, laboratory services furnished to hospital inpatients are generally included in hospitals' Medicare Part A payments. We will determine whether Part B payments for laboratory services rendered during inpatient stays were appropriate.
(OAS; W-00-05-35168; A-01-06-00505; expected issue date: FY 2008; work in progress)

Therapy Services Provided by Comprehensive Outpatient Rehabilitation Facilities

We will review the appropriateness of Medicare claims submitted by comprehensive outpatient rehabilitation facilities (CORF) for physical therapy, speech language pathology, and occupational therapy services. Section 1861(cc)(2) of the Social Security Act governs CORFs. A CORF is recognized as a provider of services that is paid under the physician fee schedule for most services. Prior OIG reviews found that Medicare paid significant amounts for unallowable or highly questionable therapy services in outpatient rehabilitation facilities and nursing homes. A majority of these services were not reasonable and necessary for the beneficiary's health condition or lacked sufficient documentation. We will determine whether Medicare payments for therapy services were made in accordance with applicable Medicare requirements.
(OAS; W-00-05-35119; various reviews; expected issue date: FY 2008; work in progress)

Emergency Health Services for Undocumented Aliens

We will review claims submitted for emergency health services furnished to undocumented aliens and other specified aliens. Section 1011 of the MMA provides $250 million for each of FYs 2005 through 2008 for payments to eligible providers, such as hospitals, physicians, and ambulance services, for providing emergency medical services (EMS) required under section 1867 of the Social Security Act. We will determine whether the payments were made in accordance with applicable criteria. We will coordinate with other departmental components that are evaluating these distributions.
(OAS; W-00-05-35170; various reviews; expected issue date: FY 2008; work in progress)

Separately Billable Laboratory Services Under the End Stage Renal Disease Program

We will review providers' compliance with the current payment policies for automated multichannel chemistry (AMCC) tests furnished to ESRD beneficiaries. Section 623(f) of the MMA requires the Secretary to develop a report on a bundled PPS for ESRD services. A bundled PPS could include certain clinical laboratory tests that are currently separately billable to Medicare. The current facility payment, the composite rate, includes payments for certain AMCC tests provided routinely at specified frequencies. Any AMCC tests performed in excess of specified frequencies or not included in the composite rate payment are to be billed separately, provided that medical necessity is documented. CMS's "Medicare Claims Processing Manual,"

Pub. No. 100-04, Chapter 16, section 40.6, outlines the billing requirements for ESRD-related laboratory tests. Prior OIG reviews found 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' compliance with the current payment policies for AMCC tests furnished to ESRD beneficiaries. We will also identify separately billed clinical laboratory tests that are regularly provided to ESRD beneficiaries in addition to the clinical laboratory tests included in the composite rate.
(OAS; W-00-07-35202; A-01-07-00506; expected issue date: FY 2008; new start)

Unallowable Payments to Terminated Medicare Providers/Suppliers

We will review Medicare payments to terminated Medicare providers/suppliers. Federal regulations at 42 CFR § 489.10 set forth the basic Medicare requirements for program participation. Providers/suppliers may be terminated from the program if these requirements are not met, pursuant to 42 CFR § 489.53. Terminated providers/suppliers generally cannot receive payment for Medicare services furnished after the program termination date, pursuant to section 1866 (b) of the Social Security Act. We will determine whether providers received unallowable payments for services furnished after the termination date for participating in the program.
(OAS; W-00-08-35416; expected issue date: FY 2008; new start)

Ambulance Services Used To Transport End Stage Renal Disease Beneficiaries

We will review the extent to which ambulance services are used to transport ESRD beneficiaries to and from dialysis facilities. "CMS Medicare Benefit Policy Manual," Chapter 10, section 10.3, describes coverage of ambulance services to renal dialysis facilities for ESRD patients who require dialysis. Furthermore, section 623(f) of the MMA requires the Secretary of HHS to develop a report on a bundled PPS for ESRD services. The bundled PPS for ESRD services generally does not provide for ambulance services. In calendar year (CY) 2005, payments for ambulance services between beneficiaries' residences and hospital-based or freestanding ESRD facilities were approximately $262 million. We will examine factors such as the percent of the population using ambulance services, the feasibility of freestanding facilities to contract with ambulance suppliers, and the coverage policies of other health insurance programs.
(OAS; W-00-08-35417; expected issue date: FY 2009; new start)

Part B Therapy Payments for Home Health Beneficiaries

We will review Part B payments for therapy services made on behalf of beneficiaries in home health episodes. Therapy services furnished to a Medicare beneficiary during a home health episode are included in an HHA prospective payment. In addition, sections 1832(a)(1) and 1842(b)(6)(F) of the Social Security Act require that, in the case of home health services furnished under a plan of care of a HHA, payment for those services be made to the HHA, including payment for therapy services provided under arrangements by outside suppliers. We will determine whether payments made to HHAs are correct and supported for the service level claimed. We will identify Part B payments made to outside suppliers for therapy services that are included in the HHA prospective payment and examine the adequacy of controls established to prevent inappropriate Part B payments for therapy services.
(OAS; W-00-08-35418; expected issue date: FY 2009; new start)

Pricing of Clinical Laboratory Tests

We will review Medicare payment rates for certain laboratory tests and compare them with the rates of other Federal, State, and private plan payers. Section 1848 of the Social Security Act requires the establishment of a payment fee schedule for physician services, including clinical diagnostic laboratory tests. We will also determine the extent of variation in payment rates among contractors. In 2006, laboratory payments exceeded $3 billion. Prior OIG work found that Medicare paid significantly higher prices than other payers for certain laboratory tests. We will analyze claims data and survey large public and private payers to determine pricing variances among contractors for the most commonly performed tests.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Part B Services in Nursing Homes: Mental Health Needs and Psychotherapy Services

We will review Medicare Part B payments for psychotherapy services provided to nursing home residents during noncovered Part A stays. Pursuant to 42 CFR § 483.25, certified nursing homes are required to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. A previous OIG review found that approximately 31 percent of outpatient claims for Part B mental health services allowed by Medicare did not meet coverage guidelines, resulting in $185 million in inappropriate payments. We will determine the medical necessity of services, appropriateness of coding, and adequacy of nursing home documentation.
(OEI; 06-06-00580; expected issue date: FY 2008; work in progress)

Ambulatory Surgical Center Payment System

We will review the appropriateness of the methodology for setting the ASC payment rates under the revised ASC payment system. Section 626 (D)(i) of the MMA requires the Secretary of HHS to implement a revised payment system for payment of surgical services furnished in ASCs, which the Secretary is required to revise no later than January 1, 2008. We will examine changes to the new ASC payment system and the rate-setting methodology used to calculate the ASC payment rates.
(OAS; W-00-08-35423; various reviews; expected issue date: FY 2009; new start)

Medicare Advantage

Stabilization Fund

We will review compliance with guidance in CMS's "Medicare Managed Care Manual" pertaining to the establishment and management of the Plan Stabilization Fund for CYs 2004 and 2005. The stabilization fund was a payment reserve to be used in future contract periods to stabilize and prevent undue fluctuations in additional benefits. We will also examine the adequacy, propriety, and timeliness of CMS's review processes for evaluating MA plan proposals and the awarding of stabilization funds in accordance with Federal requirements found at 42 CFR § 422 and in CMS's "Medicare Managed Care Manual," Chapter 8, section 80.
(OAS; W-00-07-35171; A-05-07-00020; expected issue date: FY 2008; work in progress)

Managed Care Encounter Data

We will review the accuracy of Part A encounter data on Medicare beneficiaries. All MA plans are required to submit these data for CMS's use in developing a portion of each organization's monthly capitation rate. CMS's "Medicare Managed Care Manual," Chapter 7, sections 110 and 111, requires that medical records substantiate all diagnostic information provided in the encounter data to CMS. The portion of the monthly rate that relates to the encounter data is the risk-adjusted portion, which made up 10 percent of the rate in 2003. The risk-adjusted portion increased to 50 percent in 2005 and 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-00-07-35078; various reviews; expected issue date: FY 2008; work in progress)

Followup on Adjusted Community Rate Proposals

We will review CMS's actions to resolve the problems identified in prior audits of adjusted community rate proposals (ACRP) and remedies to ensure that future proposals are accurate and that repayments or enhanced benefits are provided to account for audit findings. Pursuant to section 1857(d)(1) of the Social Security Act, CMS is required to audit the financial records of at least one-third of the managed care organizations (MCO) participating in the MA program each year, which, for plan years beginning before January 1, 2006, included the MCOs' ACRPs. Errors in the proposals identified during the audits may affect Medicare beneficiaries' additional benefits or reduced cost-sharing amounts.

(OAS; W-00-07-35077; A-14-07-02211; expected issue date: FY 2008; work in progress)

Medicare Advantage Organization Bids

We will review Medicare Advantage Organization (MAO) bids and supporting documentation to determine whether the information was supported by the MAOs' accounting records or other reliable documentation and prepared in accordance with CMS's instructions. Pursuant to section 1857(d)(1) of the Social Security Act, CMS is required to audit at least one-third of all bids submitted each year. With the CY 2006 implementation of the Medicare prescription drug benefit, CMS changed the pricing tool used by MAOs from ACRP to "bids." As was the case with ACRPs, the accuracy of the specific parts of the bids is an important administrative tool within the overall framework of ensuring that value is received for Medicare funds expended as part of the MA program. OIG has yet to perform oversight of this relatively new MA pricing tool. We will determine whether payments made to MAOs are correct and supported for the level of service claimed.

(OAS; W-00-08-35419; various reviews; expected issue date: FY 2009; new start)

Frailty Payment Adjustments for Programs of All-Inclusive Care for the Elderly Organizations

We will review frailty payment adjustments for Programs of All-Inclusive Care for the Elderly (PACE) Organizations. Section 1894(d) of the Social Security Act mandated that Medicare capitated payments to PACE organizations be based on MA rates and adjusted to account for the comparative frailty of PACE enrollees. The frailty payment adjustment is calculated by CMS based on the PACE organization's prior-year functional impairment data. We will determine the

accuracy of functional impairment data submitted to CMS for use in determining frailty payment adjustments for PACE organizations.
(OAS; W-00-08-35420; various reviews; expected issue date: FY 2009; new start)

Payments to Medicare Advantage Organizations for Deceased Enrollees

We will review payments to MAOs for enrollees who have died. Each month, MAOs receive capitation payments from CMS to provide medically necessary services for each of their Medicare enrollees. Pursuant to Federal regulation at 42 CFR § 422.74(d)(6), disenrollment from the organization is effective in the month following an enrollee's death. Therefore, CMS should not make subsequent payments to these organizations for deceased enrollees. We will review CMS's data systems to determine the accuracy of payments made subsequent to enrollees' deaths.
(OAS; W-00-08-35421; various reviews; expected issue date: FY 2009; new start)

Medicare Advantage Lock-In Provisions

We will review CMS and MA plan communications to beneficiaries and assess beneficiaries' understanding of lock-in provisions. Under 42 CFR § 422.62, the MA program includes a lock-in provision that limits the number of times and the time of year that beneficiaries may change health plans. Regulations at 42 CFR § 417.428 (a)(1) require MA plans to provide written descriptions of rules, procedures, benefits, fees and other charges, services, and other information necessary for beneficiaries to make informed decisions about enrollment. This study will assess how effectively CMS and MA plans are fulfilling this requirement.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Advantage Special Needs Plans

We will review whether and how special needs plans (SNP) operate differently than traditional MA plans. Section 231 of the MMA established SNPs as a new option for some beneficiaries. SNPs are intended to provide care for vulnerable populations, such as institutionalized Medicare beneficiaries, dual eligible Medicare beneficiaries, and those beneficiaries with severe or disabling chronic conditions. We will determine how SNP benefit packages differ from those offered by other MA plans, evaluate SNPs' coordination of care, and assess the adequacy of SNPs' provider networks.
(OEI; 05-07-00490; expected issue date: FY 2008; work in progress)

Oversight of Medicare Advantage Plans' Marketing Practices

We will review CMS's oversight of marketing and sales practices conducted by MA plans. Pursuant to 42 CFR § 422.80(e), an MA plan may not engage in discriminatory activity, mislead or confuse Medicare beneficiaries, or misrepresent plans. Pursuant to 42 CFR § 422.752, an MA plan that provides misleading information to any individual or entity may be subject to CMS-imposed sanctions, such as civil monetary penalties, suspension of beneficiary enrollment, or suspension of payments. We will assess the sanctions that CMS has imposed for marketing abuses, CMS's efforts to work with State governments to curb these abuses, and the extent of complaints about marketing and sales practices.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Contractor Operations

Preaward Reviews of Contract Proposals

We will review the cost proposals of various bidders for Medicare contracts based on criteria in Office of Management and Budget (OMB) Circular A-122, "Cost Principles for Non-Profit Organizations." The reports produced by these reviews assist CMS in negotiating favorable and cost-beneficial contract awards.
(OAS; W-00-07-35002; various reviews; expected issue date: FY 2008; work in progress)

Contractors' Administrative Costs

We will review administrative costs claimed by various contractors for their Medicare activities, focusing on costs claimed by terminated contractors. We will determine whether the costs claimed were reasonable, allocable, and allowable under Appendix B of the Medicare contract with CMS as well as Federal Acquisition Regulation (FAR), Part 31. We will coordinate the selection of contractors with CMS.
(OAS; W-00-07-35005; various reviews; expected issue date: FY 2008; work in progress)

Fiscal Integrity of Quality Improvement Organizations

We will review the fiscal integrity of Quality Improvement Organizations (QIO). QIOs receive payments to ensure that medical care is reasonable and medically necessary, is provided in the most economical settings, and meets professionally recognized standards. In FY 2004, QIOs received $367 million from CMS as part of their 3-year $1.1 billion contract. We will determine whether Medicare payments for board member and executive staff compensation and travel, legal fees and administrative charges, and equipment were reasonable and allowable pursuant to Federal requirements set out in OMB Circular A-122, "Cost Principles for Non-Profit Organizations." We will also determine whether there were any conflicts of interest in these payments and whether contract modifications were appropriate.
(OAS; W-00-06-35204; various reviews; expected issue date: FY 2008; work in progress)

Contracting Operations

We will review CMS's Office of Acquisition and Grants Management (OAGM) contracting operations to understand the procedures that CMS uses to solicit and manage its contracts and determine compliance with various FARs. In FY 2005, OAGM initiated an estimated $1.6 billion in contracts. We will initially document OAGM's operations by addressing activities for presolicitation, solicitation, evaluation, award, and postaward activities.
(OAS; W-00-06-30003; A-14-06-02207; expected issue date: FY 2008; work in progress)

Contractors' Accounting System Audits

We will review prospective Medicare contractors' accounting systems to determine whether the systems are capable of identifying, gathering, segmenting, and reporting costs by project and comply with applicable FARs, specifically FAR 16.301.
(OAS; W-00-07-35315; various reviews; expected issue date: FY 2008; work in progress)

Contractors' Provisional Billing Rates

We will review contractors' indirect cost rate proposals to determine whether the costs claimed were reasonable, allocable, and allowable and can be used for provisional billing purposes in accordance with FAR 42.7.
(OAS; W-00-07-35316; various reviews; expected issue date: FY 2008; work in progress)

Pension Segmentation

We will review 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. Applicable requirements are found in FAR 31.205; Cost Accounting Standards (CAS) 412 and 413; and the Medicare contract, Appendix B, section XVI.
(OAS; W-00-07-35094; various reviews; expected issue date: FY 2008; work in progress)

Pension Costs Claimed

We will review whether Medicare contractors have calculated pension costs claimed for reimbursement in accordance with their Medicare contracts and CAS. We will also determine whether the costs claimed were allocable and allowable under the Medicare contracts according to FAR 31.205; CAS 412 and 413; and the Medicare contract Appendix B, section XVI.
(OAS; W-00-07-35067; various reviews; expected issue date: FY 2008; work in progress)

Unfunded Pension Costs

We will review whether Medicare contractors identified and eliminated unallowable costs when computing pension costs charged to the Medicare program. We will also determine whether pension costs that would have been tax deductible had they been funded were properly reassigned to future periods to ensure that only allowable pension costs were claimed for reimbursement. Applicable requirements are found in FAR 31.205; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.
(OAS; W-00-07-35148; various reviews; expected issue date: FY 2008; work in progress)

Pension Segment Closing

We will review Medicare carriers and FIs 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. Requirements of FAR 31.205; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI, of the Medicare contract provide that pension gains that occur when a Medicare segment closes be credited to the Medicare program.
(OAS; W-00-07-35067; various reviews; expected issue date: FY 2008; work in progress)

Postretirement Benefits and Supplemental Employee Retirement Plan Costs

We will review the postretirement health benefit costs and the supplemental employee retirement plans of FIs 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 in accordance with FARs 31.201 through 31.205.
(OAS; W-00-07-35095; various reviews; expected issue date: FY 2008; work in progress)

Medicare Appeals Process: Administrative Law Judges

We will review the early implementation of the use of video conferencing in Administrative Law Judge (ALJ) hearings of fee for-service (FFS) appeals. Generally, section 1869 of the Social Security Act governs ALJ hearings for Medicare FFS claims appeals. Section 931 of the MMA (Pub. L. No. 108-173) amended this statutory section and authorized the Secretary of HHS to examine the feasibility of conducting hearings by teleconference or by video-teleconference. Previous OIG work has identified significant problems in the Medicare appeals process that resulted in the system being backlogged and untimely. Several recommendations have subsequently been addressed, including the transfer of the Medicare ALJ hearings function from the responsibility of the Commissioner of the Social Security Administration to the Secretary of 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.
(OEI; 02-06-00110; expected issue date: FY 2008; work in progress)

Medicare Appeals Process: Qualified Independent Contractor Reconsiderations

We will review whether qualified independent contractors (QIC) are meeting statutory and regulatory requirements regarding decision timeframes and reviewer qualifications. Medicare administrative appeals provide important beneficiary and provider protection. Federal regulations at 42 CFR Part 405, Subpart I, specify the requirements of the FFS claims appeals process. Since the implementation of section 521 of the BIPA and section 933 of the MMA, which amended the Medicare administrative appeals process, work has not been conducted to assess the level two reconsideration process, which includes QICs' performance regarding initial Medicare coverage determinations. We will determine whether CMS is providing adequate oversight of the QICs.
(OEI; 06-06-00500; expected issue date: FY 2008; work in progress)

Contractors' Provider Education and Training Efforts

We will review whether contractors are meeting CMS's Medicare Integrity Program requirements for provider education and training. One of program's goals is to reduce payment errors through provider education and training efforts. Section 921 of the MMA instructed the Secretary of HHS to take steps to provide education and training to Medicare participating providers. The Medicare Integrity Program budget for FY 2007 totaled $829.6 million, of which $52.8 million was intended for provider education and training efforts. CMS requires contractors to prepare a budget request using the Budget and Performance Requirements (BPR). The BPRs set forth the statement of work and level of effort for activities that the contractor will be required to perform during the year. We will determine whether contractors have met CMS's requirements for provider outreach and education and training activities through the use of BPRs and the local provider education and training program.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Medicare Summary Notice

We will review beneficiaries' use and understanding of Medicare Summary Notices (MSN). MSNs advise beneficiaries of claims paid for health care services and supplies. Chapter 21, section 10, of the "Medicare Claims Processing Manual," Pub. No. 100-04, contains contractor requirements for issuing MSNs. The MSN is CMS's primary means to address Medicare fraud.

