

Office of
Inspector
General

**Work
Plan**

FISCAL YEAR
2010



Department of Health and Human Services
Office of Inspector General

A Message From the Office of Inspector General

We are pleased to present the Office of Inspector General (OIG) Work Plan for fiscal year (FY) 2010. This publication describes activities that we plan to initiate or continue with respect to the programs and operations of the Department of Health and Human Services (HHS) in the next year. To place the Work Plan in context, we describe below our mission and activities, organization, program integrity resources, work-planning process, and related matters.

Mission and Activities

OIG's operational mission is to protect program integrity and the well-being of program beneficiaries by detecting and preventing waste, fraud, and abuse; identifying opportunities to improve program economy, efficiency, and effectiveness; and holding accountable those who do not meet program requirements or who violate Federal laws. We carry out our mission by conducting audits, evaluations, and investigations; providing guidance to industry; and, when appropriate, imposing civil monetary penalties (CMP), assessments, and administrative sanctions. We work closely with HHS and its Operating and Staff Divisions; the Department of Justice (DOJ); and other agencies in the executive branch, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds.

Organization

OIG is organized into six components through which we carry out our mission and support functions: the Office of Audit Services (OAS), Office of Evaluation and Inspections (OEI), Office of Investigations (OI), Office of Counsel to the Inspector General (OCIG), Office of Management and Policy (OMP), and Immediate Office of the Inspector General (IO). OIG is headquartered in Washington, DC, and has a nationwide network of approximately 90 regional and field offices with almost 80 percent of our staff working outside Washington, DC.

The following bullets describe the functions of the components that carry out our audit, evaluation, investigation, enforcement, and compliance activities.

- OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS's programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.
- OEI conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of HHS programs. OEI reports also present practical recommendations for improving program operations.

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- OI conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in almost every state and the District of Columbia, OI actively coordinates with DOJ and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, or CMPs.
 - OCIG provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Program Integrity Resources

OIG's program integrity resources derive from multiple sources, including a single discretionary appropriation¹ and multiple statutory funding streams provided through other legislation. On average, the discretionary appropriation represents approximately 20 percent of our total annual funding, while separate statutory funding streams that are mandated for our oversight of Medicare and Medicaid provide approximately 80 percent. Accordingly, our annual budget is devoted largely to oversight of Medicare and Medicaid, consistent with our statutory mandates.

Work Planning Process

At the beginning of each FY, we issue our annual Work Plan, which describes the specific audits and evaluations that we have underway or plan to initiate in the FY ahead with our discretionary and statutorily mandated resources. The Work Plan also provides general focus areas for our investigative, enforcement, and compliance activities.

To develop proposals for specific projects and activities, we undertake a comprehensive work-planning process. We engage our stakeholders to identify the issues of greatest priority and with the greatest potential impact on HHS programs or beneficiaries. In addition, we coordinate with and keep current with the work of other oversight entities. We also stay attuned to the latest developments and events affecting the Nation's health care, public health, and human services programs and beneficiaries.

Work planning is an ongoing and dynamic process, and adjustments are made throughout the year to meet priorities and to anticipate and respond to emerging issues with the resources available. We assess relative risks in the programs for which we have oversight authority to identify the areas most in need of attention, and, accordingly, to set priorities for the sequence and proportion of resources to be allocated. In evaluating specific work plan proposals, we consider a number of factors, including the following:

¹ OIG refers to its annual appropriation, made as part of the overall appropriation for HHS, as its "discretionary appropriation." This is distinguished from the permanent appropriation for the Health Care Fraud and Abuse Control Program (HCFAC) contained in the Social Security Act, § 1817(k), and other funds appropriated by Congress in other legislation for specified purposes.

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- requirements for OIG reviews, as set forth in laws, regulations, or other directives;
 - requests made or concerns raised by Congress, HHS's management, or the Office of Management and Budget (OMB);
 - significant management and performance challenges facing HHS;
 - work performed by partner organizations;
 - management's actions to implement our recommendations from previous reviews; and
 - timeliness.

A Note About This Edition

This edition of the OIG Work Plan, effective as of October 2009, describes ongoing and planned assignments, providing for each assignment the subject, scope of the review, and criteria related to the program being reviewed. It also provides review identification codes and the year in which we expect the report to be issued and indicates whether the work will be in progress at the start of the FY or will be a new start during the year. Typically, a review designated as "work in progress" will result in reports issued in FY 2010, but a review slated to begin in FY 2010 ("new start") could result in FY 2010 or FY 2011 reports, depending upon when the assignments are initiated during the year and the complexity and scope of the examinations.

In this Work Plan, our ongoing and planned reviews are grouped into two major parts:

- "Centers for Medicare & Medicaid Services" (CMS) describes reviews related to Medicare, Medicaid, information systems controls, the Childrens Health Insurance Program, and related investigations and legal counsel to OIG.
- "Public Health and Human Services Programs and Departmentwide Issues" describes reviews related to agencies such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Administration on Aging (AoA), and the Administration for Children and Families (ACF). This part also describes departmentwide issues, such as financial accounting and information systems management.

Our planned reviews related to the American Recovery and Reinvestment Act of 2009 (Recovery Act) are provided in Appendix A of this document.

This edition and prior editions of the Work Plan are available on our Web site at <http://oig.hhs.gov/publications.asp>. If you have questions about this publication, please contact our Office of External Affairs at 202-619-1343.

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

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Note: All acronyms and abbreviations of terms, titles, organizations, and laws used in this document are spelled out in Appendix B.

Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services (CMS), which is the largest operating division of the Department of Health and Human Services (HHS), administers Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

- Medicare, established under Title XVIII of the Social Security Act, 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 (ESRD). In fiscal year (FY) 2008, Medicare served an estimated 45 million enrollees at a cost of more than \$460.9 billion.¹
- Medicaid, established under Title XIX of the Social Security Act, is a joint Federal-State program that supports States' coverage of medical care and other support services for low-income individuals. For FY 2008, Medicaid enrollment was estimated at 48.2 million beneficiaries, and total Federal and State Medicaid costs were approximately \$352 billion, of which the Federal share was \$201.4 billion.
- CHIP, established 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 2008, CHIP served 7.4 million beneficiaries at a total Federal and State cost of \$10 billion, including a Federal share of \$6.9 billion.

The CMS part of the Office of Inspector General (OIG) Work Plan includes brief descriptions of each of these programs, our work in progress, and the reviews we plan to start in FY 2010.

Medicare Program

Medicare, which is the Nation's largest purchaser of health care (and, within that, of managed care), processes over 1 billion fee-for-service claims per year. The Medicare program is funded through the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds and is composed of four parts:

¹ The \$460.9 billion figure represents total outlays for Medicare health care and program administrative overhead (the latter being in the \$6 billion range for FY 2008). Lower Medicare outlay estimates found in budget documents typically subtract particular income items classified as offsetting receipts in the Federal budget, mainly from Part B premiums. Medicare premiums (Parts A, B, and D) go directly into one of two pertinent trust funds.

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- Medicare Part A helps pay for hospital, skilled nursing facility (SNF), home health, and hospice care for the aged and disabled. It is financed through the HI trust fund, which is funded primarily by payroll taxes paid by workers and employers.
 - Medicare Part B helps pay for physician and outpatient hospital services, laboratory tests, medical equipment, and other items and services not covered by Part A. It is financed through the SMI trust fund, which is funded primarily by transfers from the general fund of the U.S. Treasury and by monthly premiums paid by beneficiaries.
 - Medicare Part C, known as Medicare Advantage (MA), provides health care coverage choices for Medicare beneficiaries through private health care companies that contract with Medicare to provide benefits. Part C is funded by both the HI and SMI trust funds.
 - Medicare Part D, the prescription drug benefit program created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), provides subsidized access to drug insurance coverage on a voluntary basis for all beneficiaries and premium and cost-sharing subsidies for low-income enrollees. In general, coverage for this benefit is provided under private prescription drug plans (PDP) that offer only prescription drug coverage or through MA plans that integrate prescription drug coverage with the general health care coverage that they provide to Medicare beneficiaries. Part D is funded through the SMI account.

The size and scope of the Medicare program place it at high risk for payment errors. To ensure both the solvency of the trust funds and beneficiaries' continued access to quality services, correct and appropriate payments must be made for properly rendered services. Our targeted audits and evaluations continue to identify significant improper payments and problems in specific parts of the program. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments.

Medicare Part A and Part B

The original Medicare program consisted of Part A and Part B and reflected a fee-for-service approach to health insurance. For Part A, our ongoing and new reviews in FY 2010 address hospitals, home health agencies (HHA), nursing homes, and hospice care. Other Part A and Part B-related reviews address payments to and services by physicians and other health professionals, followed by durable medical equipment (DME) and supplies, prescription drugs covered by Part B, and additional reviews that relate to contractor operations.

Historically, Medicare contractors that are known as fiscal intermediaries (FI) and carriers have handled Medicare's claims administration activities, with the FIs processing claims for Medicare Parts A and B for certain facilities (including hospitals and SNFs) and the carriers processing claims for Medicare Part B (in particular for physician, laboratory, and other services). CMS also engages functional contractors that perform specific fee-for-service business functions. Pursuant to section 911 of the MMA, CMS is implementing a Medicare contracting reform initiative that will replace FIs and carriers with Medicare Administrative Contractors (MAC)

that will process both Part A and Part B workloads. Additionally, the reform plan includes four specialty MACs that will service suppliers of DME.

Descriptions of our work in progress and planned reviews of Medicare Part A and Part B payments and services follow.

Hospitals

Part A Hospital Capital Payments

We will review Medicare inpatient capital payments. Capital payments reimburse a hospital's expenditures for assets such as equipment and facilities. The basic methodology for determining capital prospective rates is found in the Code of Federal Regulations (CFR) at 42 CFR § 412.308. We will determine whether capital payments to hospitals are appropriate, and we will analyze the appropriateness of the payment level.

(OAS; W-00-08-35300, W-00-09-35300; various reviews; expected issue date: FY 2010; work in progress)

Provider-Based Status for Inpatient and Outpatient Facilities

We will review cost reports of hospitals claiming provider-based status for inpatient and outpatient facilities. Since the beginning of the Medicare program, some hospitals have operated as single entities while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main hospital for Medicare purposes. Pursuant to 42 CFR § 413.65(d), CMS has the authority to grant provider-based status for facilities that are separate from the hospital, both on and off campus, that meet specific requirements. Hospitals with provider-based facilities may receive higher reimbursement when they include the costs of a provider-based entity on their cost reports. Freestanding facilities may also benefit from enhanced disproportionate share hospital (DSH) payments, upper payment limit (UPL) payments, or graduate medical education payments for which they would not normally be eligible. In addition, provider-based status for outpatient clinics may increase coinsurance liability for Medicare beneficiaries. We will determine the appropriateness of the provider-based designation and the potential impact on both the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities.

(OAS; W-00-09-35424; W-00-10-35424; various reviews; expected issue date: FY 2010; work in progress)

Part A Inpatient Prospective Payment System Wage Indexes

We will review hospital and Medicare controls over the accuracy of the hospital wage data used to calculate wage indexes for the Inpatient Prospective Payment System (IPPS). Hospitals must accurately report wage data for CMS to properly calculate the wage index in accordance with the Social Security Act, § 1886(d)(3). Our prior work identified hundreds of millions of dollars in misreported wage data. We will 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 indexes for other provider types.
(OAS; W-00-08-35142; W-00-09-35142; W-00-10-35142; various reviews; expected issue date: FY 2010; work in progress)

Hospital Payments for Nonphysician Outpatient Services Under the Inpatient Prospective Payment System

We will review the appropriateness of payments for nonphysician outpatient services that were provided to beneficiaries shortly before or during Medicare Part A-covered stays at acute care hospitals. Pursuant to the Social Security Act, § 1886(a)(4), and 42 CFR § 412.2, IPPS payments to hospitals for inpatient stays are payment in full for hospitals' operating costs, and hospitals generally receive no additional payments for nonphysician services. In addition, for nonphysician services provided to inpatients by entities under arrangements with the hospitals, the Social Security Act, §§ 1862(a)(14) and 1861(w)(1), as interpreted by CMS in its FY 1983 IPPS final rule, prohibits submissions of any additional claims to Part B. Section 1886(a)(4) prohibits separate payments for outpatient diagnostic services and admission-related nondiagnostic services rendered up to 3 days before the dates of admission. Prior OIG work in this area identified significant numbers of improper claims.

(OAS; W-00-10-35436; various reports; expected issue date: FY 2010; new start)

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 generally reimburses OPOs under 42 CFR § 413.200 in accordance with 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-00-09-35152; W-00-10-35152; various reviews; expected issue date: FY 2010; work in progress)

Inpatient Rehabilitation Facility Submission of Patient Assessment Instruments

We will review Medicare payments for inpatient rehabilitation facilities (IRF) stays in which patient assessments were transmitted to CMS late to determine whether payments were correctly made. The Social Security Act, § 1886(j), established a prospective payment system (PPS) for IRFs. Federal regulations for IRF PPS payments at 42 CFR § 412.614(d)(2) provide that if patient assessments are not encoded and transmitted within defined time limits, payments are to be reduced. We will also review IRF claims to determine whether patient assessments were submitted in accordance with Medicare regulations.

(OAS; W-00-09-35438; W-00-10-35438; various reviews; expected issue date: FY 2010; work in progress and new start)

Critical Access Hospitals

We will review payments made to critical access hospitals (CAH). Pursuant to the Social Security Act, §§ 1814(l)(1) and 1834(g), CAHs are generally paid 101 percent of the reasonable costs of providing covered CAH services. We will determine whether CAHs have met the CAH designation criteria set forth in the Social Security Act, § 1820(c)(2)(B), and conditions

of participation set forth at 42 CFR pt. 485, subpart F, and whether payments made to CAHs were made in accordance with Medicare requirements.

(OAS; W-00-10-35101; various reviews; expected issue date: FY 2010; work in progress)

Medicare Disproportionate Share Payments

We will review Medicare DSH payments made to hospitals. Under the Social Security Act, § 1886(d)(5)(F)(i)(I), Medicare makes additional payments to acute care hospitals that serve a significantly disproportionate number of low-income patients. Medicare DSH payments have been steadily increasing. OIG will determine whether these payments were made in accordance with Medicare methodology set forth in the Social Security Act, § 1886(d)(5)(F)(v-vii). We will also examine the total amounts of uncompensated care costs that hospitals incur.

(OAS; W-00-09-35402; W-00-10-35402; various reviews; expected issue date: FY 2010; work in progress)

Duplicate Graduate Medical Education Payments

We will review provider data from CMS's Intern and Resident Information System (IRIS) to determine whether duplicate graduate medical education payments have been claimed. Medicare pays teaching hospitals for both direct graduate medical education (DGME) and indirect medical education (IME) costs. Federal regulations at 42 CFR §§ 413.78(b) and 412.105(f)(1)(iii) specify that in the calculation of payments for DGME and IME costs, no intern or resident may be counted by the Medicare program as more than one full-time-equivalent (FTE) employee. IRIS's primary purpose is to ensure that no intern or resident is counted as more than one FTE. If duplicate payments were claimed, we will determine which payment was appropriate. We will also assess the effectiveness of IRIS in preventing providers from receiving payments for duplicate graduate medical education costs.

(OAS; W-00-09-35432; W-00-10-35432; various reviews; expected issue date: FY 2010; work in progress)

Interrupted Stays at Inpatient Psychiatric Facilities Payments

We will review inpatient psychiatric facilities' (IPF) claims for Medicare reimbursement in cases of transfers from IPFs to the same or other IPFs. Federal regulations at 42 CFR part 412, subpart N, implemented a PPS for IPFs. Pursuant to 42 CFR § 412.424(d)(2)(v), CMS adjusts the PPS per diem payment based on the number of days that have elapsed since the IPF admitted a patient, the earlier days of a stay receiving larger adjustments than the later days. To ensure that IPFs do not discharge and then readmit patients to obtain per diem payments with higher adjustments, section 412.424(d)(3)(iii) states that interrupted stays in which a patient is discharged and then readmitted to the same or another IPF within 3 days following the discharge will be treated as one continuous stay. We will determine the extent to which coding errors for claims that should have been paid as transfers have resulted in the submission of improper claims by IPFs under the IPF PPS.

(OAS; W-00-09-35192; W-00-10-35192; various reviews; expected issue date: FY 2010; work in progress)

Provider Bad Debts

We will review Medicare bad debts claimed by acute care inpatient hospitals, long term care hospitals (LTCH), 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-00-09-35404; W-00-10-35404; various reviews; expected issue date: FY 2010; work in progress)

Medicare Secondary Payer

We will review Medicare payments for beneficiaries who have other insurance. Pursuant to the Social Security Act, § 1862(b), 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 amounts.

(OAS; W-00-10-35317; various reviews; expected issue date: FY 2010; work in progress)

Reliability of Hospital-Reported Quality Measure Data

We will review hospitals' controls for ensuring the accuracy of data related to quality of care that they submit to CMS for Medicare reimbursement. The Social Security Act, § 1886(b)(3)(B)(vii), requires that hospitals report quality measures for a set of 10 indicators established by the Secretary as of November 1, 2003. Section 501(b) of the MMA established a reduction in payments of 0.4 percent to hospitals that did not report quality measures to CMS. The Social Security Act, § 1886(b)(3)(viii), as added by the Deficit Reduction Act of 2005 (DRA), § 5001(a), expanded this payment reduction to 2 percent effective at the beginning of FY 2007. We will determine whether hospitals have implemented sufficient controls to ensure that their quality measurement data are valid.

(OAS; W-00-10-35438; various reviews; expected issue date: FY 2010; new start)

Hospital Admissions With Conditions Coded Present-on-Admission

We will review Medicare claims to determine the number of inpatient hospital admissions for which certain diagnoses were coded as being present when patients were admitted to the hospitals, referred to as present on admission (POA) and will determine which of the diagnoses were most frequently coded as POA. Pursuant to the Social Security Act, § 1886(d)(4)(D), and CMS Change Request 5679 (Pub. 100-20, One-Time Notification, Transmittal 289), acute care hospitals are required to report on their Medicare claims which diagnoses were present when patients were admitted to hospitals. For certain diagnoses specified by CMS, hospitals receive a lower payment amount if the specified diagnoses were acquired in the hospital. We will also determine which types of facilities are most frequently transferring patients with a POA diagnosis specified by CMS to hospitals and whether specific providers transferred a high number of patients to hospitals with POA diagnoses.

(OAS; W-00-10-35500; various reviews; expected issue date: FY 2010; new start)

Hospital Readmissions

We will review Medicare claims to determine trends in the number of hospital readmission cases. Based on prior OIG work, CMS implemented an edit in 2004 to reject subsequent claims

on behalf of beneficiaries who were readmitted to the same hospital on the same day. Pursuant to CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 3, § 40.2.5, if a same-day readmission occurs for symptoms related to or for evaluation or management of the prior stay's medical condition, the hospital is entitled to only one diagnosis-related group payment and should combine the original and subsequent stays into a single claim. Providers are permitted to override this edit in certain situations. We will test the effectiveness of the edit. We will also determine the extent of oversight of readmission cases. Pursuant to the Social Security Act, § 1154(a)(13), quality improvement organizations are required to review hospital readmission cases to determine whether the hospital services met professional standards of care.

A readmission is defined as a case in which the beneficiary is readmitted to a hospital less than 31 days after being discharged from a hospital.

(OAS; W-00-10-35438; various reviews; expected issue date: FY 2010; new start)

Adverse Events: Various Reviews

The broad term "adverse event" describes harm to a patient as a result of medical care. The terms "never events," or "serious reportable events," refer to a subcategory of adverse events that the National Quality Forum (NQF) deemed "should never occur in a health care setting," such as surgery on the wrong patient. The Tax Relief and Health Care Act of 2006 (TRHCA), Division B, § 203, requires that OIG study serious reportable events and their impact on Medicare beneficiaries and program costs. Including and expanding beyond the NQF list of serious reportable events, we will conduct various reviews of adverse events as follows.

■ Hospitals: National Incidence Among Medicare Beneficiaries

We will review adverse health care events among Medicare beneficiaries in inpatient hospital settings to estimate the national incidence of such events, identify types of adverse events experienced by Medicare beneficiaries in hospital settings, and assess the extent to which serious reportable events and other adverse events were preventable as determined by a panel of physicians with expertise in patient safety.

(OEI; 06-09-00090; expected issue date: FY 2010; work in progress)

■ Hospitals: Methods To Identify Events

We will examine various methods for identifying adverse health care events. The TRHCA specifically mandates that OIG examine methods for identifying such events. This review will examine the following methods to assess their utility: medical record reviews by both nurses and physicians, administrative data analysis using the Agency for Healthcare Research and Quality's (AHRQ) patient safety indicators and present-on-admission indicators, hospital incident reports, and interviews with Medicare beneficiaries or their representatives.

(OEI; 06-08-00221; expected issue date: FY 2010; work in progress)

■ Hospitals: Early Implementation of Medicare's Policy for Hospital-Acquired Conditions

We will review CMS's administrative processes for identifying hospital-acquired conditions and denying higher Medicare reimbursement for related care. We will determine changes in the number of claims with identified hospital-acquired conditions, Medicare reimbursement for such claims resulting from implementing CMS's policies, and the percentage of these claims that otherwise would have resulted in higher Medicare reimbursement.

(OEI; 06-09-00310; expected issue date: FY 2010; work in progress)

■ Hospitals: Responses by Medicare Oversight Entities

We will review responses of State survey and certification agencies, State licensure boards, and Medicare accreditors to adverse events in hospitals. We will identify and analyze potential overlaps, conflicts, and gaps in responses and identify opportunities for Medicare oversight entities to improve the quality of oversight and responses to adverse events.

(OEI; 01-08-00590; expected issue date: FY 2010; work in progress)

■ Public Disclosure of Adverse Event Information

We will review policies and practices of CMS and selected patient safety organizations for disclosing information about adverse health care events as well as associated protections intended to ensure patient privacy. The TRHCA requires that OIG recommend potential processes for public disclosure of adverse events that will ensure patient privacy and allow for root-cause analysis.

(OEI; 06-09-00360; expected issue date: FY 2010; 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 physicians are reimbursed by the Medicare Physician Fee Schedule (MPFS) provided that the conditions for payment for radiology services at 42 CFR §§ 415.102(a) and 415.120 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 2007, Medicare reimbursed physicians approximately \$207 million for imaging interpretations performed in emergency departments. We will determine the appropriateness of payments for diagnostic x rays and interpretations.