On its Web site and in the "Medicare & You" publication, CMS emphasizes the importance of beneficiaries checking their MSNs for any services or supplies that they do not recognize. We will review beneficiaries' experiences with MSNs and the results of their inquiries about unrecognized services.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

The Medicare and Medicaid Data Matching Project

We will review CMS's oversight and monitoring of Medicare and Medicaid Data Matching Project (Medi-Medi) contractors to determine whether they are meeting contractual requirements outlined in the Medi-Medi Task Orders. The Medi-Medi Project was initiated in 2001 by CMS in partnership with the State of California and continues, pursuant to section 1893 of the Social Security Act, to improve coordination of Medicare and Medicaid program integrity efforts. The objective of the project is to match Medicare and Medicaid data to proactively identify program vulnerabilities and potential fraud and abuse that may have gone undetected by reviewing Medicare and Medicaid program data individually. As of 2007, there were 10 active Medi-Medi Task Orders in the States of California, Texas, Washington, Pennsylvania, North Carolina, New Jersey, New York, Florida, Ohio, and Illinois. FARs at 48 CFR § 42.1500, et seq., provide policies and establish responsibilities for agencies recording and maintaining contractor performance information.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Accuracy and Completeness of the National Provider Identifier

We will review the accuracy and completeness of the National Provider Identifier (NPI). NPI is a unique identification number for health care providers. CMS regulations at 45 CFR § 162.404 require that, beginning May 23, 2007 (May 23, 2008, for small health plans), the NPI be used in lieu of legacy provider identifiers when submitting claims. Providers failing to obtain their NPIs risk losing their ability to receive payment for services provided to Medicare and Medicaid beneficiaries. By May 23, 2008, all Medicare providers must include their NPIs when submitting claims. We will determine whether CMS has met program goals for implementation of the NPI.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Recovery Audit Contractors: Reducing Medicare Improper Payments

We will review CMS's oversight and monitoring of recovery audit contractors (RAC) to determine whether they meet contractual requirements outlined in the RAC Task Orders. The RAC program, authorized in section 306 of the MMA, is designed to reduce Medicare improper payments through detection and collection of overpayments, the identification of underpayments, and the implementation of actions that will prevent future improper payments. Section 302 in Division B of the Tax Relief and Health Care Act of 2006 (Pub. L. No. 109-432) requires the Secretary of HHS to utilize RACs in the Medicare Integrity Program to identify underpayments and overpayments and recoup overpayments associated with services for which payments are made under Medicare Part A or Part B.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicare Cross-Cutting Issues

Serious Medical Errors (Never Events)

We will review the incidence, facility response, and payments associated with serious medical errors, known as never events. This series of studies will include an evaluation of medical error reporting and provider response, as well as other targeted studies. This review responds to the Tax Relief and Health Care Act of 2006 (Pub. L. No. 109-432), Division B, Title II, section 203, which requires OIG to conduct a study of never events. OIG is mandated to study incidences of never events for Medicare beneficiaries, including types of events and payments by any party; the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events; and the extent to which beneficiaries paid for such services. OIG is also required to review the administrative processes of CMS to detect such events and to deny or recoup payments for services furnished in connection with such events. We will assess the utility of current State and voluntary reporting systems and examine CMS's oversight of and processes for identifying and responding to never events.
(OEI; 06-07-00470; 06-07-00471; expected issue dates: FYs 2008 and 2009; work in progress; OAS; W-00-08-35422; various reviews; expected issue date: FY 2008; new start)

Doctors' Office Quality Information Technology Initiatives

We will assess CMS's efforts to promote the implementation and use of health information technology (IT) in physicians' offices through QIOs. Pursuant to section 1862(g) of the Social Security Act, CMS contracts with QIOs to work with physician practices to improve clinical performance through, among other things, the use of health information and communications technologies, with a particular emphasis on electronic health records (QIO statement of work, task 1d1 (pp 85-107)). Specifically, through the Doctor's Office Quality Information Technology project, QIOs are to assist independent physician practice groups (IPG) with the adoption and implementation of interoperable health IT, including electronic health records, electronic prescribing, and chronic care management technologies. We will determine whether QIOs are meeting their contractual obligations and describe how IPG health IT initiatives differ across QIOs. We will also describe variations in achievements and identify obstacles for adoption of health IT in IPGs.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicaid

Medicaid Hospitals

Hospital Outlier Payments

We will review State Medicaid payments for hospital outliers, which are cases that incur extraordinarily high costs. Section 1886(d)(5)(A) of the Social Security Act provides for supplemental Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for outlier cases. Some States make supplemental Medicaid payments for hospital outliers based on methodologies similar to Medicare methodologies. Prior OIG work

involving Medicare claims for hospital outliers identified vulnerabilities in the Medicare payment methodology. We will determine whether similar vulnerabilities exist in Medicaid State agencies' methods of computing inpatient hospital cost outlier payments.
(OAS; W-00-04-31069; W-00-05-31069; various reviews; expected issue date: FY 2008; work in progress)

Hospital Eligibility for Disproportionate Share Hospital Payments

We will review hospital eligibility for Medicaid DSH payments, which compensate hospitals that serve disproportionate numbers of low-income patients with special needs. Section 1923(b) 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 had made DSH payments to hospitals that did not meet the eligibility standards. We will determine whether States are appropriately determining hospitals' eligibility for Medicaid DSH payments.
(OAS; W-00-05-31084; various reviews; expected issue date: FY 2008; work in progress)

States' Use of Disproportionate Share Hospital Payments

We will review several State Medicaid programs to determine the magnitude of Federal DSH funding being used to pay for services provided to individuals aged 21 to 64 residing in institutions for mental diseases (IMD). Pursuant to section 1923(g) of the Social Security Act, DSH payments to an individual hospital may not exceed that hospital's uncompensated care costs. Some States have provisions in their State Medicaid plans that allow DSH payments to hospitals for the cost of services provided to persons not covered by the Medicaid program, including individuals between the ages of 21 and 64 residing in IMDs.
(OAS; W-00-08-31300; various reviews; expected issue date: FY 2009; new start)

Provider Eligibility for Medicaid Reimbursement

We will review whether States appropriately determined provider eligibility for Medicaid reimbursement. Federal regulations at 42 CFR § 440.10 require hospital providers to meet Medicare program participation requirements to receive Medicaid funding. In addition, various State regulations may extend this Federal requirement to cover other provider types, such as DME or home health. We have previously identified significant unallowable Medicaid payments made to hospitals that did not meet Medicare program eligibility requirements as part of the DSH program.
(OAS; W-00-08-31301; various reviews; expected issue date: FY 2009; new start)

Medicaid Disproportionate Share Hospital Payment Distribution

We will review the Medicaid inpatient utilization rate used to determine eligibility for Medicaid DSH payments. Section 1923(d)(3) of the Social Security Act requires hospitals to have a Medicaid inpatient utilization rate of not less than 1 percent before being deemed eligible to receive Medicaid DSH payments. We will examine the threshold that hospitals must meet to qualify for Medicaid DSH payments and, if appropriate, recommend changes to the program.
(OAS; W-00-08-31302; various reviews; expected issue date: FY 2009; new start)

Medicaid Long Term and Community Care

Billing for Medicaid Nursing Home Patients Transferred to Hospitals

We will review Medicaid payments made to nursing homes for patients transferred to hospitals. Pursuant to section 1905(a)(4)(A) of the Social Security Act, States make payments for nursing facility services for individuals 21 years of age or older. A previous OIG review found that some States had made Medicaid nursing facility payments for individuals who had transferred to hospitals. We will examine States' Medicaid claims data to determine whether Medicaid made duplicate payments to nursing facilities and hospitals for the same patients.
(OAS; W-00-07-31201; various reviews; expected issue date: FY 2008; work in progress)

Community Residence Rehabilitation Services

We will review Medicaid payments made for beneficiaries who reside in community residences for persons with mental illness to determine whether States improperly claimed Federal financial participation. OMB Circular A-87, "Cost Principles for State, Local, and Indian Tribal Governments," establishes cost principles for State and local governments. Section C.1.c. of these principles states that, to be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. Previous OIG work in one State found improperly claimed Medicaid reimbursement for individuals who were no longer residing in the community residence.
(OAS; W-00-07-31087; various reviews; expected issue date: FY 2008; work in progress)

Assisted Living Facilities

We will review Medicaid payments to assisted living facilities in one State to determine whether providers were improperly reimbursed for per diem, room and board, and personal needs allowances provided to residents and to quantify the associated financial impact on the Medicaid program. According to this State's "Provider Reimbursement Manual," assisted living facilities cannot bill for services on any day when the clients do not receive services. We will determine whether payments for services provided by assisted living facilities are proper.
(OAS; W-00-04-31076; W-00-05-31076; various reviews; expected issue date: FY 2008; work in progress)

Targeted Case Management

We will review Medicaid payments made for targeted case management services. Section 1915(g)(2) of 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. Case management does not include the direct delivery of an underlying medical, educational, social, or other service for which an eligible individual has been referred. Payments for case management services may not duplicate payments made to public agencies under other program authorities for the same service. Prior OIG work in one State identified unallowable claims. We will determine whether Medicaid payments claimed by States for targeted case management services were made in accordance with Federal requirements.
(OAS; W-00-05-31082; W-00-06-31082; various reviews; expected issue date: FY 2008; work in progress)

States' Use of Civil Monetary Penalty Funds

We will review whether States are correctly applying civil monetary penalty (CMP) funds to programs that protect the health or property of nursing facility residents as required by section 1919(h)(2)(A)(ii) of the Social Security Act. CMPs are remedies that CMS and States may use to address a nursing facility's failure to meet Medicare and Medicaid health and safety requirements. We will examine the amounts that States have received from CMPs, States' use of CMP funds, and States' and CMS's oversight of the use of CMP funds.
(OEI; 00-00-00000; expected issue date: FY 2008; new start; OAS; W-00-08-31303; various reviews; expected issue date: FY 2009; new start)

Medicaid Home Health Agency Claims

We will review HHA claims to determine whether providers have met applicable criteria to provide services and whether beneficiaries have met eligibility criteria. Federal regulations at 42 CFR §§ 440.70 and 484 set forth standards and conditions for HHA participation. Providers must meet criteria such as minimum number of professional staff, proper licensing and certification, review of service plans of care, and proper authorization and documentation of provided services. A doctor must determine that the beneficiary needs medical care at home and prepare a plan for care at home. The care must include intermittent (not full-time) skilled nursing care and may include physical therapy or speech language pathology services.
(OAS; W-00-08-31304; various reviews; expected issue date: FY 2009; new start)

Inappropriate Medicaid Payments for Personal Care Services During Periods of Institutionalization

We will review the appropriateness of claims for Medicaid personal care services for individuals during periods of beneficiary institutionalization. Section 1915(c)(4)(B) of the Social Security Act allows Medicaid payments for personal care services through home- and community-based waiver programs. State and Federal Medicaid expenditures for personal care services increased nearly 55 percent from 2002 to 2005. In five States, we will determine whether inappropriate Medicaid claims were made for personal care services during periods of beneficiary institutionalization and calculate the dollars associated with inappropriate payments.
(OEI; 07-06-00620; expected issue date: FY 2008; work in progress)

Medicaid Payments for Personal Care Services

We will review Medicaid payments for personal care services to determine whether States have improperly claimed Federal financial participation (FFP). Pursuant to section 1905(a)(24) of the Social Security Act, Medicaid covers personal care services only for individuals who are not inpatients or residents of hospitals, nursing facilities, IMDs, or intermediate care facilities for persons with mental retardation. Personal care services must be authorized for the individual by a physician in accordance with a plan of treatment, provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and furnished in a home or other location. Section 6087 of the DRA further allowed States, beginning January 1, 2007, to provide payments to individuals for self-directed personal assistance services for the elderly and disabled. These include personal care services that could be provided by a member of a person's family.
(OAS; W-00-05-31035; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Payments for Medicare-Covered Home Health Services

We will review the appropriateness of Medicaid payments for Medicare paid home health services. Pursuant to section 1902(a)(10)(D) of the Social Security Act, States are required to offer home health services to Medicaid beneficiaries who meet the States' criteria for nursing home coverage. Further, Medicaid is the payer of last resort, paying only after all other third party sources have met their legal obligation to pay. We will determine the extent to which both Medicare and Medicaid have paid for the same home health services. We will also identify the controls that selected States have established to prevent duplicate payments.
(OEI; 07-06-00640; 07-06-00641; expected due date: FY 2008; work in progress; OAS; W-00-07-31305; various reviews; expected issue date: FY 2008; work in progress)

State and Federal Oversight of Medicaid-Funded Assisted Living Facilities

We will review State and Federal oversight of Medicaid-funded assisted living facilities. These facilities may receive Medicaid funding through the home- and community-based waiver program under the Social Security Act section 1915(c). Under 42 CFR § 441.302, States are required to set their own assurances that necessary safeguards have been taken to protect the health and welfare of recipients. Medicaid beneficiaries residing in assisted living facilities must meet the same eligibility criteria as nursing home residents. However, most States provide limited oversight and regulation of assisted living facilities. We will determine the extent to which States are complying with Federal regulations for assisted living facilities receiving Medicaid funding.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Medicaid Adult Day Health Service Payments for Ineligible and Absent Beneficiaries

We will review the appropriateness of Medicaid payments for adult day health services. Section 1915(c)(4)(B) of the Social Security Act allows Medicaid payments for adult daycare services through home- and community-based waiver programs. Previous reviews of Medicaid adult day health services have identified inappropriate payments for these services. Facilities were found to have billed Medicaid for deceased patients, patients who did not require center services, and patients who attended facilities for only a fraction of the time authorized by the State. We will identify whether payments were improperly made on behalf of individuals who were not eligible for adult day health services or who were not in attendance at the adult daycare facilities.
(OEI; 09-07-00500; expected issue date: FY 2008; work in progress)

Medicaid Mental Health Services

Medicaid Supplemental Mental Health Payments to Prepaid Inpatient Health Plans

We will review States' Medicaid supplemental mental health payments to prepaid inpatient health plans. Federal regulations at 42 CFR § 438.6(c)(2) prohibit prepaid inpatient health plans from receiving supplemental payments that are not part of the actuarially certified capitated rate and are not part of the contracts between the State Medicaid agencies and the prepaid inpatient

health plans. We will determine whether prepaid inpatient health plans were paid in accordance with Federal regulations.
(OAS; W-00-06-31098; A-07-06-04067; expected issue date: FY 2008; work in progress)

Early and Periodic Screening, Diagnosis, and Treatment of Mental Health in Medicaid Managed Care Plans

We will review a national sample of children enrolled in Medicaid managed care plans that provide comprehensive health services under the early and periodic screening, diagnostic, and treatment (EPSDT) benefit, including mental health services. The EPSDT benefit provides comprehensive medical screening and services for Medicaid-eligible children under the age of 21. Section 1905(r)(1) of the Social Security Act requires States to provide any medically necessary health care service to an EPSDT recipient even if the service is not covered under the State's Medicaid plan. Previous OIG work found that enrollees in Medicaid managed care often failed to receive required EPSDT services. We will examine how EPSDT programs screen, refer, and provide mental health services to children and determine whether children received required mental health screenings.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Medicaid/State Children's Health Insurance Program

Assessing Medicaid Eligibility for Children Enrolled in Separate State Children's Insurance Programs

We will review whether children enrolled in separate SCHIPs should be enrolled in Medicaid. Because States receive a higher Federal matching rate for children enrolled in SCHIP, they have a financial incentive to enroll children in SCHIP rather than in Medicaid. The BBRA requires OIG to evaluate, every 3 years, whether States are enrolling Medicaid-eligible children in SCHIP. This is the third study conducted by OIG to fulfill the congressional mandate.
(OEI; 06-07-00310; expected issue date: FY 2008; work in progress)

Medicaid Prescription Drugs

Calculation of Average Manufacturer Prices

We will review selected drug manufacturers to evaluate the methodologies they use to calculate their AMPs for the Medicaid drug rebate program and for Medicaid drug reimbursement purposes to determine whether the methodologies are consistent with applicable statutes, regulations, their rebate agreements, and CMS's Drug Manufacturer Releases. Section 6001 of the DRA makes several changes to the Medicaid drug rebate statute and to Medicaid drug reimbursement for multiple-source drugs. These changes involve revisions to the calculation of the AMP and the best price (BP) that will affect the amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program and affect the Federal Upper Limit (FUL) for drug reimbursement. CMS uses the AMP and the BP to determine a rebate amount. Manufacturers must pay rebates to the States based on the rebate amounts.
(OAS; W-00-07-31202; various reviews; expected issue date: FY 2009; new start)

States' Medicaid Drug Claims

We will review the accuracy of States' submission of Medicaid drug claims to CMS for reimbursement. Pursuant to section 1927(a)(1) of the Social Security Act, a drug manufacturer must have a rebate agreement with CMS to have its outpatient drugs covered under Medicaid. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape that should list all covered outpatient drugs and indicate a drug's termination date, if applicable. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement. We will determine whether the tape CMS provides to States includes all covered drugs and indicates drugs' termination dates, if applicable. We will also determine whether reimbursements made to the States are correct and supported for the drugs claimed.
(OAS; W-00-07-31203; various reviews; expected issue date: FY 2008; work in progress)

States' Use of the Average Manufacturer Price To Establish Medicaid Pharmacy Reimbursement

We will review States' use of the AMP to set Medicaid pharmacy reimbursement amounts. Section 6001(b) of the DRA makes AMP data available to all States on a monthly basis. A previous OIG review found that, as of October 2006, most States had not yet decided whether to use AMP data for pharmacy reimbursement. This follow-up review will provide an update on whether and how States are using the AMP.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Pharmacies' Ability To Purchase Drugs at the Average Manufacturer Price

We will assess pharmacies' ability to purchase Medicaid drugs at or near the AMP. Section 6001(b) of the DRA makes AMP data available to all States on a monthly basis. Congress expects that this provision will create more transparency and competition in drug pricing. Most State Medicaid programs have based pharmacy reimbursement on a percentage of the AWP. Previous OIG reviews have indicated that the AWP reimbursement methodology is flawed because pharmacies' payments to drug manufacturers are significantly lower than the AWPs. We will determine how pharmacy acquisition costs compare to the AMPs.
(OAS; W-00-07-31204; various reviews; expected issue date: FY 2008; work in progress; FY 2008; new start; OEI; 00-00-00000; expected issue date: FY 2008; work in progress; FY 2008; new start)

Postimplementation Review of the Federal Upper Limit Program

We will review how changes to Medicaid FULs required under the DRA have impacted Medicaid reimbursement to pharmacies. For multiple source drugs that meet certain criteria, section 1927(e)(4) of the Social Security Act and 42 CFR § 447.514 set the FUL amount at 250 percent of the drug's lowest AMP. This change, which will be implemented in January 2008, will substantially reduce the FUL amount for most drugs. In preimplementation studies, OIG and the Government Accountability Office (GAO) have found that the new FUL amounts set under the DRA may be below pharmacy acquisition costs for certain drugs. As part of this followup, we will collect data from wholesalers for high-expenditure FUL drugs and compare this information to the new FUL amounts to determine whether pharmacies are able to acquire drugs at or below the new FUL amounts.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

States' Accountability Over Medicaid Drug Rebate Programs

We will conduct follow-up reviews to determine whether States have established adequate accountability and internal controls over their Medicaid drug rebate programs. Federal regulations at 45 CFR § 74.21 (b)(3) require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. Previous OIG reviews of 49 States and the District of Columbia have found that most States had weaknesses in accountability and internal controls over their drug rebate programs.
(OAS; W-00-07-31205; various reviews; expected issue date: FY 2008; work in progress)

Zero Dollar Unit Rebate Amounts

We will review 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. In the Medicaid Drug Rebate Program Release No. 38, CMS instructs the State agency to invoice the units at $0, and the manufacturer is required to calculate the URA and remit the proper amount with its quarterly payment. We will determine whether the rebates for these drugs were properly billed and collected.
(OAS; W-00-07-31106; various reviews; expected issue date: FY 2009; work in progress)

Additional Rebates of Brand-Name Drugs

We will review the additional rebate component of the Medicaid drug rebate law to determine whether it was properly calculated by CMS. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90, Pub. L. No. 101-508), section 4401, enacted in November 1990 and effective January 1991, requires drug manufacturers to pay rebates to States for covered outpatient prescription drugs reimbursed under States' Medicaid drug programs. The manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period, as well as each subsequent quarter that the drug is on the market. For brand-name drugs, manufacturers must pay an additional rebate when the AMP increases above the base period (baseline) AMP at a rate greater than the increases in the Consumer Price Index-Urban. CMS calculates the URA for each drug based on the AMP and BP data provided by drug manufacturers.
(OAS; W-00-08-31306; A-06-08-00000; expected issue date: FY 2008; new start)

Disputes Within the Medicaid Prescription Drug Rebate Program

We will review the dispute resolution process of the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Program, created by the OBRA 90, section 4401(a), requires manufacturers to refund States part of the cost of outpatient drugs dispensed to Medicaid patients. States and manufacturers may disagree about States' claims for rebates. In 1994, CMS established a voluntary process for resolving disputes between States and manufacturers regarding drug rebates. When disputes are not properly resolved, State Medicaid programs are at risk of not receiving drug rebates. We will determine the extent to which rebate claims are disputed and the extent to which CMS's Dispute Resolution Program resolves disputed Medicaid rebate claims.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Assessing the Accuracy of Drug Type Classification in the Medicaid Drug Rebate Initiative File

We will review the accuracy of drug type classification for purposes of the Medicaid Drug Rebate Program. Section 1927(a)(1) of the Social Security Act requires drug manufacturers to enter into a national rebate agreement with the Secretary of HHS for States to receive Federal funding for outpatient drugs dispensed to Medicaid patients. The formula to calculate rebates owed to States varies by drug type classification. Previous OIG work revealed that some manufacturers do not classify their drugs in accordance with Medicaid rebate laws and may not be paying appropriate rebate amounts to State Medicaid agencies. We will determine the extent to which drugs are incorrectly classified and the potential financial impact to States.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

States' Collection of Medicaid Rebates for Physician-Administered Drugs

We will review State Medicaid agencies' collection of drug manufacturer rebates for physician-administered drugs since the passage of the DRA. Previous OIG work found that the majority of States were not collecting Medicaid rebates for physician-administered drugs. Pursuant to section 6002 of DRA, States are required to collect data necessary to enable them to collect rebates on physician-administered drugs. We will determine whether State Medicaid agencies collect drug manufacturer rebates for physician-administered drugs and estimate the potential savings that would result if all State Medicaid agencies collected drug manufacturer rebates for physician-administered drugs.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Other Medicaid Services

Family Planning Services

We will review family planning services in several States to determine whether enhanced Federal funding was properly claimed for such services and what the resulting financial impact was on the Medicaid program. Pursuant to section 1903(a)(5) of the Social Security Act, States may claim Medicaid reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. Prior OIG work identified improper claims in this area.
(OAS; W-00-04-31078; W-00-05-31078; W-00-06-31078; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Payments for Transportation Services

We will review payments made to providers for transportation services. Federal regulations at 42 CFR § 431.53 require States to ensure necessary transportation for Medicaid beneficiaries to and from providers. Each State may have different Medicaid coverage criteria, reimbursement rates, rules governing covered services, and beneficiary eligibility for services. Expenditures for transportation services rose 48 percent nationally during the 5-year period from 1999 to 2003, reaching $1.5 billion in 2003. We will determine the appropriateness of State Medicaid agencies' payments for transportation services.
(OAS; W-00-06-31121; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Safeguards Over Payments for Nonemergency Transportation Services

We will review current State policies, procedures, and oversight activities to safeguard Medicaid nonemergency transportation services against fraud and abuse. Pursuant to 42 CFR § 431.53, Medicaid must ensure necessary transportation for recipients to and from providers. Recent OIG studies found that State Medicaid program internal controls were lacking or not fully enforced and that Medicaid nonemergency transportation was at high risk for fraud. We will determine the extent of safeguards used by States to prevent and detect fraud and abuse of Medicaid nonemergency transportation services.
(OEI; 06-07-00320; expected issue date: FY 2008; work in progress)

Medical Equipment

We will review Medicaid payments for medical equipment and identify medical equipment providers for detailed review. Prior OIG reviews have found various problems with medical equipment claims, including Medicaid allowable reimbursement rates for equipment that are much higher than the actual costs to the provider. OIG has also identified concerns regarding the allowability of Medicare claims for DME items and supplies. We will determine whether Medicaid beneficiaries received the medical equipment billed on their behalf and whether the equipment was actually used and was necessary for the beneficiary's condition.
(OAS; W-00-08-31307; various reviews; expected issue date: FY 2009; new start)

Medicaid Laboratory Tests

We will review Medicaid payments for laboratory tests. Pursuant to section 1903(i)(7) of the Social Security Act, Federal Medicaid payment will not be available if a State pays more for outpatient clinical diagnostic laboratory tests performed by a physician, an independent laboratory, or a hospital than the amount Medicare authorizes for such tests. Prior OIG work has identified Medicaid payments for laboratory tests that exceeded amounts authorized by Medicare for the same tests. We will determine whether Medicaid payments for chemistry, hematology, and urinalysis tests exceeded amounts authorized by Medicare for the same tests or were duplicated; identify tests that were not grouped together (bundled into a panel or profile) for payment purposes; and determine whether the tests were properly supported by physicians' orders.
(OAS; W-00-07-31206; various reviews; expected issue date: FY 2009; work in progress)

Adult Rehabilitative Services

We will review adult rehabilitative services claimed by a selected State to determine whether the services met Federal Medicaid reimbursement requirements as set forth in section 1905(a)(13) of the Social Security Act. Related OIG work in the area of child rehabilitation services has identified numerous claims for services not eligible for Medicaid. We will determine whether similar problems exist in the adult services program.
(OAS; W-00-03-31028; various reviews; expected issue date: FY 2008; work in progress)

Outpatient Alcoholism and Substance Abuse Services

We will review outpatient alcoholism and substance abuse services to determine whether providers claimed reimbursement in accordance with Federal rules at 42 CFR §§ 440.20 and 440.90, State Plans, and OMB Circular A-87. Medicaid reimbursement may be available for

outpatient alcoholism and substance abuse services provided in hospital-based or freestanding clinics. Prior OIG work identified significant noncompliance with Federal and State rules related to outpatient alcoholism and substance abuse services. In several States, we will conduct reviews of providers that receive the largest amounts of Medicaid reimbursement for these services.
(OAS; W-00-07-31079; various reviews; expected issue date: FY 2008; work in progress)

Freestanding Inpatient Alcoholism and Substance Abuse Providers

We will review Medicaid payments for inpatient alcoholism and substance abuse services provided in freestanding facilities that are IMDs to determine whether States have improperly claimed Federal Medicaid reimbursement. The IMD criteria found at section 1905(a) of the Social Security Act and 42 CFR §§ 441.13 and 435.1008 preclude Federal Medicaid funding for any services to residents under the age of 65 who are in an IMD, except for inpatient psychiatric services to individuals under the age of 21 and, in some cases, under the age of 22. A prior review in this area found that one State had improper claims totaling about $3.8 million in Federal reimbursement.
(OAS; W-00-06-31107; various reviews; expected issue date: FY 2008; work in progress)

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. Pursuant to section 1903(v) of the Social Security Act, States may claim Federal funds for medical services provided to undocumented aliens only when those services are necessary to treat emergency conditions. Our work in one State and discussions with CMS officials indicated the possibility of improper claims in this area.
(OAS; W-00-06-31108; various reviews, expected issued date: FY 2008; work in progress)

Reimbursement Rates for Services Provided by Indian Health Service Facilities

We will review Indian Health Service (IHS) hospital cost reports to determine the allowability of costs for Medicare and Medicaid reimbursement. Section 402 of the Indian Health Care Improvement Act of 1976 authorizes IHS facilities to be reimbursed for services that are provided to individuals eligible for Medicare and Medicaid. The services are reimbursed using rates that are developed from data contained in the cost reports of 46 IHS hospitals. The rates are used as the basis for payment for services provided for all inpatient and outpatient IHS facilities. For Medicaid services, there is no State share; the Federal Government reimburses 100 percent of the costs. In 2005, Medicare and Medicaid reimbursement for services provided by IHS facilities totaled nearly $140 million and $800 million, respectively.
(OAS; W-00-07-31221; various reviews; expected issue date: FY 2008; work in progress)

Medicaid's Use of an All-Inclusive Rate for Reimbursing the Indian Health Service and Tribes for Prescription Drugs

We will review States' use of the IHS all-inclusive rate (AIR) for reimbursing Medicaid prescription drug services provided by IHS and tribes. Pursuant to section 1911 of the Social Security Act, services provided by IHS are eligible for Medicaid reimbursement under State plans. Federal guidance regarding the use of the AIR has been limited to the approval of

Medicaid State plan amendments that incorporate the AIR. We will determine the extent to which States have used the AIR, compare actual costs with projected costs if States used other reimbursement methodologies, and examine whether the AIR is being used for any unintended purposes.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Improper Medicaid Payments for Laboratory Services for Dual-Eligible Beneficiaries

We will review the appropriateness of Medicaid payments for FFS laboratory services provided to dual-eligible beneficiaries. Because Medicaid is the payer of last resort under section 1902(a)(25) of the Social Security Act, Medicare will reimburse 100 percent of allowable laboratory-service charges for beneficiaries enrolled in both Medicare and Medicaid pursuant to sections 1833(a)(1)(D) and 1822(h)(5)(C) of the Act. A State Medicaid program should not pay any portion of charges for laboratory services provided to dual-eligible beneficiaries unless the services are provided in a hospital or rural health clinic. We will determine whether selected State Medicaid programs made improper payments in FY 2005.
(OEI; 04-07-00340; expected issue date: FY 2008; work in progress)

Medicaid Physical and Occupational Therapy Services: Appropriateness of Payments

We will review the appropriateness of payments for Medicaid physical and occupational therapy services. Pursuant to 42 CFR § 440.110, States may provide physical and occupational therapy services to Medicaid beneficiaries. Previous OIG studies found that some physical and occupational therapy services provided were medically unnecessary, billed incorrectly, or rendered by unqualified providers in the Medicare program. Through a medical review, we will determine whether Medicaid has similar program integrity issues.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Use of Bundled Rates for Payment to Medicaid School-Based Providers

We will review the use of bundled rates for Medicaid school-based services compared to an FFS reimbursement methodology. School-based health services are reimbursable under the Medicaid program for students with special needs pursuant to individualized education plans. Under section 1902(a)(30)(A) of the Social Security Act, States are required to have methods and procedures to ensure that payments are consistent with efficiency, economy, and quality of care. A 2000 GAO review concluded that the bundled payment methods used in seven States failed in some cases to consider variations in service needs among children. We will determine whether the bundled rate systems currently used by States result in payments that are different from the amounts that would be paid under an FFS reimbursement methodology.
(OEI; 05-07-00570; expected issue date: FY 2008; work in progress)

Medicaid Administration

Contingency Fee Payment Arrangements

We will review the extent to which State Medicaid agencies have contracted with consultants through contingency fee payment arrangements and the impact these arrangements have had 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, States pay the consulting firms a percentage of the increase in Federal Medicaid funding. Under OMB Circular A-87, the cost of such contingency fee arrangements may not be claimed from the Federal Government. Prior OIG work in one State found that improper claims had been submitted by the State as a result of a contingency fee payment arrangement.
(OAS; W-00-04-31045; W-00-05-31045; W-00-06-31045; various reviews; expected issue date: FY 2008; work in progress)

Upper Payment Limits—Flow of Funds

We will review supplemental payments available under the upper payment limits (UPL) to determine whether States have eliminated the use of inappropriate financing mechanisms. Section 1902(a)(30)(A) of the Social Security Act requires State plans to include provisions for ensuring that Medicaid payments are consistent with efficiency, economy, and quality of care. CMS has been working with States to halt accounting practices involving the UPL that artificially inflate the Federal share of the Medicaid program. We will determine whether the inappropriate accounting practices have been eliminated.
(OAS; W-00-07-31207; various reviews; expected issue date: FY 2009; new start)

Medicaid Upper Payment Limits

We will review whether selected States are in compliance with Federal inpatient services UPL requirements for State-owned facilities, private facilities, and non-State-owned facilities. In 2001, CMS revised the UPL regulation (42 CFR § 447.272) to change the manner in which States calculate the UPL for various categories of providers. The UPL is a reasonable estimate of the maximum amount that would be paid for Medicaid services under Medicare payment principles. Federal funds are not available for Medicaid payments that exceed these limits. Prior OIG work has identified errors in State UPL calculations.
(OAS; W-00-08-31313; various reviews; expected issue date: FY 2008; new start)

Medicaid Payments for Services Provided Under Section 1115 Demonstration Projects

We will review selected States' section 1115 demonstration projects to determine whether services are being provided in accordance with the conditions of the projects' approval. Section 1115 of the Social Security Act authorizes the Secretary of HHS to approve demonstration projects that are likely to assist in promoting the objectives of the Medicaid program. Under this authority, some States have expanded Medicaid eligibility to individuals not otherwise eligible for Medicaid, provided services not typically covered by Medicaid, or used innovative systems to deliver services.
(OAS; W-00-07-31208; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Waiver Safety Net Care Pools

We will review section 1115 waivers that contain safety net care pools (SNCP) to determine whether States are abiding by the Medicaid waiver terms and conditions as they relate to the SNCP. Section 1115 of the Social Security Act provides broad authority to authorize experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the

Medicaid statute. SNCPs permit the reimbursement of a broad array of uncompensated costs. For example, the pools may be used to reimburse the cost of providing to the uninsured physician services, clinic services, and any other services that CMS does not consider to be inpatient or outpatient "hospital services."
(OAS; W-00-08-31308; various reviews; expected issue date: FY 2009; new start)

Medicaid Payments for Services Provided Under Section 1915(b) Managed Care/Freedom of Choice Waivers

We will review the cost effectiveness of selected States' section 1915(b) waivers. Under the waiver authority in section 1915(b) of the Social Security Act, CMS may authorize States to provide medical assistance through MCOs. These waivers affect service delivery to some or all of the individuals eligible for Medicaid in the State. States may elect to enroll on a mandatory basis beneficiaries in managed care programs or may "carve out" specialty care. Section 1915(b) and regulations at 42 CFR § 431.55 provide that these waivers are not to negatively affect beneficiary access or quality of care or service and must be cost effective. We will also review the effectiveness of CMS's national review protocol for the oversight process.
(OAS; W-00-08-31125; various reviews; expected issue date: FY 2009; new start)