(OEI; 07-09-00450; expected issue date: FY 2010; work in progress)

Oversight of Hospitals' Compliance With the Emergency Medical Treatment and Labor Act

We will review CMS's oversight of hospitals' compliance with the Emergency Medical Treatment and Labor Act of 1986 (EMTALA). Pursuant to the Social Security Act, §§ 1866 and 1867, and regulations at 42 CFR § 489.24, hospitals must agree to comply with EMTALA requirements. Hospitals with emergency departments are required to provide medical screening examinations to individuals who come to their emergency departments, regardless of whether the individuals have insurance. CMS is responsible for evaluating EMTALA complaints and referring to State licensing agencies cases that warrant investigation. CMS may terminate facilities' participation in Medicare if investigations, which must include peer review if a medical opinion is required, identify EMTALA violations. A previous OIG review raised concerns about CMS's EMTALA oversight, specifically regarding long delays to investigate complaints and inadequate feedback provided to hospitals on alleged violations. We will identify variations, if any, among regions in the number of EMTALA complaints and cases referred to States, examine CMS's methods for tracking complaints and cases, and determine whether required peer reviews have been conducted prior to CMS's making a determination about whether to terminate noncompliant providers from the Medicare program.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Observation Services During Outpatient Visits

We will review Medicare payments for observation services provided during outpatient visits in hospitals. The Social Security Act, §§ 1832(a) and 1833(t), provides for Part B coverage of hospital outpatient services and reimbursement for such services under the Hospital Outpatient Prospective Payment System (OPPS). CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 4, § 290, provides the billing requirements. We will assess whether and to what extent hospitals' use of observation services affects the care Medicare beneficiaries' receive and their ability to pay out-of-pocket expenses for health care services.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Coding and Documentation Changes Under the Medicare Severity Diagnosis Related Group System

We will review the impact of the October 1, 2007, implementation of the Medicare Severity Diagnosis Related Group (MS-DRG) system. CMS revised its hospital inpatient reimbursement system to improve recognition of severity of illness and resource consumption, as recommended in a March 2005 MedPAC report. As a result, the number of DRGs has increased from 538 to 745. We will examine coding trends and patterns under the new system and determine whether specific MS-DRGs are vulnerable to potential upcoding.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Financial Status of Hospitals in the New Orleans Area

We will review the financial status of hospitals in the New Orleans area in the aftermath of Hurricane Katrina to assess the needs of hospitals and options for policymakers as the area rebuilds its health care infrastructure. HHS has played a central role in Katrina recovery efforts, including the funding of provider stabilization grants and workforce supply grants under the authority of section 6201(a)(4) of the DRA 72 Fed. Reg. 9538 (Mar. 2, 2007). Among other things, these grants were intended to compensate health care providers for wage rates that had not yet been reflected in the Medicare reimbursement system methodologies and to help retain and recruit the licensed health care professionals needed to restore access to health care. We will determine whether the grantees were effective in meeting the objectives.

(OAS; W-00-09-35203; various reviews; expected issue date: FY 2010; work in progress)

Home Health Agencies

Part B Payments for Home Health Beneficiaries

We will review Part B payments for services and medical supplies provided to beneficiaries in home health episodes. Most services and nonroutine medical supplies furnished to Medicare beneficiaries during home health episodes are included in the HHA prospective payments. The Social Security Act, §§ 1832(a)(1) and 1842(b)(6)(F), require that in the case of home health services furnished under a plan of care of an HHA, payment for those services be made to the HHA, including payment for services and supplies provided under arrangements by outside suppliers. We will identify Part B payments made to outside suppliers for services and medical

supplies that are included in the HHA prospective payment and examine the adequacy of controls established to prevent inappropriate Part B payments for services and medical supplies. *(OAS; W-00-09-35418; W-00-10-35418; various reviews; expected issue date: FY 2010; new start)*

Home Health Agencies: Accurately Coding Claims for Medicare Home Health Resource Groups

We will review Medicare claims submitted by HHAs to determine the extent to which the billing codes for home health resource groups (HHRG) are used in determining whether payments to HHAs are accurate and supported by documentation in the medical record. The Social Security Act, § 1895, 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 patterns of miscoded HHRGs.

(OEI; 01-08-00390; expected issue date: FY 2011; work in progress)

Medicare Home Health Payments for Insulin Injections

We will review the incidence of Medicare home health services outlier payments for insulin injections. Insulin is customarily self-injected by a patient or is injected by a family member. However, CMS's "Medicare Benefit Policy Manual," Pub. No. 100-02, ch. 7, § 40.1.2.4.A.2, states that when a patient is either physically or mentally unable to self-inject insulin and no other person is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service under the Medicare home health benefit. The unit of payment under the home health PPS is a national 60-day episode rate with applicable adjustments. The law requires the 60-day episode to include all covered home health services, including medical supplies. When beneficiaries experience an unusually high level of services in a 60-day period, Medicare systems will provide additional "outlier" payments to the episode payment. Outlier payments can result from medically necessary high utilization of home health services. CMS makes outlier payments when the cost of care exceeds a threshold dollar amount. We will also examine billing patterns in geographic areas with high rates of home health visits for insulin injections.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Home Health Agency Outlier Payments

We will review CMS's methodology for calculating outlier payments to HHAs to determine whether the methodology reimburses HHAs as intended for high cost episodes. Pursuant to the Social Security Act, § 1895(b)(5), the HHS Secretary may provide outlier payments for episodes of care that incur unusually high costs. In recent years, outlier payments have significantly increased.

(OAS; W-00-09-35107; W-00-10-35107; various reviews, expected issue date: FY 2010; work in progress)

Home Health Prospective Payment System Controls

We will review compliance with various aspects of the home health PPS, including billings for the appropriate location of the services provided. Pursuant to the Social Security Act, § 1895, the home health PPS was implemented in October 2000. Since that time, total payments to

HHAs have substantially increased from \$8.5 billion in 2000 to \$16.4 billion in 2008. We will also analyze various trends in HHA activities, including the number of claims submitted to Medicare, the number of visits provided to beneficiaries, arrangements with other facilities, and ownership information.

(OAS; W-00-10-35501; various reviews; expected issue date: FY 2010; new start)

Home Health Agency Profitability

We will review cost report data to analyze HHA profitability trends under the home health PPS to determine whether the payment methodology should be adjusted. The Social Security Act, § 1895, added by the Balanced Budget Act of 1997 (BBA), § 4603, requires a PPS for home health services. Since the PPS was implemented in October 2000, HHA expenditures have significantly increased. We will examine various trends, including profitability trends in Medicare and the overall profitability trends for freestanding and hospital-based HHAs.

(OAS; W-00-09-35428; W-00-10-35428; various reviews; expected issue date: FY 2010; work in progress)

Medicare Home Health Payments for Diabetes Self-Management Training Services

We will review Medicare home health payments for diabetes self-management training services. Medicare covers diabetes self-management training services (DSMT) to educate beneficiaries in the successful self-management of diabetes. The Social Security Act, §§ 1861(s)(2)(S) and (qq), permits Medicare coverage of DSMT when these services are furnished by a certified provider who meets certain quality standards. Other conditions for coverage of DSMT are included in 42 CFR pt. 410, subpart H, which includes requirements for plans of care and physician certification. Services include instructions in self-monitoring of blood glucose, diet and exercise education, an insulin treatment plan, and motivation for patients to use the skills for self-management. We will examine billing patterns in geographic areas with high utilization of diabetes self-management training services.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Oversight of Home Health Agency Outcome and Assessment Information Set Data

We will review CMS's oversight of Outcome and Assessment Information Set (OASIS) data submitted by Medicare-certified HHAs. Federal regulations at 42 CFR § 484.55 require HHAs to conduct accurate comprehensive patient assessments that include OASIS data items and submit the data to CMS. OASIS data reflect HHAs' performance in assisting patients to regain or maintain their ability to function and perform activities of daily living. OASIS data also include measures of physical status and use of services, such as hospitalization or emergent care. CMS has used OASIS data for its HHA PPS since 2000; began posting OASIS-based quality performance information on its Home Health Compare Web site in fall 2003; and started a home health pay-for-performance demonstration based on OASIS data on January 1, 2008. We will review CMS's process for ensuring that HHAs submit accurate and complete OASIS data.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Nursing Homes

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 Medicare Part A SNF 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 2010; work in progress)

Medicare Requirements for Quality of Care in Skilled Nursing Facilities

We will assess how skilled nursing facilities (SNF) have addressed certain Federal requirements related to quality of care. Specifically, we will determine the extent to which SNFs: (1) developed plans of care based on assessments of beneficiaries, (2) provided services to beneficiaries in accordance with these plans of care, and (3) planned for beneficiaries' discharges. As a part of this study, we will review SNFs' use of the standardized Resident Assessment Instrument (RAI) to develop nursing home residents' plans of care. The Social Security Act, §§ 1819(b)(3) and 1919(b)(3), requires nursing homes participating in the Medicare or Medicaid program to use the 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 their care plans and that nursing home residents did not receive all psychosocial services identified on care plans.

(OEI; 02-09-00201; expected issue date: FY 2010; work in progress)

Accuracy of Skilled Nursing Facility Resource Utilization Groups Coding

We will review SNF claims for Medicare reimbursement to determine the accuracy of Resource Utilization Groups (RUG) coding. The Social Security Act, § 1888(e), establishes the amount paid to SNFs for all covered services. Medicare pays Part A-covered SNF stays using a PPS that applies a case-mix adjustment based on the resident's RUG, which is an indication of the level of care and resource needs. In 2006, we reported that 22 percent of claims had RUGs associated with higher payment rates than those generated in and supported by patients' medical records. This represented \$542 million in potential overpayments for FY 2002. We will also explore other opportunities to improve the accuracy of payments to SNFs.

(OEI; 02-09-00200; expected issue date: FY 2010; work in progress)

Nursing Home Emergency Preparedness and Evacuations During Selected Natural Disasters

We will review nursing homes' emergency plans and emergency preparedness deficiencies cited by State surveyors to determine the sufficiency of the nursing homes' plans and implementation of the plans. Pursuant to 42 CFR § 483.75(m), Medicare- and Medicaid-certified nursing home facilities must have plans and procedures to meet all potential emergencies and train all employees in these emergency procedures. In 2006, OIG reported that nursing homes in certain

Gulf States had plans that lacked a number of provisions suggested by emergency preparedness experts and that staff did not always follow emergency plans. We will describe the experiences of selected nursing homes, including challenges, successes, and lessons learned, when they implemented their plans during recent disasters.

(OEI; 06-09-00270; expected issue date: FY 2010; work in progress)

Criminal Background Checks for Nursing Facility Employees

We will determine whether and the extent to which nursing facilities have employed individuals with criminal convictions. Pursuant to the Social Security Act, §§ 1819(b)(2) and 1919(b)(2), nursing facilities participating in the Medicare and Medicaid programs are required to provide services that maintain the dignity and well-being of all nursing home residents. Federal regulations at 42 CFR § 483.13(c)(1)(ii) prohibit Medicare and Medicaid long term care (LTC) facilities from employing individuals found guilty of abusing, neglecting, or mistreating residents. We will also categorize the types of crimes, if any are found, for which nursing facilities' employees have been convicted.

(OEI; 07-09-00110; expected issue date: FY 2010; work in progress)

Oversight of Poorly Performing Nursing Homes

We will review CMS's and States' use of enforcement measures to determine their impact on improving the quality of care beneficiaries received in poorly performing nursing homes and the performance of these nursing homes. The Social Security Act, §§ 1819(g) and 1864, established a survey and certification process to ensure that nursing homes meet Federal standards for participation in the Medicare and Medicaid programs. We will examine enforcement measures, such as survey and certification reviews and actions taken by CMS and States. We will also determine the extent to which CMS and States follow up to ensure that poorly performing nursing homes implement plans of correction.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Part B Services in Nursing Homes: 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 in accordance with 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 the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 313, to monitor these services for abuse. This review will determine the extent of Part B services provided to nursing home residents during 2007 and assess patterns of billing among nursing homes and providers.

(OEI; 06-07-00580; expected issue date: FY 2010; work in progress)

Nursing Home Residents Aged 65 or Older Who Received Antipsychotic Drugs

We will review the extent to which nursing home residents aged 65 or older received selected antipsychotic drugs in the absence of conditions approved by the Food and Drug Administration (FDA). Pursuant to the Social Security Act, §§ 1819 and 1919, SNFs are required to respect certain rights of patients, including the right to be free from chemical restraints administered for discipline or convenience. The regulation at 42 CFR § 483.25(l) defines safeguards to protect nursing home residents from being prescribed unnecessary drugs. We will examine Medicare

Part D and Part B program reimbursements for selected antipsychotic drugs received by elderly nursing home residents and the extent to which these drugs were prescribed and paid for in accordance with Federal regulations.

(OEI; 07-08-00150; expected issue date: FY 2010; work in progress)

Other Part A and Part B Providers Payments

Physician Billing for Medicare Hospice Beneficiaries

We will review the extent of Part B billing for physician services provided to Medicare hospice beneficiaries. The regulations at 42 CFR § 418.304 list the physician services that are already covered by Medicare under the hospice benefit. The regulation provides that for physicians employed by or in an arrangement with the hospice, payments for certain services are reimbursed to the hospice as part of the hospice payment while other services are paid to the hospice under the Part B Medicare Physician Fee Schedule. Physicians may receive reimbursement for hospice services under Medicare Part A or Part B. This study is a followup to recent OIG studies on hospice care. We will determine the frequency of and total expenditures for physician services under Part A and Part B for hospice beneficiaries. We will identify whether physicians double-billed hospice services to Part A and Part B.

(OEI; 02-06-00224; expected issue date: FY 2010; work in progress)

Trends in Medicare Hospice Utilization

We will review Medicare Part A hospice claims to identify trends in hospice utilization. When the hospice benefit was created by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), § 122, Medicare did not cover more than 210 days of hospice care per beneficiary. Congress changed the benefit in section 4443 of the BBA, implemented by CMS at 42 CFR § 418.21, to eliminate the limit on the number of days covered by Medicare. Since then, the number and types of diagnoses associated with hospice utilization have increased and longer stays have become more common. We will examine the characteristics of hospice beneficiaries, geographical variations in utilization, and differences between for-profit and not-for-profit providers.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Medicare Incentive Payments for E-Prescribing

We will review Medicare incentive payments made in 2010 to eligible health care professionals for their 2009 electronic prescribing (e-prescribing) activities. The Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), § 132, amended the Social Security Act, § 1848(m), to provide for incentive payments to eligible health care professionals for e-prescribing beginning in 2010 and continuing through 2013. Physicians will be eligible for incentive payment if they are “successful electronic prescribers.” In its final rule for the calendar year (CY) 2009 Physician Fee Schedule, 73 Fed. Reg. 69726 (Nov. 19, 2008), CMS stated that successful electronic prescribers will be those physicians who report on CMS’s e-prescribing quality measure with respect to at least 50 percent of cases in which services are billed to Medicare Part B. We will assess whether, and, if so, the extent to which incentive payments for e-prescribing activities in 2009 were made in error. In addition, if erroneous payments were made, we will assess CMS’s actions to remedy erroneous payments and its plans for overseeing

payments made throughout the MIPPA-authorized program. This review will lay a foundation for our future evaluations of the integrity of payments authorized by the American Recovery and Reinvestment Act of 2009 (Recovery Act), including CMS's incentive payments to providers that implement electronic health records. We will identify potential vulnerabilities to assist in CMS's oversight preparations.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Place-of-Service Errors

We will review physician coding of place of service on Medicare Part B 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 nonfacility 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-00-09-35113; W-00-10-35113; various reviews; expected issue date: FY 2010; work in progress)

Ambulatory Surgical Center Payment System

We will review the appropriateness of the methodology for setting ASC payment rates under the revised ASC payment system. Section 626(b) of the MMA requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. We will examine changes to the revised ASC payment system and the rate-setting methodology used to calculate ASC payment rates.

(OAS; W-00-09-35423; W-00-10-35423; various reviews; expected issue date: FY 2010; 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," Pub. No. 100-04, ch. 12, § 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. 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-00-09-35207; W-00-10-35207; various reviews; expected issue date: FY 2010; work in progress)

Medicare Payments for Part B Imaging Services

We will review Medicare payments for Part B imaging services. Physicians are paid for services pursuant to the Medicare physician fee schedule, which covers the major categories of costs, including the physician professional cost component, malpractice costs, and practice expense. The Social Security Act, § 1848(c)(1)(B), defines "practice expense" as the portion of the resources used in furnishing the service that reflects the general categories of expenses, such as office rent, wages of personnel, and equipment. For selected imaging services, we will focus on

the practice expense components, including the equipment utilization rate. We will determine whether Medicare payment reflects the actual expenses incurred and whether the utilization rate reflects current industry practices.

(OAS; W-00-10-35219; various reviews; expected issue date: FY 2011; 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 may not 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-00-10-35405; various reviews; expected issue date: FY 2010; new start)

Outpatient Physical Therapy Services Provided by Independent Therapists

We will review outpatient physical therapy services provided by independent therapists to determine whether they are in compliance with Medicare reimbursement regulations. The Social Security Act, § 1862(a)(1)(A), provides that Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” CMS’s “Medicare Benefit Policy Manual,” Pub. No. 100-02, ch. 15, § 220.3, contains documentation requirements for therapy services. Previous OIG work has identified claims for therapy services provided by independent physical therapists that were not reasonable, medically necessary, or properly documented. Focusing on independent therapists who have a high utilization rate for outpatient physical therapy services, we will determine whether the services that they billed to Medicare were in accordance with Federal requirements.

(OAS; W-00-10-35220; various reviews; expected issue date: FY 2010; new start)

Appropriateness of Medicare Payments for Polysomnography

We will examine the appropriateness of Medicare payments for sleep studies. Sleep studies are reimbursable for patients with symptoms consistent with sleep apnea, narcolepsy, impotence, or parasomnia in accordance with the CMS “Medicare Benefit Policy Manual,” Pub. No. 102, ch. 15, § 70. Medicare payments for polysomnography increased from \$62 million in 2001 to \$215 million in 2005. We will also examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Laboratory Test Unbundling by Clinical Laboratories

We will review the extent to which clinical laboratories have inappropriately unbundled laboratory profile or panel tests to maximize Medicare payments. Pursuant to the “Medicare Claims Processing Manual,” Pub. No. 100-04, ch. 16, § 90, to ensure the accuracy of payments, Medicare contractors must group together individual laboratory tests that clinical laboratories can perform at the same time on the same equipment and then consider the price of related profile tests. Payment for individual tests must not exceed the lower of the profile price or the total price of all the individual tests. We will determine whether clinical laboratories have unbundled profile or panel tests by submitting claims for multiple dates of service or by drawing

specimens on sequential days. We will also determine the extent to which the Medicare carriers have controls in place to detect and prevent inappropriate payments for laboratory tests.
(OAS; W-00-10-35222; various reviews; expected issue date: FY 2010; new start)

Medicare Billings With Modifier GY

We will review the appropriateness of providers' use of modifier GY on claims for services that are not covered by Medicare. CMS's "Medicare Carriers Manual," Pub. No. 14-3, pt. 3, § 4508.1, states that modifier GY is to be used for coding services that are statutorily excluded or do not meet the definition of a covered service. Beneficiaries are liable, either personally or through other insurance, for all charges associated with the provision of these services. Pursuant to CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 1, § 60.1.1, providers are not required to provide beneficiaries with advance notice of charges for services that are excluded from Medicare by statute. As a result, beneficiaries may unknowingly acquire large medical bills that they are responsible for paying. In FY 2008, Medicare received over 75.1 million claims with a modifier GY totaling approximately \$820 million. We will examine patterns and trends for physicians' and suppliers' use of modifier GY.
(OEI; 00-00-00000; expected issue date: FY 2011; 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 is independent of a physician's office or hospital. It may have a fixed location or be a mobile entity, and the practitioner 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; 09-09-00380; expected issue date: FY 2010; work in progress)

Enrollment Standards for Independent Diagnostic Testing Facilities

We will review IDTFs enrolled in Medicare to determine whether they meet Medicare's enrollment standards. Pursuant to Federal regulations at 42 CFR § 410.33, IDTFs, which received payments of approximately \$1 billion in 2007, are required to certify on their enrollment applications that they comply with 14 standards. Such standards include, among others, requirements that IDTFs be in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients, provide complete and accurate information on their enrollment applications, and have technical staff on duty with the appropriate credentials to perform tests.
(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Physician Reassignment of Benefits

We will review the extent to which Medicare physicians reassign their benefits to other entities. The Social Security Act, § 1842(b)(6), prohibits physicians who provide services to Medicare beneficiaries from reassigning their right to Medicare payments to other entities, unless a specific exception applies. For example, physicians are permitted to reassign benefits to other entities

enrolled in Medicare when contractual arrangements that meet certain program integrity safeguards exist between the physicians and the entities 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. We will examine the extent to which physicians are aware of their reassignments.

(OEI; 07-08-00180; expected issue date: FY 2010; work in progress)

Medicare Providers' Compliance With Assignment Rules

We will examine the extent to which providers comply with assignment rules and determine if and to what extent beneficiaries are inappropriately billed in excess of amounts allowed by Medicare requirements. Pursuant to the Social Security Act, § 1842(h)(1), physicians participating in Medicare agree to accept payment on an "assignment" for all items and services furnished to individuals enrolled in Medicare. CMS defines assignment as a written agreement between beneficiaries, their physicians or other suppliers, and Medicare. The beneficiary agrees to let the physician or other supplier request direct payment from Medicare for covered Part B services, equipment, and supplies by assigning the claim to the physician or supplier. The physician or other supplier in return agrees to accept the Medicare-allowed amount by the carrier as the full charge for the items or services provided. We will also assess beneficiaries' awareness of their rights and responsibilities regarding potential billing violations and Medicare coverage guidelines.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Payments for Services Ordered or Referred by Excluded Providers

We will review the nature and extent of Medicare payments for services ordered or referred by excluded providers. Excluded or terminated providers, practitioners, or suppliers have engaged in fraud, program abuse, or other conduct that formed the basis for termination from Medicare, Medicaid, and all other Federal health care programs. Pursuant to the Social Security Act, §§ 1128 and 1156, no payment shall be made for any items or services furnished, ordered, or prescribed by an excluded individual or entity. In April 2009, CMS completed its transition to the use of national provider identifiers (NPI) to identify its Medicare providers. It is possible that during the transition period to NPIs, some referring or ordering providers, referred to as "secondary" providers, did not have NPIs. Secondary providers are not required to enroll in Medicare, and no edits currently exist to determine whether secondary providers have been barred, suspended, or excluded by Medicare or Medicaid, which represents a potential vulnerability. We will also examine CMS oversight mechanisms to identify and prevent improper payments for services based on orders or referrals by excluded providers.

(OEI; 00-00-00000; expected issue date: FY 2010; 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's "Medicare Benefit Policy Manual," Pub. No. 100-02, ch. 10, § 10.3, describes coverage of ambulance services to and from renal dialysis facilities for ESRD patients who require dialysis. Furthermore, section 623(f) of the MMA requires the Secretary 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 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 percentage of the population using ambulance services, the feasibility of contracting by freestanding facilities with ambulance suppliers, and the coverage policies of other health insurance programs.

(OAS; W-00-10-35417; various reviews; expected issue date: FY 2010; new start)

Medicare Payments for Transforaminal Epidural Injections

We will review Medicare claims to determine the appropriateness of Medicare Part B payments for transforaminal epidural injections. Transforaminal epidural injections are used as an interventional technique to diagnose or treat back problems, such as pain that starts in the back and radiates down the leg. The Social Security Act, § 1862(a)(1)(A), states that Medicare will cover only services that are considered reasonable and necessary. Reasonable and necessary items are those used to diagnose or treat illness or to improve the functioning of a malformed body part. Further, the Social Security Act, § 1833(e), states that payment may be made only when a provider has furnished appropriate information about the service for processing the claim. Medicare Part B physician claims for transforaminal epidural injections increased by 130 percent between 2003 and 2007. We will also determine whether there are policies and safeguards to prevent inappropriate payments for transforaminal epidural injections.

(OEI; 05-09-00030; expected issue date: FY 2010; work in progress)

Comprehensive Error Rate Testing Program: FY 2008 Transportation Claims Error Rate

We will review certain aspects of CMS's Comprehensive Error Rate Testing program (CERT) methodology for determining the FY 2008 transportation/ambulance claims error rate. The Improper Payments Information Act of 2002 (IPIA) requires Federal agencies to annually develop a statistically valid estimate of improper payments made under programs with a significant risk of erroneous payments. To accomplish our objective, we will review transportation claims that were selected for review by the FY 2008 CERT program. Our review will consist of a statistical subsample of claims from the CERT sample of transportation claims. For the sampled claims, we will review the beneficiaries' medical records, including pertinent records from physicians, to support claims from transportation providers. We will determine whether payments for services such as transporting the patient one way, mileage while the patient is on board, and all supplies and services are included in the charge and are appropriate. We will also determine whether the documentation supports the claims, whether the services were medically necessary, and whether the beneficiaries actually received the services. We will engage independent medical reviewers to determine the medical necessity and sufficiency of documentation for these claims.