Medicaid Payments Made for Ineligible Managed Care Members

We will review Medicaid payments to MCOs in selected States to determine whether payments are made on behalf of only eligible beneficiaries. Under waivers obtained pursuant to section 1915(b) of the Social Security Act, States operate managed care programs and contract with MCOs to provide services. Some States may implement eligibility criteria that exclude individuals eligible for both Medicare and Medicaid from being eligible for these managed care programs. States must receive Medicare eligibility information timely to avoid making duplicate payments on behalf of such individuals. Previous OIG reviews have found such payments to be a problem, and these reviews will determine whether the problem still exists.
(OAS; W-00-07-31212; various reviews; expected issue date: FY 2008; work in progress)

Sections 1915(b) and (c) Concurrent Waivers

We will review each portion of sections 1915(b) and (c) concurrent waivers to determine whether the waivers are cost effective and whether the services provided through the waivers were provided in accordance with the approved waiver terms and conditions. The 1915(b) waivers are known as managed care/freedom of choice waivers, and 1915(c) waivers are known as home- and community-based waivers. Concurrent waivers allow States to simultaneously utilize sections 1915(b) and (c) program authorities to provide services to a specific group with specific providers. States must meet the Federal requirements for each of the waivers and comply with the separate reporting requirements for each waiver.
(OAS; W-00-08-31309; various reviews; expected issue date: FY 2009; new start)

Medicaid Payments for Services Provided Under Section 1915(c) Home- and Community-Based Service Waivers

We will review Medicaid payments to providers and selected States to determine whether services provided under section 1915(c) waivers are rendered in accordance with approved waiver agreements. Under section 1915(c) of the Social Security Act waiver authority, CMS may authorize States to expand "medical assistance" to include home- and community-based

services (HCBS) pursuant to written plans of care. Such services can include both traditional medical services and nonmedical services, i.e., respite care and case management. In addition, the waivers allow family members to provide services if they meet certain requirements. *(OAS; W-00-06-39045; W-00-06-31124; various reviews; expected issue date: FY 2008; work in progress)*

Appropriateness of Level of Care Determinations for Home- and Community-Based Services Waiver Recipients

We will review the States' eligibility evaluation process for Medicaid HCBS waiver recipients. Medicaid HCBS waiver programs allow States to provide alternative services for individuals who would otherwise need nursing home care. The enrollment of Medicaid beneficiaries in HCBS waivers increased dramatically in recent years, rising more than 25 percent between 2000 and 2003. Under 42 CFR § 441.302(c) and 42 CFR § 441.352(c), States are required to assess for each waiver recipient the need for the level of care provided in a nursing home facility. We will determine the extent to which States are following Federal regulations for assessing the level of care of HCBS recipients and whether level of care assessments are appropriate. *(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

Provider Enrollment Controls for Medicaid Home- and Community-Based Services Waiver Providers

We will review States' provider enrollment safeguards for Medicaid HCBS waiver providers. Medicaid HCBS waiver programs allow States to provide alternative services for individuals who would otherwise need nursing home care. Medicaid expenditures for HCBS increased nearly 69 percent from 2000 to 2004. Nontraditional treatment settings and limited supervision of HCBS afford an increased potential for fraud. State provider enrollment practices and controls are important safeguards to deter inappropriate providers from participating in the Medicaid program. Under 42 CFR § 441.302 and 42 CFR § 441.352, States are required to provide a number of assurances in their applications for HCBS waivers, including assurance that the States will ensure, among other things, that standards for providers are adequate and that providers have met all State licensure or certification requirements. We will examine the level of oversight provided by State Medicaid agencies and identify potential vulnerabilities in States' provider enrollment controls for Medicaid HCBS waiver providers. *(OEI; 00-00-00000; expected issue date: FY 2008; new start)*

State and Federal Oversight of Home- and Community-Based Services

We will review State and Federal oversight of Medicaid HCBS waiver programs. Medicaid HCBS waiver programs allow States to provide alternative services for individuals who would otherwise require care in nursing homes. Pursuant to 42 CFR § 441.302, States must provide assurances that necessary safeguards have been taken to protect the health and welfare of the recipients. However, many States provide limited oversight and regulation of HCBS waiver programs. A 2003 GAO review found that both CMS and States often failed to provide adequate oversight of HCBS waivers. We will determine the extent to which States are complying with Federal regulations for HCBS waiver programs. *(OEI; 00-00-00000; expected issue date: FY 2008; new start)*

Additional Medicaid Payments to High-Volume Providers

We will review one State's management of its high-volume provider payment program. Payments for high-volume providers have to be made in accordance with Medicaid UPL regulations at 42 CFR § 447.272 and DSH payment requirements at section 1923(g) of the Social Security Act. To recognize significant provider service to its Medicaid program, the State has designated certain practitioners as "high-volume" providers. These providers are eligible for additional payments on traditional Medicaid and primary care case management claims. Prior OIG reviews have identified problems with supplemental payments that States make to various providers. We will determine whether the State has adequately managed its high-volume provider payment program in accordance with UPL regulations and DSH requirements.
(OAS; W-00-07-31214; expected issue date: FY 2008; work in progress)

Medicaid Provider Tax Issues

We will review State and health care-related taxes imposed on various Medicaid providers to determine whether such taxes comply with applicable Federal laws and regulations and are being used for the stated purposes. Section 1903(w)(1)(A) of the Social Security Act requires a reduction in a State's medical assistance expenditures equal to the amount of any impermissible health-care-related taxes. Federal regulations at 42 CFR § 433.68 set forth the standard for permissible 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-00-08-31094; various reviews; expected issue date: FY 2009; new start)

Physician Assistant Reimbursement

We will review claims for physician assistant reimbursement in one State to determine whether payments were proper. Many doctors' offices employ physician assistants, often in areas where doctors are difficult to recruit. Among other requirements under the State's law and regulations, 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-00-07-31089; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Asset Transfers and Estate Recovery Provision for Nursing Home Care

We will review States' procedures for determining the appropriateness of beneficiary eligibility for Medicaid nursing home care. Section 1917 of the Social Security Act requires States to impose penalties on individuals who transfer assets at less than fair market value within a specific time period of applying for Medicaid benefits and to seek recovery of amounts paid by the State for certain Medicaid beneficiaries. We will review States' procedures for seeking recovery of payment from individual estates and determine the current estate recovery rates in a sample of States.
(OAS; W-00-06-31113; various reviews; expected issue date: FY 2009; work in progress)

Medicaid Eligibility in Multiple States

We will review the appropriateness of Medicaid payments for beneficiaries with Medicaid eligibility in multiple States. Federal regulations at 42 CFR § 435.403 require States to provide

Medicaid to eligible residents, including residents who are absent from the State. We have determined that individual beneficiaries have been eligible in more than one State during a specific period. Initial survey work has confirmed that, contrary to the requirements of 42 CFR § 431.52, duplicate 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 2008; work in progress)

Medicaid Administrative Costs

We will review administrative costs claimed by several States. Section 1903(a)(7) of the Social Security Act provides for Federal cost sharing for the proper and efficient administration of Medicaid State plans. 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. We will determine whether administrative costs were properly allocated or directly charged to the Medicaid program and claimed in accordance with OMB Circular A-87 and State requirements.
(OAS; W-00-06-39044; W-00-06-31123; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Claims at Enhanced Federal Financial Participation Rates

We will review States' claims for enhanced FFP to determine whether the States' claims included only allowable categories of costs. Section 1903(a) of the Social Security Act provides for variable Federal matching rates to States for administrative functions under Medicaid. Federal regulations at 42 CFR Part 433 identify specific costs for rates of FFP for program services. For example, the design, development, or installation of an approved Medicaid management information system (MMIS), as well as the operation of an approved MMIS, are available for enhanced FFP rates of 75 percent or 90 percent. Prior OIG reviews have identified unallowable claims for enhanced FFP.
(OAS; W-00-08-31310; various reviews; expected issue date: FY 2009; new start)

Medicare/Medicaid Credit Balances

We will review providers, including independent laboratories and hospitals, to determine whether there are Medicare/Medicaid overpayments in patient accounts with credit balances. For Medicare, section 1862(b) of the Social Security Act and 42 CFR Part 411 require participating providers to furnish information about payments made to them and to refund any monies incorrectly paid. For Medicaid, section 1902(a)(25) of the Social Security Act, 42 CFR 433 Subpart D, and various States' laws require that Medicaid be the payer of last resort and that providers identify and refund overpayments received. Prior OIG work has identified Medicare/Medicaid overpayments in patients' accounts with credit balances.
(OAS; W-00-08-31311; various reviews; expected issue date: FY 2009; new start)

Medicaid Management Information System Costs

We will review MMIS costs in selected States to determine whether costs allocated to Medicaid are allowable. Section 1903(a)(3) of the Social Security Act, as implemented by Federal regulations at 42 CFR § 433, Subpart C, provides FFP in State expenditures for the design, development, or installation of mechanized claims-processing and information retrieval systems

and for the operation of certain systems. Reviews of MMIS costs have not been performed by OIG in recent years.
(OAS; W-00-08-31312; various reviews; expected issue date: FY 2009; new start)

Medicaid Statistical Information System Data Reporting

We will review Medical Statistical Information System (MSIS) data to determine whether the data are current, accurate, and sufficiently comprehensive for use in Medicaid fraud, waste, and abuse detection. Section 1903(r) of the Social Security Act requires States to electronically submit MSIS claims and eligibility information to CMS. The MSIS is the only national database of Medicaid beneficiary-level claims and eligibility information. We will identify Medicaid program integrity efforts that use MSIS data, review data accuracy and validation issues, identify State barriers to submitting accurate MSIS data, and evaluate CMS's oversight of MSIS data quality.
(OEI; 04-07-00240; expected issue date: FY 2008; work in progress)

Medicaid and State Children's Health Insurance Program Payment Error Rate Measurement

We will review CMS's Payment Error Rate Measurement (PERM) process to determine whether CMS can produce valid and reliable error rate estimates for Medicaid and SCHIP FFS, managed care, and eligibility. The Improper Payments Information Act of 2002 (IPIA, Pub. L. No. 107-300) requires Federal agencies to annually develop a statistically valid estimate of improper payments made under programs with a significant risk of erroneous payments. Medicaid and SCHIP have been identified as programs with significant risks and programs for which OMB has requested improper payment information. To comply with IPIA, CMS developed the PERM for measuring improper payments in Medicaid and SCHIP. Pursuant to Federal regulations at 42 CFR § 431, Subpart Q, the PERM sets forth requirements for conducting FFS, managed care, and eligibility reviews. The PERM was implemented for Medicaid FFS in FY 2007 and will be fully implemented in FY 2008. We will evaluate CMS's oversight of the PERM process and its analysis and use of the PERM results for Medicaid and SCHIP FFS, managed care, and eligibility reviews.
(OAS; W-00-08-31314; various reviews; expected issue date: FY 2008; new start)

Medicaid Managed Care Encounter Data: Reporting and Utilization

We will review the reporting and utilization of Medicaid managed care encounter data. Section 1903(r) of the Social Security Act requires that, for claims processed after January 1, 1999, each State have in operation an electronic claims-processing system deemed by the Secretary of HHS to be consistent with the MSIS format. We will determine the extent to which State Medicaid agencies are reporting encounter data to CMS in MSIS and how Medicaid managed care encounter data are being used.
(OEI; 07-06-00540; expected issue date: FY 2008; work in progress)

External Quality Review Organizations' Compliance With Federal Requirements

We will determine whether the External Quality Review Organization (EQRO) process for Medicaid managed care meets Federal requirements for conducting external quality reviews. Pursuant to 42 CFR § 438.358(b), CMS requires mandatory activities for an EQRO. EQRO

standards ensure that beneficiaries receive services that are accessible and timely and have quality outcomes. As States search for ways to curb escalating Medicaid costs, the number of beneficiaries enrolled in managed care and the number of services provided through managed care arrangements are expected to continue to rise. We will determine the extent to which CMS and the States ensure that Medicaid MCOs meet EQRO standards.
(OEI; 01-06-00510; expected issue date: FY 2008; work in progress)

State Medicaid Third Party Liability

We will review States' reporting of third party liability data and CMS's monitoring and evaluation of these data. A 2006 GAO review found that States had encountered problems verifying third party liability coverage for Medicaid beneficiaries. Under section 1902(a)(25) of the Social Security Act and 42 CFR 433, Subpart D, States are required to take reasonable measures to identify other sources of health coverage that Medicaid beneficiaries may have and to recover reimbursements from liable third parties. We will determine the extent to which States report cost avoidances data and the way in which CMS uses these data to monitor and evaluate the effectiveness of States' cost avoidance programs.
(OEI; 00-00-00000; OAS; W-00-07-31213; expected issue date: FY 2009; work in progress)

Medicaid Enrollment of Working Disabled

We will review Federal and State efforts to ensure Medicaid coverage for eligible working disabled individuals. Under sections 1619 (a) and (b) of the Social Security Act, disabled Supplemental Security Income beneficiaries who work may be eligible for continued Medicaid coverage. However, a 2002 review by the American Public Human Services Association found that many workers with disabilities did not know about their potential eligibility for Medicaid; many State Medicaid agency workers did not know how to enroll individuals under sections 1619 (a) and (b); and the mechanics of enrollment sometimes resulted in misunderstandings, confusion, discrepancies, and mishandled information. We will determine the extent of coordination between CMS and State Medicaid agencies to ensure that the working disabled maintain Medicaid coverage.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Other CMS-Related Issues

Medicare and Medicaid Nursing Home Issues

Quality of Care and Corporate Compliance Programs in Nursing Homes With Corporate Integrity Agreements

We will review the extent to which nursing homes improve quality of care by implementing the recommendations of external quality monitors engaged pursuant to Corporate Integrity Agreements (CIAs). A CIA is an agreement between a health care provider and OIG as part of a civil settlement resolving allegations that the provider engaged in, among other types of misconduct, the provision of egregiously poor quality of care. Quality of care CIAs typically require the provider to retain an independent, external quality monitor selected by OIG who will

monitor care provided, review the provider's internal quality controls, and make recommendations for improvement. We will evaluate how providers operating under quality of care CIAs respond to recommendations made by their external quality monitors.
(OEI; 06-06-00570, expected issue date: FY 2008; work in progress)

Plans of Care: Addressing Minimum Data Set and Resident Assessment Protocols Through Provided Services

We will review nursing homes' use of the federally required Minimum Data Set and Resident Assessment Protocols to develop nursing home residents' plans of care and guide the provision of appropriate and necessary care. Sections 1819(b)(3) and 1919(b)(3) of the Social Security Act require nursing homes participating in the Medicare or Medicaid programs to use a standardized Resident Assessment Instrument (RAI) to assess each nursing home resident's strengths and needs. Prior OIG reports revealed that approximately one quarter of residents' needs for care, as identified through the RAI, were not reflected in the residents' care plans and that nursing home residents did not receive all psychosocial services identified on care plans.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Information Systems Controls

Annual OIG Reports to Congress on Medicare Contractor Information Systems Security Programs

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and administrative contractors (MAC). Section 912 of the MMA imposes requirements for annual independent evaluations of FIs, carriers, and MAC security programs and for a subsequent OIG assessment of these evaluations. OIG is required to annually report the results of our assessments to Congress. Our report to Congress will include our assessment of the scope and sufficiency of the evaluations performed and summarize the results of independent evaluations.
(OAS; W-00-08-41008; expected issue date: FY 2008; new start)

Federal Information Security Management Act of 2002 and Critical Infrastructure Protection

We will review CMS's compliance with the Federal Information Security Management Act (FISMA, Pub. L. No. 107-347) of 2002 and critical infrastructure protection requirements. Section 35.45 of the FISMA requires OIG to perform this annual review. The FISMA and OMB Circular A-130, Transmittal Memorandum #4, "Management of Federal Information Resources," Appendix III, require agencies and their contractors to 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. This work at CMS is part of an HHS-wide review.
(OAS; W-00-08-41020; expected issue date: FY 2008; new start)

Information Technology Planning To Support Medicare Fee-for-Service Contractor Reform

We will review, with contractor support, how CMS has addressed internal control issues in its plans for Medicare contractor reform. Section 911(d) (1) (C) of the MMA establishes a deadline for competitive bidding for annual contract periods that begin on or after October 1, 2011. This effectively results in the need for the phased replacement by 2011 of the 33 corporate entities that currently serve as FIs. Section 911 of the MMA also requires the Secretary of HHS to submit to Congress a plan for accomplishing the transition.
(OAS; W-00-07-41011; various reviews; expected issue date: FY 2008; work in progress)

Smart Card Technology

We will review the use of "smart card" technology in Medicare demonstrations as a means of creating portable electronic patient medical records. In September 2002, 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 on methods to prevent fraud and abuse. Our review will focus on information security, data privacy, and program integrity concerns. 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-00-08-41005; expected issue date: FY 2009; new start)

Health Information Technology in Medicare and Medicaid—Security Issues

We will review CMS's oversight, implementation, and enforcement of the regulation implementing security standards required under sections 261 and 262 of HIPAA (referred to as the HIPAA Security Rule). Specifically, we will determine whether CMS has implemented controls to reasonably ensure that the HIPAA Security Rule achieves its intended results. Congress enacted sections 261 and 262 of the HIPAA to establish national standards to protect the confidentiality, integrity, and availability of electronic protected health information and address all aspects of the security of electronic health information while it is being stored or during its exchange between entities.
(OAS; W-00-08-41021; various reviews; expected issue date: FY 2008; work in progress and new start)

State-Based Controls Over Medicaid Payments and Program Eligibility

We will review CMS's oversight of State-based information systems controls over Medicaid claim processing and program eligibility, as provided under 42 CFR § 433.119. For selected States, we will review entitywide security program planning and management, access controls, application software development and change controls, system software, segregation of duties, and 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-00-08-40019; various reviews; expected issue dates: FYs 2008 and 2009; new start)