(OAS; W-00-09-40035; expected issue date: FY 2010; new start)

Comprehensive Error Rate Testing Program: Fiscal Year 2008 Part A and Part B Error Rates

We will review certain aspects of CMS's CERT methodology for determining the 2008 Part A and Part B error rates. The IPIA and the Office of Management and Budget's (OMB) implementation of that act in memorandum M-06-23 require Federal agencies to annually develop statistically valid estimates of improper payments made under programs with significant risks of erroneous payments. CMS has contracted with an independent medical review organization to perform a random independent review of its CERT contractor's payment determinations for 1,000 Part A and Part B claims (excluding inpatient claims). We will

determine whether the independent medical review organization met its contractual obligations to CMS and will provide an analysis of the organization's review. We will also evaluate the methodology and medical review determinations underlying the error rate testing conducted by the CERT contractor.

(OAS; W-00-10-40043; expected issue date: FY 2010; new start)

Medicare Services Billed With Dates of Service After Beneficiaries' Dates of Death

We will review Medicare claims with dates of service after beneficiaries' dates of death to assess CMS's controls to preclude or identify and recover improper fee-for-service payments. Pursuant to 42 CFR § 406.28(e), entitlement to hospital insurance (Part A) ends with the beneficiary's day of death and 42 CFR § 407.27(a) states entitlement to supplementary medical insurance (Part B) ends on the last day of the month in which the beneficiary dies. To monitor Medicare eligibility effectively, CMS uses several computer database systems that interface with death information on the Social Security Administration's and the Railroad Retirement Board's systems. The "Medicare Financial Management Manual," Pub. No. 100-06, ch. 3, § 10, defines an overpayment as a Medicare payment that a provider received in excess of amounts due and payable under the statute and regulations. The Federal Claims Collection Act of 1966 (FCCA), United States Code (U.S.C.), Title 31 § 3711, as implemented by 31 CFR § 901.1, requires the recovery of overpayments.

(OAS; W-00-09-35435; W-00-10-35435; various reviews; expected issue date: FY 2010; work in progress)

Durable Medical Equipment and Supplies

Physician Self-Referral for Durable Medical Equipment Services

We will review Medicare payments for DME services to determine their allowability in context of Federal requirements for physician self-referral prohibitions in the Social Security Act, § 1877. Specifically, sections 1877(a)(1) and 1877(a)(2) provide that unless exceptions apply, physicians are prohibited from making referrals for furnishing designated health services to entities with which the physicians have financial relationships. Designated health services identified under the physician self-referral prohibition include DME services. We will determine the allowability of physician self-referrals to DME suppliers in which physicians held ownership interests.

(OAS; W-00-10-35503; various reviews; expected issued date: FY 2010; new start)

Medicare Payments for Various Categories of Durable Medical Equipment

We will review the appropriateness of Medicare Part B payments to DME suppliers of power mobility devices (e.g., scooters), hospital beds and accessories, oxygen concentrators, and enteral/parenteral nutrition. Pursuant to the Social Security Act, §§ 1862(a)(1)(A) and 1833(e), Medicare will not pay for items or services that are "not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." Prior OIG reviews have identified issues such as Medicare payments for DME that was not ordered by physicians, not delivered to the beneficiaries, or not needed by beneficiaries. We will identify DME suppliers in selected geographic areas with high-volume claims and

reimbursement to determine whether payments were made in accordance with Medicare requirements.

(OAS; W-00-09-35223; W-00-10-35223; various reviews; expected issue date: FY 2010; work in progress)

Medicare Payments for Durable Medical Equipment Claims With Modifiers

We will review the appropriateness of Medicare Part B payments to DME suppliers that submitted claims with modifiers. The Social Security Act, § 1833(e), 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, DME suppliers must use modifiers to indicate that they have the appropriate documentation on file; the suppliers are required to provide, upon request, the documentation to support their claims 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-00-08-35305; W-00-09-35305; W-00-10-35305; various reviews; expected issue date: FY 2010; work in progress)

Comprehensive Error Rate Testing Program: Durable Medical Equipment Corrective Actions

We will review CMS's corrective actions in response to recommendations in OIG's final report dated August 22, 2008, regarding the medical review of claims for the FY 2006 CERT program DME review. In the report, we recommended that CMS require the CERT contractor to review all available supplier documentation, review all medical records necessary to determine medical necessity, and contact beneficiaries named on high-risk claims. In response to the recommendations, CMS stated that beginning with the 2009 measurement cycle, it would implement the recommendation for reviews of claims for diabetic test strips, oxygen, and powered mobility devices. CMS also indicated that it had issued directions on the appropriate use of clinical inference; would ensure that oral guidance, policy clarifications, and technical directions were followed up with written directions to medical reviewers; and would provide Medicare providers the information needed to understand the program, be informed promptly about changes, and bill correctly. We will verify actions taken by CMS to implement our recommendations.

(OAS; W-00-09-40044; expected issue date: FY 2010; work in progress)

Appropriateness of Durable Medical Equipment Categorization

We will review the appropriateness of DME categorization in the Medicare fee schedule for selected DME items. However, DME products have evolved since the DME fee schedule was created more than 20 years ago. As a result of these changes, some DME items may be in categories that no longer reflect the current costs of the equipment, expected duration of beneficiary use, or extent of servicing involved to maintain the equipment. The DME categories defined in the Social Security Act, § 1834, are: inexpensive or other routinely purchased DME, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, other covered items (other than DME), and capped rental items. Using the DME

suppliers' records and information from beneficiaries, we will determine whether DME items are properly classified according to current payment methodologies.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Enteral Nutrition Therapy Services in Nursing Homes

We will review Part B enteral nutrition therapy (ENT), commonly called tube feeding, to 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. The Social Security Act, § 1861(s)(8), 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 also examine the characteristics of inappropriately allowed claims for ENT.

(OEI; 06-07-00090; expected issue date: FY 2010; work in progress)

Medicare Pricing for Parenteral Nutrition

We will review Medicare's fee schedule for parenteral nutrition in comparison with fees paid by other sources of reimbursement. Parenteral nutrition is the practice of feeding a person intravenously to replace the function of a permanently inoperative or malfunctioning internal body organ and is covered under the prosthetic device benefit of the Social Security Act, § 1861(s)(8). In 2007, Medicare spent more than \$100 million for parenteral-nutrition-related services. Previous OIG work found that Medicare allowances for major parenteral nutrition codes averaged 45 percent higher than Medicaid prices, 78 percent higher than prices available to Medicare risk contract health maintenance organizations, and 11 times higher than some manufacturers' contract prices. We will identify reimbursement amounts paid by public and private payers for parenteral nutrition services.

(OEI; 00-00-00000; expected issue date: FY 2011; 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. The Social Security Act, § 1862(a)(1)(A), provides that Medicare will not pay for items or services that are "not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." The local medical review policies (LMRP) or local coverage determinations, whichever are applicable, issued by the four DME MACs 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 require 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; W-00-10-35407; various reviews; expected issue date: FY 2010; 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 the Social Security Act, §§ 1862(a)(1)(A) and 1834(a). 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, problems may persist. In 2007, approximately 173,300 Medicare beneficiaries received power wheelchairs, at a total cost of \$686 million.

(OEI; 04-07-00401; expected issue date: FY 2010; work in progress)

Medicare Payments to Durable Medical Equipment Suppliers for Power Wheelchairs

We will review documentation for payments to DME suppliers for standard and complex rehabilitation power wheelchairs to determine whether suppliers meet Medicare's coverage criteria and medical necessity documentation requirements. Pursuant to the Social Security Act, § 1832(a)(1), and regulations at 42 CFR §§ 410.10(h) and 410.38, beneficiaries are eligible to receive power wheelchairs under Medicare Part B coverage of durable medical equipment. Under section 1862(a)(1), items provided under Part B, including power wheelchairs, must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." We will also determine whether suppliers had documentation from the beneficiaries' medical records, as required, that clearly supported the medical necessity of the power wheelchairs.

(OEI; 04-09-00260; expected issue date: FY 2010; work in progress)

Repair and Servicing of Capped Rental Durable Medical Equipment

We will review the extent and appropriateness of payments for repair and servicing of capped rental DME. Capped rental DME items include wheelchairs and hospital beds. Section 5101(a) of the DRA mandated changes in the way Medicare pays for capped rental DME items. For capped rental DME furnished on or after January 1, 2006, Medicare requires suppliers to transfer the title of DME to the beneficiary after Medicare pays 13 months' rent under a capped rental arrangement. After that time, Medicare continues to pay for reasonable and necessary repairs to the equipment. Previous OIG work found that Medicare paid substantially more for maintenance on rented equipment than repairs on purchased equipment. We will examine servicing records from suppliers and interview beneficiaries regarding their experiences with capped rental DME to determine whether Medicare made proper payments for maintenance and repair services.

(OEI; 07-08-00550; expected issue date: FY 2010; work in progress)

Medicare Enrollment and Monitoring for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and Home Health Agencies

We will review Medicare contractors' processes for enrolling and monitoring suppliers of DME and HHAs. Pursuant to CMS's "Medicare Program Integrity Manual," Pub. No. 100-08, ch. 10, Medicare contractors must conduct prescreening, verification, validation, and final processing of Medicare provider enrollment applications. A recent OIG study found that DME suppliers and HHAs omitted or provided inaccurate information on enrollment applications, which resulted in improper enrollment. We will assess Medicare contractors' use of enrollment screening mechanisms and post-enrollment monitoring activities to identify DME and HHA applicants that pose fraud risks to Medicare and the extent to which applicants omitted ownership information on enrollment applications.

(OEI-06-09-000230; expected issue date: FY 2010; work in progress)

Part B Payments for Prescription Drugs

Comparing Average Sales Prices to Widely Available Market Prices

We will periodically review widely available market prices (WAMP) for selected prescription drugs covered by Part B and compare them to average sales prices (ASP) for those drugs. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The Social Security Act, § 1847A(d), 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, 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; 00-00-00000; various studies; expected issue date: FY 2010; new start)

Comparing Average Sales Prices to Average Manufacturer Prices

We will periodically review Medicare Part B drug prices by comparing ASPs to average manufacturer prices (AMP). In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The Social Security Act, § 1847A(d), enacted by section 303(c)(1) of the MMA, mandates that OIG compare ASPs to AMPs for Part B drugs and notify the Secretary, at such times as the Secretary may specify, 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; 00-00-00000; various studies; expected issue date: FY 2010; new start)

Oversight of Manufacturers' Average Sales Price Data Submissions

We will review the impact on Medicare Part B payments when drug manufacturers do not submit their ASP data to CMS promptly. Manufacturers are required to submit ASP data to CMS 30 days after the close of each quarter. The Social Security Act, § 1847A(b), enacted by section 303 of the MMA, established the ASP as the basis of payment for Part B drugs, effective January 1, 2005. The accuracy of payment for Part B drugs—which cost Medicare and its beneficiaries over \$11 billion in 2006—depends on timely and accurate submissions of ASP data to CMS by drug manufacturers. We will assess the impact of late ASP submissions and the adequacy of CMS's oversight of manufacturers' submissions of ASP data.

(OEI; 03-08-00480; expected issue date: FY 2010; work in progress)

Medicare Drug Payments Under the Hospital Outpatient Prospective Payment System

We will review the appropriateness of Medicare payments for billable drugs covered under the hospital OPDS. Pursuant to the Social Security Act, § 1833(t), the hospital OPDS covers certain Part B services furnished to hospital outpatients and certain hospital inpatients who have no Part A coverage. The hospital OPDS also covers partial hospitalization services furnished by community mental health centers. Under the hospital OPDS, certain drugs administered in hospital outpatient departments are billed separately to Medicare. Under CMS's final OPDS rule, 73 Fed. Reg. 68502 (November 18, 2008), effective January 1, 2009, these drugs are reimbursed at their average sales prices plus 4 percent. Many DSH providers participate in a drug pricing program (known as the Public Health Service Act (PHS Act) 340B program) that establishes ceiling prices that are typically much lower than the ASP for prescription drugs.

Because many DSHs pay 340B prices when acquiring drugs, the ASP plus 4 percent payment method may result in some payments to DSHs that are too high. However, for other non-DSH providers, the payments may be too low. We also will compare Medicare payment amounts for drugs delivered in outpatient hospital settings to the acquisition costs of the drugs paid by providers.

(OEI; 03-09-00420; expected issue date: FY 2010; work in progress)

Medicare Payments for End-Stage Renal Disease Drugs

We will review dialysis facilities' fourth-quarter 2008 average acquisition costs for selected ESRD drugs and compare these to fourth-quarter 2008 Medicare payment amounts. Medicare bases payment on 106 percent of the drugs' ASPs. However, effective January 1, 2011, MIPPA will change payments for ESRD items and services by bundling ESRD drugs, which are currently billed separately, with all of the other costs of ESRD care. Previous OIG reviews have found that Medicare payments for the majority of separately billable ESRD drugs are consistently higher than average acquisition costs reported by dialysis facilities and prices paid by the Department of Veterans Affairs (VA). We will also compare facilities' 2008 fourth-quarter average acquisition costs to the costs that facilities reported for these drugs in previous quarters.

(OEI; 03-09-00280; expected issue date: FY 2010; work in progress)

Renal Dialysis Facilities' Dosing Guidelines for Erythropoiesis-Stimulating Agents

We will review whether protocols used by renal dialysis facilities for erythropoiesis-stimulating agents (ESA) adhere to FDA labeling recommendations. In response to research published in 2007, FDA approved revised labeling for ESAs, including a "black box" warning recommending that ESAs be dosed to maintain a hemoglobin value of less than 12 g/dL. According to the revised labeling for ESAs, maintaining hemoglobin levels above 12 g/dL can adversely affect a patient's health, possibly resulting in death. There are concerns that dialysis facilities may be using dosing guidelines, standards, and protocols that are not consistent with the revised labeling recommendations. We will determine the extent to which renal dialysis facilities' protocols for administering ESAs are consistent with CMS's monitoring policy for ESA claims.

(OEI; 03-09-00010; expected issue date: FY 2010; work in progress)

Billing for Immunosuppressive Drugs

We will review Medicare Part B immunosuppressive drug claims to determine whether they were billed according to their FDA-approved labels. Pursuant to the Social Security Act, § 1832(a)(2), and CMS's "Medicare Benefits Policy Manual," Pub. No. 100-02, ch. 15, § 50, Medicare Part B covers drugs that are not usually self-administered and are furnished incident to physicians' services, such as administering immunosuppressive drugs. The manual also states at section 50 that use of such drugs must be safe and effective and otherwise reasonable and necessary and that "drugs or biologicals approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for indications specified on the labeling." Several FDA-approved labels for immunosuppressive drugs state that the drugs should not be used in combination with other immunosuppressive drugs. We will also determine whether Medicare paid for immunosuppressive drugs that should not have been used in combination with other immunosuppressive drugs.

(OAS; W-00-10-35434; various reviews; expected issue date: FY 2011; new start)

Payments for Off-Label Anticancer Pharmaceuticals and Biologicals

We will review Medicare payments for drugs and biologicals used on an off-label basis in anticancer chemotherapeutic regimens. The Social Security Act, § 1861(t)(2), provides coverage of FDA-approved drugs used for off-label indications in anticancer chemotherapeutic regimens where such uses are supported in authoritative compendia identified by the Secretary of HHS. Federal regulations at 42 CFR § 414.930(b) established a process for identifying authoritative sources of information. The DrugDex, which is a drug compendium, defines drugs in the class we will review as being medically accepted even though the given tests or treatments are indicated in only some cases and even where evidence and/or expert opinions argue against efficacy. In CY 2007, Medicare payments for anticancer drugs totaled approximately \$2.7 billion. We will determine whether patients with particular indications were prescribed anticancer drugs approved by FDA for such indications before resorting to anticancer drugs not approved for those indications and, if so, whether there were improvements in the patients' medical conditions prior to use of off-label drugs. If the beneficiaries' medical conditions improved prior to use of off-label drugs, we will determine how much Medicare could have saved had anticancer drugs continued to be used within indicated usage.

(OAS; W-00-10-35504; various reviews; expected issue date: FY 2011; new start)

Potentially Fraudulent Medicare Claims for Budesonide in South Florida

We will determine whether the number of units of budesonide billed and paid under Part B in South Florida exceeded the amount of the drug distributed for sale in the area by the manufacturer and wholesalers. Previous OIG work has uncovered aberrant billing patterns for the inhalation drug budesonide billed to Medicare Part B by suppliers in South Florida. Based on an analysis of these billing patterns, we believe that a large number of these budesonide claims may be fraudulent. This study will further assess the likelihood of fraudulent activity by examining sales data and other information provided by budesonide's manufacturer and large wholesalers/distributors.

(OEI-00-00-00000; expected issue date: FY 2010; new start)

Medicare Part A and Part B Contractor Operations

Preaward Reviews of Contract Proposals

We will review the cost proposals of various bidders for Medicare contracts based on criteria in 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-00-10-35002; various reviews; expected issue date: FY 2010; 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 the Federal Acquisition Regulation (FAR) at 48 CFR pt. 31. We will coordinate the selection of contractors with CMS.

(OAS; W-00-08-35005; W-00-09-35005; W-00-10-35005; various reviews; expected issue date: FY 2010; work in progress)

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. CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 21, § 10, contains contractor requirements for issuing MSNs. On its Web site and in the "Medicare & You" publication, CMS emphasizes the importance of checks by beneficiaries of their MSNs for any services or supplies that they do not recognize. We will review beneficiaries' experiences and understanding of MSNs.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Quality Improvement Organizations' Beneficiary Complaint Process

We will review the extent to which Quality Improvement Organizations (QIO) notify Medicare beneficiaries and/or their representatives of the final outcomes of their quality-of-care complaints to QIOs and determine trends in the receipt and disposition of beneficiary complaints by QIOs. Pursuant to the Social Security Act, § 1154(a)(14), QIOs are required to review complaints about the quality of care Medicare beneficiaries receive and inform beneficiaries and/or their representatives of the final outcome of their complaints. OIG reviews from 1995 and 2001 found issues with the QIO process for reporting the outcomes of their quality-of-care complaints to beneficiaries. Further, in 2002 the U.S. Court of Appeals for the District of Columbia Circuit found that HHS had not implemented the requirement to notify Medicare beneficiaries and/or their representatives of the final disposition of the quality-of-care complaints they had made to QIOs.

(OEI; 00-00-00000; OAS; W-00-10-35505; various reviews; expected issue date: FY 2010; new start)

First Level of the Medicare Appeals Process

We will review the timeliness of Medicare contractors in making determinations on requests for reconsideration at the first level of the Medicare appeals. Pursuant to the Social Security Act, § 1869(a)(3)(C)(ii), Medicare contractors have 60 days to conclude a redetermination regarding a denied claim. We will review the processes Medicare contractors use to conduct first level Medicare appeals.

(OEI; 00-00-00000; expected issue date; FY 2011; new start)

Handling of Hotline Referrals

We will review CMS's handling of complaints referred by OIG from callers to the hotline. OIG operates 1-800-HHS-TIPS to receive calls alleging fraud, waste, or mismanagement in HHS programs, such as Medicare. The availability of the hotline is widely publicized on the Internet and in various publications, including CMS's "Medicare & You" booklet, which is distributed annually to Medicare beneficiaries. In 2009, the hotline referred approximately 2,580 complaints to CMS for assessment and appropriate action. We will review CMS's handling of these referrals, including its research related to the issues of the complaints, corrective actions taken, and communications with the complainants.

(OEI; 07-09-00020; expected issue date: FY 2010; work in progress)

Medicare and Medicaid Data Match Project

We will review CMS's oversight and monitoring of the Medicare and Medicaid Data Match Project (Medi-Medi) to determine whether it is 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 the Social Security Act, § 1893, 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 separately. Federal regulations at 48 CFR § 42.1500 provide policies and establish responsibilities for agencies to record and maintain contractor performance information. 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.

(OEI; 09-08-00370; expected issue date: FY 2010; work in progress)

Accuracy and Completeness of the National Provider Identifier

We will review the accuracy and completeness of the NPI registry. NPIs are unique identification numbers for health care providers. CMS regulations at 45 CFR § 162.404 require that beginning May 23, 2007 (May 23, 2008, for small health plans), NPIs 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 had to include their NPIs when submitting claims. We will determine whether providers are including NPIs on claims as required.

(OEI; 07-09-00440; expected issue date: FY 2010; work in progress)

Implementation of Payment Suspensions

We will review how CMS and its contractors implement payment suspensions intended to prevent payments to providers and suppliers suspected of fraud. Pursuant to 42 CFR § 405.371, CMS or its contractors may suspend payments to providers or suppliers based upon the existence of reliable information of an overpayment or fraud. Payment suspensions temporarily stop payment until contractors identify and determine overpayments. We will examine CMS's oversight and contractors' implementation of payment suspensions and other administrative sanctions.

(OEI; 01-09-00180; expected issue date: FY 2010; work in progress)

Collection of Medicare Overpayments Referred by Program Safeguard Contractors

We will review overpayments that program safeguard contractors (PSC) referred to claims processors for collection in 2007. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 202(a), established the Medicare Integrity Program, which requires CMS to engage contractors to review Medicare claims, among other things, for possible overpayments. Pursuant to this provision, program safeguard contractors perform investigative work on Medicare payments to detect and deter fraud and abuse. When they identify overpayments that have been made to Medicare providers and beneficiaries, they refer them to Medicare claims processors for collection. We will examine the amount of overpayments that Medicare claims processors have collected as a result of overpayment referrals and identify the procedures that the program safeguard contractors and claims processors use to identify and track possible fraud and abuse related to the overpayments.

(OEI; 03-08-00030; various reviews; expected issue date: FY 2010; work in progress)

Recovery Audit Contractors' Referrals of Potential Fraud and Abuse

We will review CMS's oversight of Recovery Audit Contractors (RAC) during a 3-year demonstration program to determine the extent to which RACs, which are responsible for identifying Medicare overpayments and underpayments, also identified and reported potential fraud and abuse to CMS. Section 306 of the MMA directed the Secretary of HHS to conduct a demonstration project using RACs to identify Medicare underpayments and overpayments. Following the conclusion of the RAC demonstration program, CMS made the RACs a national program. For both the demonstration and national RACs, we will examine the number of cases referred to CMS, CMS's processing of those referrals, CMS's guidance and training to the demonstration RACs to identify and report potential fraud, and CMS's guidance and training to national RACs on appropriately reporting potential fraud.

(OEI; 03-09-00130; expected issue date: FY 2010; work in progress)

Transition From Program Safeguard Contractors to Zone Program Integrity Contractors

We will review the process PSCs have used to transition their work to Zone Program Integrity Contractors (ZPIC), which are assuming the PSCs' responsibility for ensuring the integrity of all Medicare-related claims. We will examine changes in the workload levels of the outgoing PSCs and incoming ZPIC contractors and determine whether benefit integrity task order activities have been performed adequately. Under section 911 of the MMA, Congress mandated that the Secretary of HHS replace existing fee-for-service contractors with MACs. CMS began its transition from PSCs to ZPICs in late 2008 and expects the transition to be complete by March 2010. As part of that change, CMS is transitioning its PSCs into ZPICs. We will also determine whether the transition is progressing as required.

(OEI; 03-09-00520; expected issue date; FY 2010; work in progress)

Provider Education and Training: Medicare-Affiliated Contractors' Progressive Correction Action

We will review the progressive corrective action (PCA) provider education and training programs conducted by selected Medicare-affiliated contractors to determine whether such programs have reduced billing and payment error rates and aberrant provider behavior. PCA is a medical review tool used by Medicare contractors. In FY 2000, CMS included PCA in its "Medicare Program Integrity Manual," Pub. 100-08, ch. 3, as a strategy for conducting medical reviews and provider education and training. Section 921(d) of the MMA directs the Secretary of HHS to coordinate education activities provided through Medicare contractors to maximize the effectiveness of Federal education efforts for providers and oversee contractors' education and training programs. We will also assess CMS's processes for overseeing the education and training programs of selected affiliated contractors.