Medicare Contractor Information Technology Closeout Audits

We will review CMS's policies, instructions, and procedures designed to ensure adherence to Federal data privacy, information security, and contractual requirements and conduct IT closeout audits at Medicare contractors leaving the program in FY's 2007 and 2008 to assess compliance with applicable Federal requirements. Section 911 of the MMA requires the Secretary of HHS to submit to Congress a plan outlining a strategy for accomplishing the replacement of current FIs and carriers with MACs no later than 2011. The plan that the Secretary submitted to Congress calls for the establishment of 23 new administrative contracts by 2009. It also includes steps to consolidate the number of contracted data centers from 16 to no more than 4. Consequently, over the next several years, a number of contractors will leave the program. Our experience with previous workload transitions suggests that problems could arise with the disposition of Government systems and data when contractors leave Medicare. For example, these contractors' access rights to Medicare shared systems, the CWF system, and Medicare banking records need to be terminated as soon as the contractors' performance periods end.
(OAS; W-00-08-41022; various reviews; expected issue date: FY 2008; work in progress)

Selected Medicare Part D General and Application Controls for Systems That Track True Out-of-Pocket Costs

We will review selected Medicare Part D general and application controls at the CMS contractor responsible for collecting information on TrOOP from payers secondary to Medicare Part D. TrOOP calculations are critical to the Medicare Part D payment process because they affect the proportions of the drug cost for which the beneficiary, the Part D plan, and Medicare are each responsible. With respect to general controls, we will focus on continuity of service planning and software development change controls. We will also review the application controls, including the accuracy and completeness of standard transactions generated at the CMS contractor for covered prescriptions and documenting payers secondary to Medicare. The transactions are transmitted by the CMS contractor to the applicable plans and CMS, which uses them to compute beneficiary TrOOP for covered prescription drugs.
(OAS; W-00-08-41024; expected issue date: FY 2008; new start)

Implementation of Medicare Part D at Small- and Medium-Size Plans and Plans New to Medicare

We will review implementation of the Part D prescription drug benefit plan and expansion of beneficiary choices at MA-PDPs and PDPs run by small- to medium-size sponsor organizations and other sponsor organizations with little or no previous involvement in the Medicare program. We will evaluate systems that support designated Part D functions and the general and application controls that are critical to support these functions. We will also assess the plans' compliance with Medicare Part D contractual requirements, CMS regulations, and CMS instructions for key Part D components, such as beneficiary enrollment, coordination of benefits TrOOP costs, and prescription drug event operations.
(OAS; W-00-08-41024; various reviews; expected issue dates: FYs 2008 and 2009; new start)

Point-of-Sale System for Handling Emergency Billing Under Medicare Part D

We will review the system used by CMS's contractor responsible for handling emergency billing for potential dual eligibles not identified as enrolled in Part D. CMS has contracted with a national health benefits company to provide a system for paying pharmacies for prescriptions for

individuals who present evidence of dual (Medicare and Medicaid) eligibility but for whom queries by the pharmacies to the Medicare Part D eligibility database return negative responses. We will also review the process for reversing payments and billing the appropriate plan once correct enrollment status has been determined.
(OAS; W-00-08-41026; expected issue date: FY 2008; new start)

Oversight of System Conversions, Redesigns, and Transitions of State Medicaid Management Information Systems

We will review the nature of oversight, guidance, and assistance that CMS provides to the States to ensure that new MMIS initiatives are appropriately focused, risks are reduced, and successful implementation of new systems is achieved. Pursuant to Title XIX of the Social Security Act, States may receive 90-percent FFP for the costs of converting, redesigning, or transitioning their MMISs.
(OAS; W-00-08-41077; various reviews; expected issue date: FY 2009; new start)

Medicaid Management Information Systems—Business Associate Agreements

We will review CMS's oversight of States' MMISs to ensure that business agreements have been properly executed to protect beneficiary information, including safeguards implemented pursuant to HIPAA standards. States' MMISs process and pay claims for Medicaid health benefits. Business associates of States' MMISs typically include support organizations, such as data processing services and medical review services. State Medicaid agencies must comply with HIPAA Security Final Rules, which stipulate minimum requirements that contracts with business associates must include to protect the privacy and security of certain personally identifiable health information.
(OAS; W-00-08-41028; various reviews; expected issue date: FY 2008; new start)

Security Planning for Systems Under Development

We will review CMS's security-planning process to determine whether information systems security requirements are adequately addressed as major new systems are designed, developed/acquired, and implemented. Federal regulations and departmental policy require that information security be practiced throughout the life cycle of each system. We will also review security plans and related internal control deliverables for major new systems and databases, such as the Health Insurance General Ledger Accounting System, the CWF System Redesign, and the Integrated Data Base, to determine whether they conform to Federal guidelines and incorporate best practices from the public and private sectors.
(OAS; W-00-08-41001; various reviews; expected issue date: FY 2008; new start)

Claims-Processing Controls To Prevent Duplicate Payments for Medicaid Services

We will determine whether States have effective controls in place to preclude duplicate payments. Under the Medicaid program, FFP is available for design, development, installation, and operation of State mechanized Medicaid claims-processing and information retrieval systems. Federal regulations require that States conduct prepayment claims reviews to prevent duplicate claims. A prior OIG review disclosed that duplicate payments were made as a result of ineffective claims resolution.
(OAS; W-00-08-41040; various reviews; expected issue date: FY 2009; new start)

Medicare/Medicaid Gulf Coast Hurricane Response

Billing for Durable Medical Equipment in Hurricane-Affected Areas

We will review payments for DME supplies and equipment in the areas affected by the Gulf Coast hurricanes to determine whether the equipment was medically necessary and whether the beneficiary actually had used the equipment. Section 1832 of the Social Security Act provides Medicare coverage for medical and other health services, including DME. Section 1862(a) (1) (A) of the Act requires that such items and services be reasonable and necessary.
(OAS; W-00-07-35319; various reviews; expected issue date: FY 2008; work in progress)

Duplicate Medicaid Payments to Providers

We will review Medicaid payments to determine whether two providers were paid for the same service. As a result of the hurricanes, thousands of beneficiaries were evacuated from their home States and relocated to other (host) States. Beneficiaries were eligible for Medicaid in their new host States and may have received services from providers in their host States. We will determine whether providers in the host States billed and received payment from both the beneficiaries' home States and host States.
(OAS; W-00-06-31117; various reviews; expected issue date: FY 2008; work in progress)

Medicaid Payments for Evacuees

We will review the appropriateness of Medicaid claims submitted for 100-percent FFP in hurricane-affected areas. Sections 6201(a)(1)(A) and (C) of the DRA provide funding to CMS to pay for the State share of services provided to Medicaid beneficiaries in the affected areas. Medicaid claims for beneficiaries who are not in the affected areas should have been submitted at the regular matching rate.
(OAS; W-00-07-31216; various reviews; expected issue date: FY 2008; work in progress)

Uncompensated Care Costs

We will review whether State Medicaid agencies appropriately spent Federal funding for uncompensated care. Sections 6201(a)(1)(B) and (D) of the DRA provide for the payment of uncompensated care costs for medically necessary services and supplies for hurricane-affected individuals. CMS approved Federal funding for an uncompensated care pool to cover medical services furnished to low-income uninsured individuals who did not meet eligibility requirements for Medicaid or State SCHIP.
(OAS; W-00-07-31219; various reviews; expected issue date: FY 2008; work in progress)

Financial Status of Hospitals in the New Orleans Area

We will examine the financial status of hospitals in the New Orleans area in the aftermath of Hurricane Katrina. We will examine cost and revenue data to assess the needs of hospitals and options for policymakers as the area rebuilds its health care infrastructure. As part of our work, we will review various expense data at selected hospitals. The Department has played a central role in Katrina recovery efforts, including the funding of provider stabilization grants. We will also determine whether the funds were distributed and used and assess the implications for future funding. To obtain a better understanding of the financial status of Katrina-impacted hospitals,

we will also perform various profitability analyses and analysis of the trends of costs and revenues.
(OAS; W-00-07-35203; various reviews; expected issue date: FY 2008; work in progress)

CMS-Related Investigations and Legal Counsel

Investigations

OIG 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 detect and prevent waste, fraud, and abuse in Department programs. Our investigations result in criminal investigations and program exclusions; recovery of damages and penalties through civil and administrative proceedings; and corrective management actions, regulations, or legislation. Each year, thousands of complaints from various sources are brought to OIG's attention for development, investigation, and appropriate resolution. Such complaints cannot be predicted in advance. This work plan, however, identifies investigative focus areas in which we will concentrate our resources, subject to the demands of current complaint referrals. In addition to meeting our programmatic requirements, OIG will continue to review and investigate allegations of misconduct and wrongdoing within the Department. We carry out this responsibility to ensure that HHS personnel and contractors uphold the highest level of integrity.

Health Care Fraud

OIG devotes significant resources to the investigation of fraud committed against the Medicare and Medicaid programs. We conduct numerous 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 State Medicaid Fraud Control Units (MFCU).

OIG will investigate individuals, facilities, or entities that bill or are alleged to have billed 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. We will also investigate business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians.

OIG will conduct investigations related to the new Medicare Part D drug benefit and assist CMS in identifying program vulnerabilities. We will continue to provide training to special agents and others on the intricacies and developing trends of the Part D benefit so that focused investigations can be conducted. OIG is investigating matters involving enrollment and marketing schemes, prescription shorting, and health care fraud.

Working jointly with other law enforcement partners at the Federal, State, and local levels, OIG will continue to identify and investigate schemes to illegally market, obtain, and distribute prescription drugs. In doing so, we seek to protect the Medicare and Medicaid programs from making improper payments, to deter the illegal use of prescription drugs, and to curb the danger associated with street distribution of highly addictive medications.

OIG will apply lessons learned through our work related to fraudulent DME suppliers in South Florida to other areas of the Nation. Our efforts in South Florida have resulted in significant recoveries to the Medicare program. Applying these methods to additional high-risk areas could produce similar results.

OIG will continue to examine quality-of-care issues for beneficiaries residing in nursing facilities and other care settings. With the continuing growth of the elderly population, we have found that 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 or for substandard care that is so deficient that it constitutes a "failure of care." We will expand our focus on these issues to additional institutions and community-based settings. We will also investigate allegations of patient abuse or neglect and work jointly with the MFCUs to provide assistance in this area.

OIG does not pursue legal action against individuals, facilities, or entities that merely make mistakes on claims submitted to the Medicare or Medicaid program. CMS and its contractors address claims errors and mistakes. We work with CMS 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.

Medicaid Program

OIG has received additional funding under section 6035 of the DRA to expand OIG Medicaid fraud and abuse control activities. We will use a portion of this funding to provide customized training to our special agents and our Federal, State, and local partners. OIG will continue to conduct investigations related to claims submitted to Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, claims for care that was not provided to nursing home residents, and other false claims submitted to obtain program funds.

OIG will continue to provide customized training and education to better identify Medicaid program vulnerabilities, coordinate investigative activities and efforts, highlight successful Medicaid investigative accomplishments, illustrate new approaches to working cases, and hold information-sharing sessions to increase the efficiency and effectiveness of our efforts to protect the Medicaid program.

Exclusions

OIG has authority to exclude individuals and entities from participation in the Medicare, Medicaid, and all Federal health care programs to protect the programs and beneficiaries from providers that pose a risk. Providers are excluded for reasons that include program-related

convictions, patient abuse or neglect convictions, and licensing board disciplinary actions. OIG imposes exclusions based on referrals received from various Federal and State agencies. We will continue to work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. OIG excluded in FY 2006 over 3,400 individuals and entities from Federal health care programs and anticipates reviewing and implementing the exclusion of several thousand more providers during FY 2008. As appropriate, OI and the Office of Counsel (see below) expect to initiate affirmative 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.

Provider Self-Disclosure

OIG will continue to encourage health care providers to promptly self-disclose improper conduct that violates Federal health care program requirements. We have made a concerted effort to educate providers on the advantages of self-disclosure. In October 1998, OIG announced a self-disclosure protocol for use by all health care providers. The protocol offers health care providers specific steps, including a detailed audit methodology that they may use if they choose to work openly and cooperatively with OIG. Numerous providers have been accepted under this protocol. These providers range from hospitals to laboratories and physicians. Both the Federal Government and the providers benefit from this program.

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

Legal Counsel

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General (OCIG) coordinates OIG's role in the resolution of civil and administrative health care fraud cases, including the litigation of program exclusions and civil monetary penalties and assessments. OCIG also negotiates and monitors CIAs. OCIG 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 2008 includes the following:

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

OIG investigators and auditors will continue to work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue False Claims Act cases against individuals and entities that defraud the Government, when 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 invoke OIG's exclusion authority based on these defendants' conduct. When appropriate and necessary, we will 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 CIAs (and settlements with integrity provisions) into which they entered as part of the settlement of fraud and abuse allegations. We will 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. When warranted, we will continue to impose sanctions, in the form of stipulated penalties or exclusions, against providers that breach their integrity agreement obligations.

Advisory Opinions, Fraud Alerts, and Other Industry Guidance

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 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. We will also review existing Compliance Program Guidances to identify those that should be revised or updated.

Civil Monetary Penalties

We will continue to pursue CMP 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; violation of the Emergency Medical Treatment and Labor Act; and other conduct actionable under section 1128A of the Act or other CMP authorities delegated to OIG.

OIG Work Related to Public Health and Human Service Programs and Departmentwide Issues

OIG allocates about 20 percent of its resources to reviews of HHS's 300 public health and human service programs and to departmentwide issues that affect more than one program. OIG has discretion in allocating most of these resources; a portion, however, is used for mandatory reviews. These include financial statement audits conducted pursuant to section 405(b) of the Government Management Reform Act of 1994 and the Chief Financial Officers Act of 1990 (CFO Act) and information systems reviews required by the Federal Information Security Management Act (FISMA).

This chapter describes OIG's ongoing and planned activities addressing the following:

Public Health Programs – Several HHS agencies perform a wide spectrum of public health activities. Public health activities and programs represent this country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Public health agencies within the Department include the following:

- The Centers for Disease Control and Prevention (CDC) operates a system of health surveillance to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.

- The Food and Drug Administration (FDA) is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.

- The Health Resources and Services Administration (HRSA) maintains a safety net of health services for people who are low-income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.

- The Indian Health Service (IHS) provides or funds health care services for 1.6 million American Indians and Alaska Natives.

- The National Institutes of Health (NIH) supports medical and scientific research examining the causes of and treatments for diseases such as cancer and HIV/AIDS.

- The Substance Abuse and Mental Health Services Administration (SAMHSA) funds services to improve the lives of people with or at risk for mental and substance abuse disorders.

- The Agency for Healthcare Research and Quality (AHRQ) sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access.

Within the Office of the Secretary (OS), issues related to public health are also addressed by several offices. For example, the Office of the Assistant Secretary for Preparedness and Response (ASPR) serves as the Secretary's principal advisor on matters related to Federal public health preparedness and response to public health emergencies. In addition, the Office of Human Research Protections (OHRP) oversees the protection of volunteers involved in research.

Human Services Programs – Several HHS agencies support human services to assist vulnerable individuals of all ages, including the following:

- The Administration for Children and Families (ACF) operates over 30 programs that promote the economic and social well-being of children, families and communities, including Temporary Assistance for Needy Families, the national child support enforcement system, the Head Start program for preschool children, and assistance for childcare, foster care, and adoption services.

- The Administration on Aging (AoA) supports programs that provide services such as meals, transportation, and caregiver support to older Americans at home and in the community through the nationwide network of services for the aging.

Departmentwide Issues – Certain financial, performance, and investigative issues cut across HHS programs. Our ongoing and planned work addresses departmentwide issues, such as financial accounting, information systems management, and oversight of grants and contracts.

Public Health Programs

Centers for Disease Control and Prevention

Select Agent Shipments

We will review CDC's handling of select agent shipments. Federal regulations at 42 Code of Federal Regulations (CFR) § 73.10(a) require that access to select agents, which are dangerous substances, be restricted to persons approved by the Secretary of HHS following a security risk assessment by the Attorney General. Department of Transportation hazardous materials regulations (49 CFR Parts 171-180) govern how hazardous materials, such as select agents, are to be packaged, shipped, and transported. Prior OIG reviews of select agent transfers by laboratories subject to Federal regulations at 42 CFR § 73.10(a) found that unauthorized individuals at three separate laboratories had access to select agent shipments. We will review CDC's select agent shipments from October 1, 2005, to March 31, 2007, to identify shipments made by unauthorized persons, shipments made without filing appropriate forms with CDC, and weaknesses in the shippers' handling of select agents.
(OAS; W-00-07-56150; A-02-07-02010; expected issue date: FY 2008; work in progress)

Management of the Select Agent Oversight Program

We will review CDC's management of the select agent program. Pursuant to Federal regulations at 42 CFR Part 73, CDC is responsible for regulating entities that possess dangerous substances, known as select agents. Earlier OIG work showed that CDC needed to improve its program oversight in such areas as onsite inspections, written procedures, and data management. We will determine whether CDC has implemented recommendations from our earlier review and assess CDC's progress in overseeing entities' implementation of regulatory requirements for select agent security, accountability, and access. Since our earlier work, CDC has issued more stringent regulations for these areas.
(OAS; W-00-07-52022; A04-07-01052; expected issue date: FY 2008; work in progress)

Centers for Disease Control and Prevention's Implementation of Select Agent Regulations

We will review CDC's implementation of select agent regulations at its laboratories. This effort continues our previous reviews at university, State, and private laboratories, which generated recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR Part 73, we will assess compliance with select agent Federal regulations regarding security plans, accountability for select agents, and access to select agents.
(OAS; W-00-07-58200; A-04-07-01051; expected issue date: FY 2008; work in progress)

Deemed Exports

We will review CDC's compliance with Department of Commerce export control regulations at 15 CFR, Chapter VII, subchapter C, for foreign nationals who work at CDC and have access to certain equipment. Release of covered goods and technologies to a foreign national constitutes a "deemed export" and requires a license in accordance with the Export Administration Act of

1979 and Executive Order 13222 (August 17, 2001). The Department of Commerce controls the export of certain goods and technologies for reasons of national security. We will determine whether CDC obtained the required licenses for foreign nationals who work at CDC and had access to covered equipment.
(OAS; W-00-08-52400; expected issue date: FY 2009; new start)

Vaccines for Children Program

We will review CDC's centralized distribution system for its Vaccines for Children program, which is authorized by the Omnibus Budget Reconciliation Act of 1993, Public Law (Pub. L.) No. 103-66, to provide vaccines at no cost to eligible children through enrolled public and private providers. CDC is in the final stages of implementing a new centralized distribution system designed to simplify the processes for ordering, distributing, and managing vaccines. With this new system, CDC expects to be able to respond more quickly and effectively to public health crises related to disease outbreaks, vaccine shortages, and disruptions of the vaccine supply; implement a more efficient vaccine distribution system; and reduce the lead time between orders for and delivery of vaccines. We will review the flow of vaccine funds from CDC to the States, CDC's allocations to the States, the States' distribution of vaccine, and CDC's estimates of the cost savings associated with this new system.
(OAS; W-00-08-52400; expected issue date: FY 2008; new start)

Implementation of Early Event Detection Technology

We will review the implementation and current status of early event detection technology among the States. CDC's Public Health Information Network (PHIN) Preparedness initiative seeks to implement, at an accelerated pace, a consistent and capable national network of preparedness systems that can be used to effectively detect, track, and respond to public health threats. In particular, the PHIN Preparedness Initiative sets forth functional requirements for early event detection (EED) systems used by public health partners. Pursuant to authority granted in 42 United States Code (U.S.C.) §§ 247d-3 and 247d-3a, CDC has required grantees receiving Public Health Emergency Preparedness Cooperative Agreement funds to develop information technology in support of EED and begin a CDC certification process of that technology by August 31, 2006. We will examine the systems that State health partners are implementing to address EED functional requirements and identify both successes and potential barriers to future implementation.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Public Health Laboratory Preparedness

We will review the extent to which laboratories that confirm the presence of biological threats to public health are prepared to handle increased testing in a bioterrorism event or public health emergency. Pursuant to authority granted in 42 U.S.C. §§ 247d-3 and 247d-3a, CDC has provided funding to States since 1999 to prepare for and respond to natural and man-made health threats through its Public Health Emergency Preparedness Cooperative Agreement. In addition to meeting other requirements, grantees must maintain public health laboratory support for identifying biological, chemical, or other agents. A previous OIG study examined the coordination between sentinel laboratories and reference laboratories and found that although some coordination is occurring between them, many were overwhelmed during the 2001 anthrax events. We will address whether laboratories are now better prepared to handle a bioterror event.

We will also assess the extent to which these laboratories are receiving support from CDC to strengthen their testing capacity.
(OEI; 04-06-00630; expected issue date: FY 2008; work in progress)

State 24/7 Reporting Systems

We will review the status of States' systems for receiving urgent reports of bioterrorism agents and other public health emergencies. Pursuant to authority granted under 42 U.S.C. §§ 247d-3 and 247d-3a, CDC funds Public Health Emergency Preparedness Cooperative Agreements that include critical tasks that States must accomplish to improve the timeliness and accuracy of communications regarding threats to the public's health and to decrease the time needed to classify health events such as terrorism or naturally occurring disasters. The State must operate 24-hours-per-day, 7-days-per-week, urgent disease and public health emergency reporting systems (24/7 systems) that enable health care providers to report to or consult with State or local health department staff at any time regarding suspected or confirmed diseases that require urgent reporting. A previous OIG review identified vulnerabilities in the existing State 24/7 systems. We will evaluate State 24/7 systems to assess State preparedness for receiving urgent reports and the functionality of these systems.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Oversight of Public Health Emergency Preparedness Cooperative Agreement Grantees

We will review mechanisms for monitoring the performance of grantees receiving funding through CDC's Bioterrorism Preparedness and Response Cooperative Agreement Program. Pursuant to authority granted in 42 U.S.C. §§ 247d-3 and 247d-3a, CDC has awarded over $4 billion in Federal funding since 1999 in an effort to bolster State and local emergency preparedness capabilities. In its fiscal year (FY) 2006 Program Announcement guidance (Funding Opportunity Number AA154), CDC indicated that it would substantially increase staff involvement in program activities and evaluate State performance. We will review the extent to which CDC has performed oversight of grantees, worked directly with States to measure and assist with their progress, and provided appropriate guidance and support to States.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Centers for Disease Control and Prevention's Monitoring of Conflicts of Interest

We will review how CDC officials monitor conflicts of interest reported by employees. The Federal conflict-of-interest statute, 18 U.S.C. § 208, and the Standards of Ethical Conduct at 5 CFR § 2635, prohibit Federal employees from participating in official matters with which they have conflicts of interest. HHS's Supplemental Standards of Ethical Conduct at 5 CFR § 5501 impose additional restrictions and procedures on all HHS employees. Pursuant to 5 CFR § 2634, the HHS Designated Agency Ethics Official and Deputy Ethics Counselors appointed by him or her oversee submission and review of financial reports required of executives and senior employees in the Department, as well as employee requests to engage in outside activities. Conflicts of interest are of particular concern for CDC employees because their research results and regulatory decisions affect citizens' health and welfare. This is the third evaluation in a series examining the handling of conflicts of interest within HHS. OIG has previously reviewed this issue at NIH and FDA.
(OEI; 04-07-00260; expected issue date: FY 2008; work in progress)

Food and Drug Administration

Implementation of Pandemic Influenza Preparedness Strategic Plan

We will review FDA's implementation of its Pandemic Influenza Preparedness Strategic Plan. The plan focuses on accelerating development, production, and regulatory reviews of vaccines, antivirals, and diagnostic devices for an effective national response. We will determine whether FDA is meeting the timeframes it has established for deliverables in the plan.
(OAS; W-00-08-51000; expected issue date: FY 2009; new start)

Food and Drug Administration's Implementation of Select Agent Regulations

We will review FDA's implementation of select agent Federal regulations at its laboratories. This effort continues our previous work at university, State, and private laboratories, which generated recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR Part 73, we will assess compliance with select agent Federal regulations regarding security plans, accountability for select agents, and access to select agents.
(OAS; W-00-08-00000; A-03-08-51001; expected issue date: FY 2008; new start)

Oversight of Off-Label Drug Promotion

We will assess FDA's oversight and review of allowable off-label drug promotion and enforcement. Pursuant to provisions of the Food, Drug, and Cosmetic Act at 21 U.S.C. §§ 331 and 355, among others, FDA has the authority to regulate the labeling and promotion of drugs and to restrict off-label marketing.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Submission of Electronic Drug Labels

We will review FDA's oversight of drug manufacturers' compliance with the requirement to electronically submit to FDA complete and accurate drug labels for currently marketed prescription drugs. In December 2003, FDA published final regulations (21 CFR §§ 314.50(l), 314.94(d), 601.14(b), and 314.81(b), respectively) requiring drug manufacturers to electronically submit to FDA specific labeling content for new drug applications, abbreviated new drug applications, certain biologics license applications, and annual reports. In November 2005, drug manufacturers were required to begin electronic submission of prescribing and product information for prescription drug labels in a structured product-labeling format. The format is intended to give health care providers accurate, up-to-date drug information using standardized medical terminology in a readable, accessible format. We will examine the accuracy and completeness of electronic labels submitted to FDA and identify any factors that contribute to inaccurate or missing information.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Generic Drug Approval Process

We will review FDA's timeframes for reviewing original generic drug applications and identify factors that affect the timely review of these applications. FDA is required by 21 CFR § 314.100 to approve or disapprove applications for generic drugs within 180 days of submission. As of 2006, the agency had a backlog of approximately 1,000 generic drug applications, one-third of

which had exceeded the 180-day statutory time limit. We will assess average application review times and identify factors contributing to the backlog.
(OEI; 04-07-00280; expected issue date: FY 2008; work in progress)

Adverse Event Reporting for Medical Devices

We will review FDA's adverse-event-reporting system for medical devices. Medical device manufacturers are required under 21 CFR Part 803 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 after they reach the market. We will evaluate the extent to which FDA ensures compliance with adverse-event-reporting requirements and the way in which FDA uses medical device adverse event reports to identify and address safety concerns.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Oversight of Research Misconduct by Clinical Investigators

We will review FDA's oversight and discipline of clinical investigators found to have engaged in research misconduct. Regulations at 21 CFR Part 312 provide FDA with authority to oversee and discipline clinical investigators for research misconduct. We will review FDA's progress in implementing recommendations made by OIG during a 2000 review. We recommended at the time that FDA develop internal guidance on the thresholds that violations must meet to justify disqualifying a clinical investigator from receiving investigational products for use in clinical trials.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Management of Information Technology Projects

We will review the adequacy of management and contracting practices of the Office of Information Technology (OIT) within FDA's Center for Drug Evaluation and Research. Requirements found in the Federal Acquisition Regulation (FAR), specifically parts 5-16 and 39, govern FDA's contracting practices. We will review a sample of FDA information technology contracts, including those for the Adverse Event Reporting System II, and determine the adequacy and effectiveness of OIT's acquisition management processes. Our review will also focus on contractor selection and oversight.
(OEI; 01-07-00450; expected issue date: FY 2008; work in progress)

Financial Disclosure Requirements for Clinical Investigators

We will review the disclosure to FDA of financial interests of clinical investigators, as required by 21 CFR § 54, associated with drug, device, and biologic applications. Financial conflicts of interest create a potential for bias that may negatively impact the integrity of the data as well as human subject protection. We will determine the nature of financial interests disclosed by clinical investigators, the extent to which applicants monitor their clinical investigators for financial interests, and the extent to which FDA oversees the process.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Traceability in the United States Food Supply Chain

We will review FDA's ability to trace food products back through the U.S. food supply chain. The food traceability model, known as "one-up, one back," is incorporated in regulations that FDA has issued to implement section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and is intended to help FDA respond to a deliberate attack on the Nation's food supply or other public health emergency involving food. The Bioterrorism Act and FDA's regulation at 21 CFR Part 1, Subpart J, require persons that manufacture, process, pack, hold, transport, distribute, receive, or import food under FDA's jurisdiction to maintain records that identify the immediate previous sources and immediate subsequent recipients of food that they receive or release. Compliance with this requirement will enable FDA to trace back through the supply chain any food FDA believes may pose a serious health threat and to trace forward through the food chain to alert facilities of potentially contaminated food. We will assess selected food facilities' implementation of Federal requirements to maintain records that FDA may access if it has a reasonable belief that the food may present a threat of serious adverse health consequences or death to humans or animals.

(OEI; 02-06-00210; expected issue date: FY 2008; work in progress)

Oversight of Food Safety Operations

We will review FDA's oversight and operations related to three broad areas: imported foods, imported pet food and feed products, and recall procedures for human food and pet food. In the area of imported foods, we will determine the extent of FDA's enforcement authorities; whether and how it determines that foreign countries' food safety standards and inspections meet U.S. food safety requirements (or that their food products exported to the United States are in compliance with requirements), whether and how it determines that foreign measures are equivalent to U.S. food safety measures, and how frequently FDA evaluates companies that export food products to the United States. In area of the area of imported pet food and feed products, we will determine the extent of FDA's enforcement authorities, including whether it requires imported pet food and feed to be produced under the same safety standards as those under which pet food and feed are produced in the United States. We will also determine whether FDA samples imported pet food and feed for chemicals and microbial pathogens. If FDA is not sampling food and feed products, OIG will determine why. In the area of human food and pet food recall procedures, we will determine the extent of FDA's enforcement authorities, identify FDA procedures to implement those authorities, determine whether and how FDA is carrying out the activities called for in its procedures, and determine whether FDA conducted tests for melamine in human food immediately after melamine was found in pet food. These various reviews are being conducted in response to a congressional request.

(OAS; W-00-08-51002; expected issue date: FY 2008; new start)

Food Facility Inspections

We will review FDA's food facility inspection process and its methods for determining which facilities will be inspected. FDA monitors the safety of domestic food primarily through inspections of farms, warehouses, manufacturers, packers, and other types of food establishments. Section 702(a) of the Food, Drug, and Cosmetic Act authorizes FDA to conduct inspections to enforce the provisions of that statute and other applicable laws. Under this authority, FDA carries out surveillance inspections to gauge overall industry compliance with

manufacturing practices and compliance inspections based on known or suspected problems with specific manufacturers. FDA's district officers, with guidance from FDA headquarters, determine the number, type, and specific firms to be inspected. We will identify trends in the types of FDA facility inspections and their effectiveness in protecting the food supply.
(OEI; 02-07-00000; expected issue date: FY 2008; new start)

Health Resources and Services Administration

Ryan White HIV/AIDS Program Part B: Payer of Last Resort

We will review States' compliance with the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) payer of last resort requirement in the administration of Title II AIDS Drugs Assistance Program (ADAP) funds. The Ryan White CARE Act stipulates that grant funds not be used to make payments for items or services that are eligible for coverage by any other Federal or State program or by any health insurance policy. This requirement, commonly referred to as the payer of last resort provision, is outlined in section 2617(b)(7)(F) of the Public Health Service Act. In FY 2006, ADAP grant awards totaled more than $750 million. A previous OIG report indicated that a significant percentage of payments made for ADAP medications in one State should have been paid by parties other than the ADAP.
(OAS; W-00-08-54260; expected issue date: FY 2009; new start)

Oversight of the Core Medical Services Requirement Under the Ryan White HIV/AIDS Treatment Modernization Act

We will review HRSA's oversight of the core medical services requirement of the Ryan White HIV/AIDS Treatment Modernization Act of 2006. Pursuant to the Act, grantees must spend at least 75 percent of funds for Ryan White Titles I-III on "core medical services," such as outpatient health services, medications, and mental health care. HHS may waive this requirement for a grantee requesting a waiver if there is no ADAP waiting list and if core medical services are otherwise available to all those identified and eligible under the Act. Grantees seeking a waiver self-certify that core medical services are otherwise available. We will assess HRSA's oversight of grantee compliance with the 75-percent requirement, grantees' processes for self-certifying availability of core medical services, and HRSA's oversight of self-certification.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Oversight of Health Centers

We will review health centers' quality assurance activities as well as HRSA's oversight of these activities. Pursuant to 42 CFR § 51c.303(c), health centers receiving HRSA grants are required to have ongoing quality assurance programs. In FY 2002, Congress appropriated for the President's Health Initiative an additional $780 million over 5 years to expand the Nation's health center network and manage quality improvement activities at health centers. We will examine the quality assurance programs and periodic assessments of a random sample of health centers. We will also use this sample to determine the extent to which HRSA performance reviews have assessed health centers' quality assurance programs and quality of care.
(OEI; 09-06-00420; expected issue date: FY 2008; work in progress)

Indian Health Service

Accounting for Medication Inventory

We will review IHS's accounting for medication inventory. Office of Management and Budget (OMB) Circular A-123, "Management's Responsibility for Internal Control," section II, requires Federal managers to implement controls to provide reasonable assurance that assets are safeguarded against waste, loss, unauthorized use, or misappropriation. Although IHS is required to implement inventory procedures for drugs controlled by the Drug Enforcement Administration (DEA), there is no commensurate Federal requirement for inventories of non-DEA-controlled drug products, which account for most of the drugs on hand. We will determine whether pharmacies in IHS facilities have implemented controls to ensure accountability for their medication inventories.
(OAS; W-00-08-55060; expected issue date: FY 2009; new start)

Background Investigations To Protect Indian Children

We will review the handling of background investigations required by the Indian Child Protection and Family Violence Prevention Act (Pub. L. No. 101-630). This law requires that all IHS employees and contractors with regular contact with, or control over, Indian children be investigated for any history of certain criminal acts. Previous OIG work found inconsistent practices regarding staff background investigations. We will determine whether IHS and tribal organizations have completed required background investigations.
(OAS; W-00-08-55010; expected issue date: FY 2009; new start)

Incentive Payments to Indian Health Service Physicians

We will review incentive payments made to IHS physicians. Pursuant to section 1833(m) of the Social Security Act, incentive payments are made to an IHS physician who provides physician services to Medicaid beneficiaries in a designated rural or urban Health Professional Shortage Area. We will determine the allowability of incentive payments made to IHS physicians and whether services were performed in a Health Professional Shortage Area.
(OAS; W-00-08-55011; expected issue date: FY 2009; new start)

Tribal Governments' Third Party Collections in Emergency Medical Services Programs

We will review the effectiveness of tribal governments' efforts to collect third party payments from Medicare and Medicaid for EMS provided to covered tribe members. If EMS service providers meet the participation requirements in Medicare and Medicaid regulations, they are eligible to bill for services provided to tribe members who are Medicare and Medicaid beneficiaries. Properly billing such third parties for services would augment funds obtained from 638 contracts and other programs, freeing up such funds for activities such as improving the infrastructure of tribal health care facilities or expanding services.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

National Institutes of Health

Superfund Financial Activities for FY 2007

We will review the payments, obligations, reimbursements, and other uses of Superfund monies by NIH's National Institute of Environmental Health Sciences (Institute). As required by section 42 U.S.C. § 9611(k) enacted in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, OIG must conduct an annual audit of the Institute's Superfund activities, carried out by its own staff and through cooperative agreements, which include training for people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals.
(OAS; W-00-08-56030; expected issue date: FY 2008; new start)

National Institutes of Health's Implementation of Select Agent Regulations

We will review NIH's implementation of select agent regulations at its laboratories. This effort continues our previous work at university, State, and private laboratories, which led to OIG recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR Part 73, we will assess compliance with select agent Federal regulations regarding security plans, accountability for select agents, and access to select agents.
(OAS; W-00-08-56031; expected issue date: FY 2009; new start)

Procurements for Property and Services on Behalf of the Department of Defense

We will review whether NIH has complied with Federal procurement regulations when awarding task orders on behalf of the Department of Defense (DoD). Section 817 of the John Warner National Defense Authorization Act for Fiscal Year 2007, Pub. L. No. 109-364, requires the DoD OIG and the HHS OIG to jointly review contract actions made by NIH in FY 2006 on behalf of DoD for compliance with applicable laws and regulations. Our review of 2006 task orders found that NIH generally complied with laws and regulations. However, because some problems were found with the FY 2006 task orders, the Act required a follow-up review of FY 2007 task orders to determine whether corrective actions were taken.
(OAS; W-00-08-56032; expected issue date: FY 2008; new start)

Grantee Management of Financial Conflicts of Interest in Research Funded by the National Institutes of Health

We will examine NIH's oversight of requirements relating to the monitoring of financial conflicts of interest by NIH extramural grantee institutions. We will review the nature of financial conflicts of interest reported by grantee institutions to NIH in FY 2006 and the grantee institutions' reporting of how they managed those conflicts of interest. Eighty percent of NIH funding is allocated through extramural research grants. Federal regulations at 42 CFR Part 50, Subpart F, establish standards to ensure that research is not biased by financial conflicts of interest and require grantee institutions to have written policies for identifying financial conflicts of interest and ensuring that conflicts are managed, reduced, or eliminated.
(OEI; 03-07-00700; expected issue date: FY 2008; work in progress).