(OEI; 00-00-00000; expected issue date; FY 2011; new start)

Contractors' Conflicts of Interest: Oversight and Monitoring by the Centers for Medicare & Medicaid Services

We will examine CMS's process for overseeing contractors' disclosures of organizational conflict-of-interest statements at the time of initial contracting and throughout the terms of the contracts. The FAR (48 CFR subpart 9.5), along with the Health and Human Services Acquisition Regulation (HHSAR) and other authorities, prescribe the responsibilities, general rules, and procedures to identify, evaluate, and resolve organizational conflicts of interest.

We will determine the extent to which contractors disclosed or identified conflicts of interest and examine how CMS resolved the identified conflicts of interest.
(*OEI; 00-00-00000; expected issue date: FY 2010; new start*)

Competitive Bidding Program: Supplier Influence on Physician Prescribing

We will review DME claims to determine the extent to which suppliers participating in the competitive bidding program are soliciting physicians to prescribe certain brands or modes of delivery of covered items that are more profitable to suppliers. Pursuant to section 302(b) of the MMA, CMS is required to establish a competitive bidding process for the purchase of selected DME items. Section 302(e) of the MMA and section 154(a) of the MIPPA require that OIG conduct reviews examining the competitive bidding process, including this review. We will also review billing patterns to identify changes resulting from competitive bidding.
(*OEI; 00-00-00000; expected issue date; FY 2011; new start*)

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 the FAR at 48 CFR § 31.205; Cost Accounting Standards (CAS) 412 and 413; and the Medicare contract, Appendix B, section XVI.
(*OAS; W-00-09-35094; W-00-10-35094; various reviews; expected issue date: FY 2010; 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 pursuant to the FAR at 48 CFR § 31.205; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.
(*OAS; W-00-09-35067; W-00-10-35067; various reviews; expected issue date: FY 2010; 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 the FAR at 48 CFR § 31.205; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.
(*OAS; W-00-09-35148; W-00-10-35148; various reviews; expected issue date: FY 2010; work in progress*)

Pension Segment Closing

We will review Medicare carriers and FIs whose Medicare contracts have been terminated, resulting in the closing of the Medicare segments of their pension plans. We will determine the amount of any excess pension assets related to each Medicare segment as of the segment closing date. Requirements of the FAR at 48 CFR § 31.205; CAS 412 and 413; and the

Medicare contract, Appendix B, section XVI, provide that pension gains that occur when a Medicare segment closes be credited to the Medicare program.

(OAS; W-00-09-35067; W-00-10-35067; various reviews; expected issue date: FY 2010; 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 the FAR at 48 CFR §§ 31.201 through 31.205.

(OAS; W-00-09-35095; W-00-10-35095; various reviews; expected issue date: FY 2010; work in progress)

Medicare Part C (Medicare Advantage)

Beneficiaries must be enrolled in both Part A and Part B to join one of the Part C MA plans, which are administered by MA organizations. MA organizations are public or private organizations licensed by States as risk-bearing entities that are under contract with CMS to provide covered services. MA organizations may offer one or more MA plans. The plans provide all Part A and Part B services and generally provide additional services not covered by traditional Medicare. Beneficiaries usually pay monthly premiums and copayments that will likely be less than the coinsurance and deductibles under the original Medicare Parts A and B. In most cases, these plans also offer Part D prescription drug coverage. Costs and benefits vary by plan. Descriptions of our ongoing and planned reviews of Medicare Part C follow.

Enhanced Payments for Certain Beneficiary Types

We will review the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, ESRD, or Medicaid eligible. Pursuant to the Social Security Act, § 1853(a)(1)(c), CMS adjusts the payment to MA organizations for risk factors, including disability status, institutional status, and such other factors as deemed appropriate. We will determine the impact of inaccurate or invalid classification of beneficiaries on Medicare payments to MA plans.

(OAS; W-00-09-35227; W-00-10-35227; various reviews; expected issue date: FY 2011; work in progress)

Administrative Costs Included in Medicare Advantage Bid Submissions

We will review administrative costs supporting the amounts submitted by MA plans in their annual bid proposals to CMS. Under the Social Security Act, § 1854(a), and 42 CFR § 422.254, MA plans are required to submit bid amounts for all services covered under their planned MA plans, including administrative costs. Congress has expressed interest in how MA plans determine funding amounts to meet administrative costs. In previous reviews, we found insufficient documentation of administrative costs and improper allocation of administrative costs to Medicare contracts. We will determine whether MA plans have improved their

reporting of administrative costs and the impact of inappropriate cost submissions on the MA program.

(OAS; W-00-09-35229; W-00-10-35229; various reviews; expected issue date: FY 2010; work in progress)

Investment Income Earned by Medicare Advantage Plans

We will review the effect of using computations that include income earned by MA organizations from their investments of current Medicare funds. Pursuant to the Social Security Act, § 1854, MA organizations are required to provide additional services in an amount equal to any excess amount remaining in their plans for the contract year and to return any remaining funds to the Medicare trust fund. However, neither the Social Security Act nor the Federal regulations require MA organizations to include investment income earned on monthly capitation payments prior to their expenditure in developing the benefit packages or calculating the excess for the purposes of section 1854. In responding to prior OIG audits, CMS has agreed that policies and procedures are needed to ensure that investment income funds are used to benefit Medicare enrollees, but no such requirement has been implemented. We will determine the financial impact of requiring MA organizations to factor investment income earned on current Medicare funds in computing the annual bid proposal for estimated revenues needed to provide the Medicare benefit package and the impact of investment income in computing additional benefits and Medicare payments.

(OAS; W-00-08-35426; W-00-09-35426; W-00-10-35426; various reviews; expected issue date: FY 2010; work in progress)

Disenrollments From Medicare Advantage Plans

We will review the financial impact on the Medicare program when beneficiaries disenroll from MA plans. A previous OIG review showed that under Medicare fee-for-service, the costs of providing medical services to disenrollees increased by approximately 800 percent in the first 6 months after disenrollment. Following our work, CMS initiated various election periods that limit the window of opportunity for enrollees to disenroll from the MA plan. We will examine the cost of providing health services in both the fee-for-service and managed care arenas for Medicare beneficiaries who were enrolled in MA plans and subsequently disenrolled during 2004–2007. We will also review MA plans' compliance with the election of coverage period.

(OAS; W-00-09-35427; W-00-10-35427; various reviews; expected issue date: FY 2010; work in progress)

Managed Care Encounter Data

We will review the accuracy of Part A encounter data for Medicare beneficiaries' contacts with MA plans for health care services related to one or more medical conditions. 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," Pub. No. 100-16, ch. 7, §§ 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. Risk adjustments are processes that minimize financial incentives MA plans may have to select healthier-than-average enrollees. 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-00-08-35078; W-00-09-35078; W-00-10-35078; various reviews; expected issue date: FY 2010; work in progress)

Medicare Advantage Risk Adjustment Validation

We will review CMS's process for validating MA risk adjustment scores that are used to calculate the MA plans' capitated payment rates. Risk adjustment scores are also used to align Medicare payment rates with beneficiaries' predicted costs. Risk adjustments are processes that minimize financial incentives MA plans may have to select healthier-than-average enrollees. Pursuant to the regulation at 42 CFR § 422.310(b), MA organizations must report risk adjustment data to CMS. To ensure the integrity and accuracy of risk adjustment data and risk adjustment scores, CMS conducts risk score validations of plan submissions for each contract year. We will determine the extent to which CMS validates MA plans' submissions and uses findings of data discrepancies to change payments.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Beneficiary Appeals in the Medicare Advantage Program

We will review the response of MA plans and CMS's independent contractor to beneficiaries' appeals of denials, reductions, or terminations of services. The first level of appeal is called a "request for reconsideration." Under 42 CFR § 422.578, a beneficiary may request that the MA plan reconsider an adverse determination. Regulations at 42 CFR § 422.592 require that if the plan's reconsideration is unfavorable to the beneficiary, the determination be reviewed by an independent contractor. Federal regulations require CMS to monitor and assess MA plans' operations and independent contractors' performance. We will determine whether MA plans and the independent contractors have fulfilled their appeal review requirements and assess CMS's oversight of the appeals system for MA plans.

(OEI; 01-08-00280; expected issue date: FY 2010; work in progress)

Marketing of Medicare Advantage Plans by Sales Agents

We will review beneficiaries' complaints about MA plans' marketing practices to assess plans' compliance with CMS's marketing requirements for plan year 2009. Section 103 of the MIPPA limited marketing practices of MA plans, including prohibiting door-to-door solicitation and telemarketing. In light of these limits, we will determine whether beneficiaries continued to complain about abusive marketing practices and how MA plans have worked to comply with the law. We will also assess CMS's oversight of MA plans' compliance for plan year 2009.

(OEI; 05-09-00070; expected issue date: FY 2010; work in progress)

Medicare Advantage Plans' Oversight of Contractors

We will review MA plans' oversight of contractors that provide enrollees various benefits, such as prescription drugs and mental health services. MA plans are accountable for the performance of related entities, subcontractors, and first-tier and downstream entities. As required by Federal regulations at 42 CFR § 422.504(i)(4), an MA organization that delegates responsibilities under its contract with CMS to another entity must include in its contract with that entity provisions specifying that the entity must comply with all applicable Medicare laws, regulations, and CMS instructions. We will determine the extent to which MA plans oversee and monitor their

contractors' compliance with 42 CFR § 422.504 and examine the processes that they use to ensure that contractors fulfill their contractual obligations.

(OEI; 00-00-00000; expected issue date: FY 2010, new start)

Health Care Organizations' Compliance With Standards on Culturally and Linguistically Appropriate Services in Medicare

We will review whether health care organizations comply with Office for Civil Rights (OCR) and Office of Minority Health (OMH) issuances regarding the prohibition in section 601 of Title VI of the Civil Rights Act of 1964 against national origin discrimination and the protection that provision affords to persons with limited English proficiency. Pursuant to Executive Order 13166, which required Federal agencies to publish guidance regarding the applicability of Title VI to persons with limited English proficiency, OCR issued its "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons." Further, in March 2001, OMH published national standards for adoption or adaptation by stakeholder organizations. Section 187 of the MIPPA requires OIG to review the extent to which Medicare providers and plans are complying with the OCR guidance and OMH standards and to describe the costs associated with or savings related to the provision of language services to comply with these guidances.

(OEI; 00-00-00000; expected issue date: FY 2010, new start)

Medicare Part D Prescription Drug Program

The MMA established a Medicare outpatient prescription drug benefit, known as Medicare Part D, which took effect on January 1, 2006. This voluntary benefit is available to all Medicare beneficiaries. The 2009 "Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" stated that during CY 2008, Part D expenditures were approximately \$49.3 billion and, under intermediate assumptions, were estimated to reach \$140.8 billion in 2018.

The administration of Part D is dependent upon extensive coordination and information sharing among Federal and State government agencies, drug plan sponsors, contractors, health care providers, and third-party payers. CMS and drug plan sponsors share responsibility for protecting the Part D program from fraud, waste, and abuse. Payments to drug plan sponsors based on bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit.

Descriptions of our ongoing and planned reviews of Medicare Part D program administration follow.

Duplicate Drug Claims for Hospice Beneficiaries

We will review the appropriateness 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," Pub. No. 100-04, ch. 11, § 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 per diem amounts, which

include payments for these drugs. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), 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. Therefore, Medicare Part D drug plans should not pay for drugs that are covered under the Part A hospice benefit. We will determine whether payments made under Part D are correct, supported, and not duplicated in hospice per diem amounts. We will also determine the extent of duplication between Part D payments and Part A hospice payments and identify the controls to prevent duplicate drug payments.