Contracting Procedures
We will review NIH's contracting procedures by performing a risk assessment. NIH's contracting is subject to the FAR and the HHS Acquisition Regulation (HHSAR). The objectives of this risk assessment are to determine the extent to which NIH contracts for goods and services and whether there are risks in the contracting process that require further OIG review.
(OAS; W-00-08-56033; expected issue date: FY 2009; new start)

University Administrative and Clerical Salaries
We will review administrative and clerical salaries charged to federally sponsored grants and cooperative agreements by colleges and universities. OMB Circular A-21, "Cost Principles for Educational Institutions," section F, paragraph 6.b.2, provides that charging such costs as direct costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support. We will determine whether colleges and universities have appropriately charged these costs.
(OAS; W-00-05-56009; expected issue date: FY 2008; work in progress)

Colleges' and Universities' Compliance With Cost Principles
We will review colleges' and universities' compliance with selected aspects of OMB Circular A-21. We will conduct reviews at selected schools based on the dollar value of Federal grants received and on input from HHS' operating divisions and the offices of the Assistant Secretary for Budget, Technology, and Finance and the Assistant Secretary for Administration and Management.
(OAS; W-00-08-56033; expected issue date: FY 2009; new start)

Securing and Accounting for Controlled Substances
We will review NIH's controls in intramural clinical settings for securing and accounting for highly addictive pharmaceutical products regulated under the Controlled Substances Act of 1970 (Pub. L. No. 91-513). This act classifies certain federally regulated drugs as controlled substances and divides them among five schedules based on their medical use and potential for abuse and addiction. Our review will focus on Schedule II controlled substances, which have the highest potential for abuse among controlled substances with accepted medical uses, including narcotics such as Percodan and Demerol and stimulants such as Ritalin. Establishments that store and dispense Schedule II controlled substances must register with DEA and comply with Federal regulations at 21 CFR § 1304.04, which specify requirements for the security, inventory, and transaction recordkeeping for such substances. We will determine whether NIH has complied with these requirements.
(OAS; W-00-08-56020; expected issue date: FY 2009; new start)

Handling of Allegations of Ethical Misconduct Related to Conflicts of Interest
We will review NIH's handling of allegations of employee ethical misconduct related to conflicts of interest. Under 5 CFR § 2638, Federal departments and agencies carry out ethics programs which include reviewing financial disclosure reports and outside activity requests filed by employees. This review helps ensure that agency employees do not participate in official matters with which they have conflicts of interest, pursuant to 18 U.S.C. § 208 and 5 CFR § 2635. A 2005 OIG report recommended that NIH improve the quality and amount of

information that employees provide to request approval to engage in outside activities and address the inadequacies in the review process for outside activities. We will assess the roles, policies, and procedures used by NIH offices responsible for addressing conflict-of-interest issues: the Office of Management Assessment, the Office of General Counsel Ethics Division satellite office at NIH, the central NIH Ethics Office within the Office of the Director, and the ethics functions within NIH's various Institutes and Centers.
(OEI; 03-07-00220; expected issue date: FY 2008; work in progress)

Monitoring of Extramural Conflicts of Interest

We will review NIH's monitoring of extramural grantees for potential conflicts of interest. Under 42 CFR §§ 50.604(a) and (g)(1), institutions must certify that they maintain a "written, enforced policy" on conflicting interests. Pursuant to 42 CFR § 50.604(g)(2), institutions must also report to NIH the existence of any conflicting interests and ensure that the interests have been "managed, reduced or eliminated." Conflicts of interest in the scientific community pose serious risks to clinical trial subjects and consumers, because a risk of bias can affect the quality of treatment decisions. We will focus on financial conflicts of interest that grantee institutions report to NIH, as well as the extent to which NIH oversees grantees' monitoring and management of potential financial conflicts of interest.
(OEI; 03-06-00460; expected issue date: FY 2008; work in progress)

National Cancer Institute Monitoring of Research Grants

We will evaluate the extent to which the National Cancer Institute (NCI) monitors its research project grants. We will review grant files to determine whether grantees are complying with the uniform administrative requirements in Federal regulations at 45 CFR § 74. We will also review NCI's enforcement of those grant rules and any grant-monitoring requirements in HHS Grants Policy Directives established by the HHS Office of Grants and as further implemented by the "Awarding Agency Grants Administration Manual" (e.g., 1.04.104 and 3.06.106) and NIH and NCI policies and procedures established in the NIH Grants Policy Statement. In FY 2005, an estimated 54 percent of NIH's $28.8 billion budget was disbursed to more than 39,000 research program grants. NCI is the largest of the Institutes and Centers, with over $3.1 billion in research project grants in FY 2005. We will evaluate NCI's compliance with grants-monitoring requirements, including the extent to which NCI evaluates required reports, initiates actions in response to these evaluations, and ensures grantee responsiveness to action requests to comply with regulatory requirements and grant terms and conditions.
(OEI; 07-07-00120; expected issue date: FY 2008; work in progress)

Use of Data and Safety Monitoring Boards in Clinical Trials

We will review the extent to which Data and Safety Monitoring Boards (DSMB) in clinical trials. A DSMB is a group of individuals with pertinent expertise that regularly reviews accumulated data from one or more ongoing clinical trials to ensure the safety of participants in the trials and the validity and integrity of the scientific data generated. The NIH Policy for Data and Safety Monitoring, set forth in June 1998, requires that all NIH-funded clinical trials establish data and safety monitoring plans. A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial. This requirement sets minimum responsibilities that sponsoring Institutes and Centers must meet to

ensure and oversee data and safety monitoring. We will determine how and to what extent NIH is ensuring that grantees comply with NIH policy for DSMBs in multisite clinical trials.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Substance Abuse and Mental Health Services Administration

Implementation of the Access to Recovery Grant Program

We will review how States have implemented the Access to Recovery Program, including an assessment of the operational and program integrity controls currently in place. The Access to Recovery Program, 42 U.S.C. §§ 290aa(d)(5) and 290bb-2, are competitive grants that enable States and tribal organizations to offer vouchers that pay for a range of community-based services to people seeking drug and alcohol treatment. The President's FY 2008 budget requested $98 million to fund grants to expand access to treatment and recovery services. We will assess how States and tribal organizations have met grantee accountability requirements and how SAMHSA has managed these grants. In addition to the relevant statutory and regulatory requirements and the terms and conditions of the grant awards, we also will use the HHS "Awarding Agency Grants Administration Manual," as well as SAMHSA's policy issuances, to identify criteria for our review of grants.
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

Cross-Cutting Public Health Activities

Use of Bioterrorism Emergency Preparedness Grants in Selected Gulf Coast States

We will review the use of HHS bioterrorism emergency preparedness grant funding in the Gulf Coast States. The bioterrorism program is authorized under sections 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2 of the Public Health Service Act. We will determine whether grants awarded annually by CDC and HRSA were used in accordance with program requirements for approved purposes and whether items funded by these grants were effective in hurricane response and recovery efforts. Reviews will be performed in Florida, Alabama, Louisiana, Texas, and Mississippi.
(OAS; W-00-07-58201; various reviews; expected issue date: FY 2008; work in progress)

Effectiveness of Agency for Healthcare Research and Quality Bioterrrorism Preparedness Resources

We will evaluate the extent to which the AHRQ bioterrorism preparedness planning resources are utilized by grantees of the Department's National Bioterrorism Hospital Preparedness Program and the CDC Public Health Emergency Preparedness Cooperative Agreements. AHRQ has researched and produced a suite of community planning guides and models regarding provision of medical care during a mass casualty event. Although there are no specific requirements for grantees to utilize these models, AHRQ has worked collaboratively with the Office of the ASPR to develop the guides and disseminate them within the preparedness community. Anecdotal evidence suggests that these guides and models have aided grantees in their preparedness efforts. We will evaluate the impact that these guides and models have had

within the Department's preparedness grantee community, the processes used to fund and develop these products, the extent to which grantees have found them useful in preparedness planning and exercises, and how AHRQ can improve the usefulness and accessibility of future bioterrorism research products.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Testing of Departmental Continuity of Operations Plans Within Regional Offices

We will review HHS's regional office continuity of operations (COOP) plans and their compliance with the Federal Preparedness Circular's (FPC 65) testing, training, and exercising mandates. According to FPC 65, Federal executive branch departments and agencies are responsible for developing contingency plans and programs for COOP. We will also determine the extent to which regional offices in the Department have tested their COOP plans and examine their plans' communication structures.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Emergency System for Advance Registration and Credentialing of Health Professionals: Ability To Use Health Volunteers in Multistate or National Emergencies

We will review the extent to which State and Territory Emergency Systems for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) have been implemented and integrated within States and territories. Congress recognized the need to make optimum use of volunteer health personnel in an emergency and authorized the development of an ESAR-VHP (Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, section 107). The program was initially administered by HRSA; however, under the Pandemic and All-Hazards Preparedness Act (Pub. L. No. 109-417) it was transferred to the Office of the Assistant Secretary for Preparedness and Response (ASPR) in April 2007. In addition to transferring the program, the statute specifies that, beginning in FY 2009, States and territories will be eligible for funding only if they participate in the ESAR-VHP.

In October 2006, HRSA issued the ESAR-VHP Draft Compliance Requirement, identifying capabilities and procedures that ESAR-VHP programs must have in place by 2007 to ensure effective management and interjurisdictional movement of volunteer health personnel in emergencies. We will review ESAR-VHP electronic systems, their operational capabilities, and their evaluation and reporting capabilities to determine whether they comply with the Department's requirements. We will also review other State and territory systems used to track volunteer health professionals to identify the extent to which those systems integrate with the ESAR-VHP system and determine States' and territories' progress in implementing the ESAR-VHP system.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Office of Human Research Protections Compliance Reviews

We will review the OHRP oversight of human subject protections. Section 4-91 of the Public Health Service Act (42 U.S.C. § 289(a)) authorizes OHRP to establish an oversight system for research sponsored by the Department to ensure that the rights of research subjects are protected. Regulations pertaining to OHRP oversight are located at 45 CFR Part 46. We will

assess OHRP's process for conducting compliance reviews of external clinical investigators and institutional review boards (IRB), as well as clinical investigators and IRBs associated with Department-sponsored clinical trials. We will also determine whether OHRP faces any barriers in conducting compliance reviews.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Legal Counsel

In addition to providing day-to-day internal legal advice and representation to OIG, OCIG coordinates OIG's role in the resolution of civil and administrative fraud cases and promotes compliance measures by recipients of Department grant funding. In the public health area, OCIG will continue to work closely with OIG investigators and auditors and with prosecutors from the Department of Justice (DOJ) to develop and pursue False Claims Act cases against institutions that receive grant funds from NIH and other public health service agencies. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases.

Investigations

Investigations of Violations of Select Agent Requirements

OIG continues to receive requests for information and investigations of alleged terrorist and bioterrorist activities relating to select agents. On March 18, 2005, HHS issued a final rule on Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73), which applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. The rule authorizes OIG to conduct investigations and to impose civil monetary penalties against individuals or entities for violations of these select agents and toxins requirements. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of the statute governing the registration, storage, and transfer of select agents and toxins.

Human Service Programs

Child Support

Undistributable Child Support Collections

We will review undistributable child support collections and program income reported by States. In accordance with Federal regulations at 45 CFR § 304.50, undistributable child support collections that are retained by a State must be counted as program income and used to reduce Title IV-D program expenditures. Historically, States have had difficulty in distributing sizable amounts of support payments because certain identifiers, such as custodial parents' addresses,

were not current or the case numbers were omitted from collection receipts. Prior OIG reviews have identified several States that did not recognize or report as program income undistributable child support collections or interest earned on these balances. We will 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.
(OAS; W-00-07-23080; W-00-08-23080; various reviews; expected issue dates: FYs 2008 and 2009; work in progress and new start)

Child Support Incentive Payments

We will review child support incentive payments made to States. States are eligible to receive child support incentive payments after meeting certain performance measures. Section 458(f) of the Social Security Act requires a State receiving child support incentive payments to reinvest the payments into its Child Support Enforcement (CSE) Program or use the funds for other approved activities that will improve its CSE. We will determine whether States properly used child support incentive payments.
(OAS; W-00-08-23150; expected issue date: FY 2009; new start)

Interest Earned on Child Support Enforcement Funds

We will review interest earned by local government entities receiving CSE funds. Pursuant to Federal regulations at 45 CFR § 92.21(i), interest earned on advances, except for interest earned on advances of funds exempt under the Intergovernmental Cooperation Act (Pub. L. No. 90-577), must be remitted to the Federal Government at least quarterly. A prior OIG review found that Federal funds that a county received for administering the CSE program were commingled with other county funds and that the interest earned on the commingled funds was considered general-purpose revenue and used to support countywide operations. We will determine whether the Federal Government received credit for the income received on invested funds and whether Federal program funds were drawn down and disbursed before the funds were needed.
(OAS; W-00-08-23151; expected issue date: FY 2009; new start)

Use of Financial Institution Data Match

We will review the effectiveness of States' use of the Financial Institution Data Match (FIDM) to collect payment of arrears and ongoing support obligations. Section 466(a)(17) of the Social Security Act requires States to establish procedures under which State child support enforcement agencies enter into agreements with financial institutions doing business in the State for purposes of securing information leading to the enforcement of child support orders. Since its inception in 1999, FIDM has enabled the 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 the National Child Support Enforcement FYs 2005-2009 Strategic Plan. Payment of arrears through FIDM may also reestablish contact between States and noncustodial parents and result in increases in ongoing support. We will also assess factors inhibiting FIDM's effectiveness in increasing collections and reducing arrears.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Federal Employer Collaboration With Child Support State Disbursement Units

We will review Federal employer collaboration with child support State Disbursement Units. Section 454B of the Social Security Act requires States to centralize the collection and disbursement of child support payments. In a 2000 OIG review of State Disbursement Units, managers reported that payments from Federal agencies were often labeled poorly or delivered incorrectly, resulting in delayed disbursement to families. OIG recommended that the Office of Child Support Enforcement (OCSE) work with Federal employers to improve payment practices. This study will determine whether problems have been corrected. We will determine whether Federal payers label and submit payments accurately, identify barriers to proper labeling and submission, and assess the impact on agencies and families of any deficient practices by Federal payers.

(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Child Welfare

Foster Care and Adoption Assistance Training and Administrative Costs

We will review foster care and adoption assistance training and other administrative costs claimed under Title IV-E. Sections 474(a)(3)(A)-(B) and 474(a)(3)(E) of the Social Security Act provide for Federal reimbursement of training and administrative costs, respectively. Title IV-E training and other administrative costs have increased dramatically in relation to maintenance payments in recent years. Prior OIG reviews have found that unallowable costs were claimed, costs were improperly allocated, and/or costs were otherwise unsupported. We will determine whether current and retroactive claims were allowable and reasonable and were supported in accordance with laws and regulations and the State's cost allocation plan.

(OAS; W-00-00-24100; various reviews; expected issue date: FYs 2008 and 2009; work in progress and new start)

Foster Care Per Diem Rates in Excess of $300

We will review foster care maintenance payments claimed under Title IV-E on behalf of children for whom the per diem rate exceeded $300. Section 475(4)(A) of the Social Security Act defines foster care maintenance payments as payments to cover the cost of food, clothing, shelter, daily supervision, school supplies, a child's personal incidentals, liability insurance with respect to a child, and reasonable travel to the child's home for visitation. A prior OIG review found that some services included in per diem rates in excess of $300 were not eligible for Title IV-E foster care maintenance payments. We will determine whether State agencies claimed Title IV-E maintenance and associated administrative costs in accordance with Federal requirements.

(OAS; W-00-08-24101; expected issue date: FY 2009; new start)

Costs Billed by Child-Placing Agencies

We will review child-placing agencies' maintenance payments and administrative costs claimed under Title IV-E. Under Section 475(4)(A) of the Social Security Act, foster care maintenance payments cover a child's basic needs, such as food, clothing, shelter, and personal incidentals. In the case of institutional care, maintenance costs also include the costs of administration and operation of the institution. Preliminary work in one State showed that even though the

administrative costs for child-placing agencies were included in the maintenance payments, these costs were also being billed to the State as additional administrative costs. We will determine

whether and to what extent the State is providing duplicate reimbursement for the administrative costs of child-placing agencies.
(OAS; W-00-08-24102; expected issue date: FY 2009; new start)

Group Home and Foster Family Agency Rate Classification

We will review a State's foster care payment rates made for group homes and/or foster family agency treatment programs. Federal regulations at 45 CFR §§ 1356.60(a)(1)(i) and 1356.71(d)(2) provide that Federal financial participation is available for allowable costs in expenditures for foster care maintenance payments and that the States must review the amount of the payments to ensure the continued appropriateness of the amounts. The State's Welfare and Institution Code provides that rates be established by classifying each group home program and applying the standardized schedule of rates. Pursuant to this code, the foster care payment amount correlates with 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. We will determine whether foster care payment rates made for group homes and/or foster family agency treatment programs are accurate.
(OAS; W-00-08-24103; expected issue date: FY 2009; new start)

Adoption Assistance Subsidies

We will review claims for Federal reimbursement of adoption assistance subsidies to determine compliance with eligibility requirements. Sections 473(a) and (c) of the Social Security Act establish adoption assistance 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. A previous OIG review of a State's adoption assistance subsidies identified payments to families that did not meet eligibility requirements.
(OAS; W-00-06-24009; W-00-08-24009; A-01-06-02506, expected issued dates: FYs 2008 and 2009; work in progress and new start)

Accountability Over Child Welfare Funds

We will review one State's accountability over Title IV-B funds for child welfare services. Title IV-B of the Social Security Act authorizes funds to States to provide a wide array of services to prevent the occurrence of abuse, neglect, and foster care placements. Subpart 2 of Title IV-B, Promoting Safe and Stable Families, funds similar types of services but is more prescriptive as to how States can spend the funds. At the request of ACF, we will review the State agency's cash management, internal controls, use of Title IV-B funds, and compliance with requirements of Title IV-B and OMB Circular A-87.
(OAS; W-00-08-24105; expected issue date: FY 2009; new start)

Foster Care Claims for the Placement of Delinquent Children

We will review foster care maintenance costs claimed by several States under Title IV-E for the placement of delinquent children. Under section 475(4)(A) of the Social Security Act,

maintenance costs include room and board payments to licensed foster parents, group homes, and residential childcare facilities for children who meet Title IV-E program requirements. A prior OIG review found claims submitted for ineligible children, services not provided, and ineligible services. We will determine whether foster care maintenance costs under Title IV-E for the placement of delinquent children were claimed in compliance with applicable Federal requirements.
(OAS; W-00-06-25023; expected issue date: FY 2008; work in progress)

Foster Care Preplacement/Candidacy Costs

We will review State claims for foster care candidate costs. Section 472(i)(2) of the Social Security Act allows States to claim Title IV-E administrative costs for allowable preplacement activities on behalf of foster care candidates. A candidate for foster care is a child who is at serious risk of removal from his/her home. Under 45 CFR § 1356.60(c)(2), administrative costs cover staff activities such as case management and supervision of children placed in foster care and children considered to be Title IV-E candidates. In several States, we will determine whether costs for candidates were properly claimed.
(OAS; W-00-06-24002; A-03-06-00575; expected issue date: FY 2008; work in progress)

Foster Children Over 19 Years Old

We will review foster care maintenance payments made on behalf of children over the age of 19. Children over 19 years old are ineligible for foster care maintenance payments. Sections 406 and 472 of the Social Security Act limit Title IV-E eligibility to children under age 18 or over age 18, but under age 19 if full-time students (Title IV-A State plan option). The Adoption and Foster Care Analysis and Reporting System database, maintained by ACF, listed more than 9,900 of 513,000 children who were over 19 years old as of September 30, 2005. We will determine whether foster care maintenance payments were made on behalf of children over the age of 19.
(OAS; W-00-06-24013; A-03-06-00575; expected issue date: FY 2008; work in progress)

Family Assistance

Temporary Assistance for Needy Families Improper Payments

We will review Temporary Assistance for Needy Families (TANF) basic assistance payments to determine the extent to which State agencies made payments to individuals who did not meet Federal and State eligibility requirements. The IPIA of 2002, (Pub. L. No. 107-300) requires Federal agencies to estimate improper payments. The Department and OMB have requested that OIG review State TANF programs to establish a statistically valid estimate of improper payments. We will review TANF basic assistance expenditures for a 1-year period ending March 31, 2007, in eight States. Our objective is to use the results to establish an improper payment rate for each State reviewed and a nationwide TANF improper payment rate.
(OAS; W-00-08-20016; expected issue date: FY 2008; work in progress)

Head Start/Child Care

Head Start Matching Costs

We will review Head Start matching claims to determine whether grantees met the 20-percent match required for Federal Head Start funding. Regional ACF officials have indicated to us that grantees might not be meeting Head Start matching requirements. Federal regulations at 45 CFR §§ 74.23 and 1301.20 require the matching share of 20 percent to be from non-Federal sources which may be in the form of cash or in-kind contributions. We will also identify any challenges facing grantees in meeting the matching requirement.
(OAS; W-00-08-24014; expected issue date: FY 2008; new start)

Head Start Agencies' Compliance With Administrative Cost Limit

We will review costs supporting payments for administrative and direct program costs to Head Start agencies. Head Start agencies must comply with a 15-percent administrative cost limit imposed by Federal regulations at 45 CFR § 1301.32. We will determine whether agency administrative costs exceeded 15 percent of total approved costs to determine whether reimbursement was appropriate. Past OIG reviews have indicated that some agencies may be reporting certain administrative costs as direct program expenses, thereby circumventing this requirement/limitation.
(OAS; W-00-08-24015; expected issue date: FY 2009; new start)

Head Start Agencies' Use of Grant Funds

We will review the use of funds received by Head Start agencies. Recipients of Head Start funds are required to ensure that these funds are used for authorized purposes, as required by 45 CFR § 74.21(b)(3). We will determine whether funds were properly used for the purposes outlined in Federal award letters and approved Head Start agency grant applications and program requirements.
(OAS; W-00-08-24016; expected issue date: FY 2009; new start)

Resolution of Head Start Audit Findings and Repayment

We will review audit resolution for three areas within Head Start and ACF's compliance with departmental and program requirements contained in the HHS "Grants Administration Manual," Chapter 1-105, and cash management requirements pursuant to Federal regulations at 45 CFR § 74. Past reviews have indicated that ACF may not be consistent in its enforcement of resolution requirements and agency policies. We will determine whether ACF has required Head Start agencies to fully repay disallowed costs by an appropriate repayment method and appropriately resolved unsupported costs.
(OAS; W-00-8-24017; expected issue date: FY 2009; new start)

Accuracy of Head Start's Program Review Instrument for Systems Monitoring Process

We will review Head Start's Program Review Instrument for Systems Monitoring (PRISM). PRISM monitoring requirements are found in the Head Start Act, as amended by Pub. L. No. 103-252. Triennial reviews enable the Head Start Bureau to assess grantee compliance with grant requirements; however, there is no procedure to independently and systematically verify the quality of the review or whether the team of reviewers followed the review framework. In

2005, the Government Accountability Office (GAO) found that that some reviewers may not follow PRISM guidelines and, as a result, some grantees are not reviewed as thoroughly as others. We will determine the extent to which the Head Start program's PRISM process accurately identifies grantee noncompliance and the extent to which Head Start grantees have addressed any noncompliance noted in their PRISM reviews.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Licensing, Health, and Safety Monitoring of Childcare Facilities

We will review compliance with licensing, health, and safety standards at selected childcare facilities that have received Federal funding from the Child Care and Development Fund Block Grant. Federal regulations at 45 CFR § 98.15(b) require States to certify that they have licensing and health and safety requirements applicable to childcare services. States must also provide a detailed description of these requirements and the way in which they are enforced. Previous OIG work has 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. We will determine the extent to which States are able to demonstrate that childcare facilities receiving Federal funding are in compliance with applicable requirements.
(OEI; 00-00-00000; expected issue date: FY 2008; new start)

Administration on Aging

Aging Programs in One State

We will review one State's aging program grants. HHS, pursuant to the Older Americans Act of 1965, Title III (Pub. L. No. 89-73), awards funds to States to develop systems for support services through designated State agencies. These grants also seek to maximize support to enable senior citizens to remain in their homes and communities and to support nutrition services. Non-Federal audits have identified problems in accounting for funds, unspent funds, and inadequately documented matching contributions. We will determine whether aging program grants in a State complied with Federal requirements.
(OAS; W-00-08-58202; expected issue date: FY 2009; new start)

Investigations

Investigations Under the Child Support Enforcement Task Force Model

Project Save Our Children is a coordinated effort to identify, investigate, and prosecute individuals who fail to meet their court-ordered support obligations. This project brings together OIG, the U.S. Marshals Service, DOJ, State and local law enforcement, local prosecutors, State child support agencies, and other interested parties to enforce Federal and State criminal child support statutes. For FY 2006, OIG reported, as part of Project Save Our Children, 97 criminal convictions and approximately $5.7 million in court-ordered fines, penalties, and restitution. In FY 2008, we plan to continue our efforts to encourage and coordinate the efforts in the States, particularly in States that have not pursued prosecutions of nonsupport cases.

Departmentwide Issues

Financial Statement Audits

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

Audits of Fiscal Years 2007 and 2008 Financial Statements

We will review the independent auditor's workpapers to determine whether financial statement audits of HHS and its components were conducted in accordance with applicable laws and regulations. The purpose of a financial statement audit is to determine whether the financial statements present fairly, in all material respects, the financial position of the audited entity for the specified time period. The audited consolidated HHS FY 2007 financial statements are due to OMB by November 15, 2007; for FY 2008, they are due November 15, 2008.

The following FY 2007 financial statement audits will be completed and reports will be issued during FY 2008:

- Consolidated HHS – This audit incorporates all operating divisions, including those that will receive separate audit reports (listed below). *(OAS; W-00-07-40009; A-17-07-00001)*

- CMS *(OAS; W-00-07-40008; A-17-07-02007)*

- HHS Service and Supply Fund *(OAS; W-00-07-40027; A-17-06-00004)*

- NIH Service and Supply Fund *(OAS; W-00-07-40013; A-17-07-00005)*

The following FY 2008 financial statement audits will be completed and reports will be issued during FY 2009:

- Consolidated HHS – This audit will incorporate all operating divisions, including those that will receive separate audit reports (listed below). *(OAS; W-00-08-4009)*

- CMS *(OAS; W-00-08-40008)*

- HHS Service and Supply Fund *(OAS; W-00-08-40027)*

- NIH Service and Supply Fund *(OAS; W-00-08-40013)*

Fiscal Year 2008 Statement on Auditing Standards 70 Examinations

We will review the independent auditor's workpapers to determine whether the Statement on Auditing Standards (SAS) 70 examinations of HHS's service organizations were conducted in accordance with applicable laws and regulations. An SAS 70 examination reports on the controls of a service organization that may be relevant to the user organization's internal control structures. The following SAS 70 examinations of HHS service organizations will support FY 2008 financial statement audits and will be issued during FY 2008:

- Center for Information Technology (NIH Computer Center) *(OAS; W-00-08-40012)*
- Program Support Center (PSC) and Major Administrative Support Services
    - Payment Management System *(OAS; W-00-08-40012)*
    - Division of Financial Operations *(OAS; W-00-08-40012)*
    - Enterprise Support Service *(OAS; W-00-08-40012)*

Fiscal Years 2007 and 2008 Financial-Related Reviews

The purpose of the financial-related reviews is to fulfill requirements in OMB Bulletin No. 06-03, "Audit Requirements for Federal Financial Statements," sections 11 and 13.

FY 2007 financial-related reviews:

- Closing-Package Audit Reports for the Government-wide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports. *(OAS; W-00-07-40009; A-17-07-00006)*
- Intragovernmental Agreed-Upon Procedures for the Closing Package. These procedures are intended to assist with accounting for and eliminating intragovernmental activity and balances in the preparation of governmentwide financial statements and reports. *(OAS; W-00-07-40009; A-17-07-00007)*

FY 2008 financial-related reviews:

- Closing-Package Audit Reports for the Government-wide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports. *(OAS; W-00-08-40009)*
- Intragovernmental Agreed-Upon Procedures for the Closing Package. These procedures are intended to assist with accounting for and eliminating intragovernmental activity and balances in the preparation of governmentwide financial statements and reports. *(OAS; W-00-08-40009)*
- Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the DoD OIG in performing the

OMB Bulletin 06-03, "Audit Requirements for Federal Financial Statements," section 11, Agreed-Upon Procedures. *(OAS; W-00-08-40009)*

Other Financial Accounting Reviews

Expired Appropriations

We will determine whether HHS should retain the expired appropriations on its financial statements for the mandatory 5-year period. In accordance with 31 U.S.C. §§ 1551-1555, HHS is required to retain the expired appropriations on its financial statements for 5 years, after which any remaining balances would be returned to Treasury. New legislation would need to be enacted to allow HHS to return the funds to Treasury in less than 5 years.
(OAS; W-00-08-40030; expected issue date: FY 2008; new start)

Accounting for Federal Emergency Management Agency Mission Assignment Funds

We will review whether HHS appropriately accounted for Federal Emergency Management Agency (FEMA) mission assignment funds for Gulf Coast hurricane activities. As of January 3, 2006, the spending authority for HHS FEMA requested mission assignments totaled $272.8 million. We will determine whether the Department followed the HHS "Departmental Accounting Manual" when accounting for Gulf Coast-related costs that were to be reimbursed by FEMA and whether funds not expended were returned to the Department of Homeland Security, FEMA's parent organization.
(OAS; W-00-08-40031; expected issue date: FY 2009; new start)

Annual Accounting of Drug Control Funds

We will review HHS agencies' compliance with the requirement at 21 U.S.C. § 1704 that agencies expending funds on National Drug Control Program activities submit to the Office of National Drug Control Policy (ONDCP) an annual accounting of the expenditure of drug control funds. ONDCP policy also requires that an agency submit with its annual accounting an "authentication" by the agency's OIG, in which OIG expresses a conclusion on the reliability of the agency's assertions in its accounting. We will make this authentication with respect to HHS's FY 2007 annual accounting.
(OAS; W-08-40032; expected issue date: FY 2008; new start)

Automated Information Systems

Information System Security Audits

We will review the reliability of the Information System Security Program at FDA and PSC. The Department and its components are responsible for administering and implementing this security program in compliance with the FISMA and directives issued by 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-00-08-42020; expected issue date: FY 2008; new start)

Federal Information Security Management Act of 2002 and Critical Infrastructure Protection

We will review various operating divisions' compliance with the FISMA and critical infrastructure protection requirements for FY 2007. The FISMA, and OMB Circular A-130, "Management of Federal Information Resources," 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.

(OAS; W-00-08-42010; various reviews; expected issue date: FY 2008; new start)

Payment Management System Controls

We will review Payment Management System (PMS) controls. This will involve documenting and evaluating the existence and reliability of information systems controls over the electronic funds transfer function of PMS, which is administered by HHS's PSC. As the largest grant payment and cash management system in the Federal Government, PMS disburses more than $200 billion of the more than $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 PMS as one of the Department's most important national-level assets.

(OAS; W-00-08-42011; expected issue date: FY 2009; new start)

Grants and Contracts

Open and Inactive Grants in the Payment Management System

We will review open and inactive grants at HHS agencies to determine whether the agencies should close out more than 32,000 open and inactive grants for which the net obligation balances total $2.6 billion. HHS's PMS charges agencies a fee to maintain open grants. HHS Grants Policy Directive 4.02 states that HHS agencies should close their grants within 180 days after the end of the grant periods consistent with grant management requirements in 45 CFR Parts 74 and 92. We will be issuing separate reports for ACF, HRSA, and CDC.

(OAS; W-00-07-40023; A-02-07-02008; A-02-07-02000; expected issue date: FY 2008; work in progress)

Non-Federal Audits

We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations." State, local, and Indian tribal governments; colleges and universities; and nonprofit organizations receiving Federal awards are required to have annual organizationwide audits of all Federal money they receive. 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 upfront 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, designates which Federal agency has lead responsibility for audit of all Federal funds the entity receives. HHS OIG has audit cognizance over all State governments and most major research colleges and universities. Agreements have been reached among many OIG offices to reimburse the cognizant agencies for audits performed at their request or the request of their program offices. *(OAS; W-00-08-50012; various reviews; expected issue date: FY 2008; new start)*

Requested Audit Services

Throughout the year, Congress, the Department, and other Federal organizations request that we perform a variety of audit services. These services include:

- recipient capability audits,
- contract and grant closeouts,
- indirect cost audits,
- bid proposal audits, and
- other reviews designed 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.

Other Issues

Use of Discounted Airfares in the Office of the Secretary

We will review OS's use of discounted airfares during FY 2006. Under a General Services Administration (GSA) agreement negotiated with airlines, Government employees traveling on Government business may be eligible for a discounted airfare, known as a City Pair with Capacity Limits. Preliminary indications are that HHS travelers have not routinely obtained discounted airfares. This review will determine the frequency with which OS's travelers obtain discount airfares and whether that frequency could be increased. The review will also examine how Govtrip, the user interface for booking travel, affects user choices.
(OAS; W-00-07-58120; A-03-07-00500; expected issue date: FY 2008; work in progress)

Travel Cards

We will review HHS's compliance with requirements for the use of travel cards. Such cards are to be used for official Government travel. OMB Circular A-123, Appendix B, sets forth Federal agency requirements for administering charge card programs, and Chapter 9 of the "HHS Travel Manual" governs employees' use the travel card. GAO conducted a review of the Federal Government travel card program using FY 2001 data and found cases of unauthorized use, including personal purchases. It also found that HHS's process for monitoring the travel card program focused primarily on identifying and addressing existing delinquencies rather than preventing or detecting unauthorized use. We will determine whether HHS has an effective process for monitoring the card program to minimize delinquency rates, writeoffs, and unauthorized use of the card and determine the extent of travel cards purchases that do not comply with Departmental guidance.
(OEI; 07-07-00480; expected issue date: FY 2008; work in progress)

Purchase Cards

We will review the use of HHS Purchase Cards by one HHS operating division. To reduce the burden in procuring items under the simplified acquisition threshold, GSA's Federal Supply Service awarded a contract in February 1998 for Government-wide Commercial Purchase Card Services to four banks under the GSA SmartPay Program. The use of the purchase credit card is a simplified acquisition mechanism that is subject to the simplified acquisition provisions established in the FAR and the HHSAR. The purchase card is designed to reduce procurement lead time and the cost of processing purchase orders, streamline payment procedures and reduce paperwork, improve cash management practices such as forecasting and consolidating payments, and provide procedural checks and feedback to improve management control and decisionmaking. The objectives of these reviews are to detect and deter improper uses of the purchase cards.
(OAS; W-00-08-58121; expected issue date: FY 2009; new start)

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