(OAS; W-00-09-35307; W-00-10-35307; various reviews; expected issue date: FY 2010; work in progress)

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

We will review claims submitted for payment under Medicare Part D to determine whether they were duplicated in Medicare Part A or Part B. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), 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 beneficiaries 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 also determine the extent to which payments for the sampled Part D claims were correct and supported.

(OAS; W-00-09-35409; W-00-10-35409; various reviews; expected issue date: FY 2010; work in progress)

Medicare Part D Reconciliation Calculations

We will review whether CMS's Part D reconciliation calculations were performed in accordance with applicable regulations. Pursuant to the Social Security Act, § 1860D-15(e), Medicare shares a portion of sponsors' losses or profits from the Part D program. Regulations at 42 CFR § 423.343 provide for retroactive adjustments and reconciliations to account for changes in health status risk or a difference in the amount payable to a sponsor for eligible individuals and the amount actually paid. These adjustments are calculated based on information provided by the sponsors. We will determine whether payments made to sponsors or recoveries made by CMS were correct and properly paid or received for the end-of-year reconciliations.

(OAS; W-00-10-35232; various reviews; expected issue date: FY 2010; work in progress)

Medicare Part D Data Submitted by Sponsors for Reconciliations

We will review the accuracy of Part D sponsors' data submissions for reconciliation purposes to CMS, pursuant to Federal regulations at 42 CFR §§ 423.343(c)(1) and (d)(1). Specifically, we will determine the accuracy of prescription drug event (PDE) data and direct and indirect remunerations (DIR) data (which are required information for reconciliation purposes) reported in accordance with these provisions. The PDE summary is a record that documents the final adjudication of a dispensing event. Regulations at 42 CFR § 423.308 state that DIR data include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or

other price concessions. Medicare shares a portion of sponsors' losses or profits from the Part D program, and the reconciliation identifies the amount of any such losses or profits.

(OAS; W-00-08-35200; W-00-09-35200; W-00-10-35200; various reviews; expected issue date: FY 2010; work in progress)

Medication Therapy Management Program

We will review whether Part D sponsors have enrolled qualified beneficiaries into a medication therapy management program (MTMP) and submitted administrative costs that were supportable, reasonable, and allowable. An MTMP is designed 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 are likely to incur annual costs of at least \$4,000 for all covered Part D drugs for CYs 2007 and 2008. We will determine whether MTMPs have operated in accordance with Federal regulations.

(OAS; W-00-10-35410; various reviews; expected issue date: FY 2010; work in progress)

Less-Than-Effective and Terminated Drugs in Part D

We will review PDE data to determine whether less-than-effective or terminated drugs were included in the Part D drug claims. The Social Security Act, § 1860D-2(e)(1), defines a Part D drug to include those drugs that may be dispensed only by prescription and that meet the requirements of the Social Security Act, § 1927(k)(2), which requires drug approval by FDA. FDA may disapprove an application for approval of a new drug as being less than effective if, pursuant to 21 CFR § 314.125(b), the application lacks substantial evidence of effectiveness of the drug for all conditions of use prescribed, recommended, or suggested in its labeling.

Terminated drugs are drugs that have been pulled from the market or whose expiration dates on the last batches sold have passed. We will determine whether PDEs for less-than-effective or terminated drugs are included as part of the Part D sponsors' reconciliations.

(OAS; W-00-09-35233; W-00-10-35233; various reviews; expected issue date: FY 2010; work in progress)

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 Part D sponsors are appropriately processing Medicare Part D claims for Schedule II drugs (drugs with an accepted medical use and a high potential for abuse and dependency). Pursuant to the Social Security Act, § 1860(D)-15(f)(1), sponsors must submit the information necessary for the Secretary to determine payments to the plan and HHS has the right to inspect and audit the sponsors' records pertaining to this information.

(OAS; W-00-10-35411; various reviews; expected issue date: FY 2010; work in progress)

Medicare Prescription Drug Plans' Formulary Changes

We will review whether Medicare Part D sponsors reporting of midyear formulary changes to CMS complies with applicable requirements. Pursuant to 42 CFR § 423.120(b)(5), Part D sponsors must notify CMS and receive approval prior to removing covered Part D drugs from their plans' formularies or changing the preferred or tiered cost-sharing status of covered Part D

drugs during a contract year. Changes in formularies during the contract year can adversely affect beneficiaries. Beneficiaries may lose coverage of a needed drug or may pay larger copayments if a Part D sponsor moves a drug to a higher tier. We will determine the extent to which Part D sponsors met the 60-day requirement to submit proposed midyear formulary changes to CMS.

(OEI; 01-08-00540; expected issue date: FY 2010; work in progress)

True Out-of-Pocket Costs for Part D

We will review the accuracy of Part D sponsors' tracking of beneficiaries' true out-of-pocket (TrOOP) costs. The Social Security Act, § 1860D-2(b)(4), "Annual Out-of-Pocket Threshold," states that for 2007, once an enrollee has reached \$3,850 in annual TrOOP costs (or \$5,451 in total drug spending), the enrollee has met the annual out-of-pocket threshold and the enrollee's cost sharing is capped (referred to as the catastrophic coverage phase). We will determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify toward such catastrophic coverage.

(OAS; W-00-09-35234; W-00-10-35234; various reviews; expected issue date: FY 2010; new start)

Beneficiaries' Experiences With Low-Income Subsidies and Availability of Drug Benefits

We will survey Medicare beneficiaries about their experiences with low-income subsidies (LIS) and the availability of benefits in Medicare Part D. The Social Security Act, § 1860D-14, added by the MMA, includes an LIS provision to help beneficiaries with limited income and resources pay for prescription drugs. Reports by the Government Accountability Office (GAO) and MedPAC have raised concerns about the LIS, including low enrollment of eligible beneficiaries in the LIS program, decreases in the number of prescription drug plans available to LIS beneficiaries, and a lack of coverage stability from year to year. We will also describe the drug benefits in prescription drug plans available to LIS beneficiaries.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Bid Submission by Part D Sponsors

We will review the approved bids submitted to CMS by Part D sponsors to determine whether negotiated price estimates were properly supported. As provided in the Social Security Act, § 1860D-11(b), to become a Part D sponsor, 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 providing coverage of Part-D-qualified prescription drugs. The Secretary determines the monthly payment amounts based on these approved bids as described in the Social Security Act, § 1860D-15(a)(1)(A) and 42 CFR § 423.329. CMS's Bid Instructions require sponsors to report all rebates as part of bid proposals. Specifically, all rebates and price concessions not used to directly reduce the cost at the point of sale must be included in a bid. Further, rebates and price concessions must be reported in full. This review will determine whether sponsors followed CMS's instructions for reporting price concession estimates in their bids.

(OAS; W-00-08-35413; W-00-09-35413; W-00-10-35413; various reviews; expected issue date: FY 2010; work in progress)

Administrative Costs Included in Bid Submissions

We will review the appropriateness of Part D sponsors' documentation supporting administrative costs included in their annual bid proposals to CMS. The Social Security Act, § 1860D-11(b), and regulations at 42 CFR § 423.265(c)(1) require that Part D sponsors submit bids for the costs of providing prescription drug coverage, including administrative costs. Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. *(OAS; W-00-10-35506; various reviews; expected issue date: FY 2011; new start)*

Part D Sponsors' Audits of Pharmacies

We will review the process that Part D sponsors and their pharmacy benefit managers (PBM) use in auditing pharmacies. These audits are needed to validate payments by the sponsors to pharmacies and the contracts between pharmacies and sponsors generally allow for these audits. We will identify amounts recouped from the pharmacies and ensure that the amounts have been properly reported as overpayments to CMS. The "Medicare Part D Reporting Requirements for Contract Year 2007," section X, "Overpayments," states: "Part D Contracts will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Contract erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit." We will determine whether recoveries made by Part D sponsors or their PBMs are properly accounted for. *(OAS; W-00-10-35235; various reviews; expected issue date: FY 2011; new start)*

Disenrollment of Deceased Beneficiaries

We will review whether Part D sponsors carry deceased beneficiaries as current enrollees. Pursuant to Federal regulations at 42 CFR § 423.44(b)(2)(iii), "Required Involuntary Disenrollment," Part D sponsors must disenroll individuals upon their deaths. We will determine whether CMS made payments to Part D sponsors for deceased beneficiaries. We performed similar reviews in Medicaid and found several instances in which States reimbursed claims for deceased beneficiaries. *(OAS; W-00-09-35415; W-00-10-35415; various reviews; expected issue date: FY 2010; work in progress)*

E-Prescribing in Part D

We will review the extent to which Medicare Part D sponsors have adopted the standards established by CMS for e-prescribing. E-prescribing allows providers and pharmacists to electronically transmit prescriptions and other prescription-related information for Part D eligible individuals. The Social Security Act, § 1860D-(4)(e), as amended by the MMA, requires Part D plans to support an electronic prescription program for any providers and pharmacies that voluntarily choose to use e-prescribing. CMS promulgated technical standards for e-prescribing at 42 CFR § 423.160. The Secretary identified e-prescribing as a priority health information technology initiative for HHS. We will also describe the design and implementation of sponsors' initiatives to promote adoption of CMS e-prescribing standards. *(OEI; 05-08-00322; expected issue date: FY 2010; work in progress)*

Oversight of Pharmacy Benefit Managers

We will review CMS's and Medicare Part D plan sponsors' oversight of PBMs, which are subcontractors that administer important Part D functions on behalf of the Part D plan sponsors. Part D sponsors' contracts with PBMs are required by 42 CFR § 423.505(i) to contain certain

administrative and legal provisions that include reporting responsibilities, performance monitoring, and compliance. As part of our review of the effectiveness of CMS's and sponsors' oversight of PBMs, we will specifically determine whether Part D plan sponsors' contracts with PBMs include provisions required by Federal regulations.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Oversight of Prescription Drug Event Data

We will examine CMS's validation of PDE data and determine whether CMS has sufficient edits in place to validate PDE records with invalid provider identifiers or national drug codes. Pursuant to the Social Security Act, §§ 1860D-15(c)(1)(C) and (d)(2), added by the MMA, and 42 CFR § 423.322, sponsors must submit the information necessary for CMS to administer Part D payment provisions for the coverage year. We will determine the extent to which CMS's validation of the provider numbers, alternate service provider numbers, and national drug codes included in PDE records ensured that final PDE data included only records with valid provider and drug identifiers.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Part D Drug Claims With Inactive or Invalid Physician Identifier Numbers

We will review Part D prescription drug event records for prescription drug claims to determine the extent to which prescription drugs are being billed and paid using inactive or invalid unique physician identifier numbers (UPIN), NPIs, and provider identifiers. Pursuant to the Social Security Act, §§ 1860D-15(c)(1)(C) and (d)(2), and 42 CFR § 423.322, sponsors must submit information necessary for CMS to administer Part D payment provisions for the coverage year. CMS uses PDE data to validate claims and to perform oversight of quality and program integrity. We will also explore the characteristics of invalid identifiers and PDE records submitted with these invalid identifiers.

(OEI; 03-09-00140; expected issue date: FY 2010; work in progress and OAS; W-00-10-35513; various reviews; expected issue date: FY 2010; new start)

Medicare Part D Payments for Drugs Prescribed or Provided by Excluded Providers

We will review whether Medicare Part D sponsors have appropriately denied claims for drugs prescribed or provided by providers who have been excluded from Medicare, Medicaid, and other Federal health care programs. The Social Security Act, § 1862(e)(1), and regulations at 42 CFR § 1001.1901(b)(1) prohibit payments for drugs prescribed by excluded providers. Further, CMS's "Prescription Drug Benefit Manual," Pub. No. 100-18, ch. 9, § 50.2.6.3.3, states that Part D sponsors should not pay for drugs prescribed or provided by providers excluded by HHS OIG or the General Services Administration (GSA). We will examine Medicare Part D payment data and nationwide drug utilization to determine whether costs submitted by Part D sponsors were for drugs prescribed or provided by excluded providers.

(OAS; W-00-09-35231; W-00-10-35231; various reviews; expected issue date: FY 2010; work in progress)

Investment Income Earned by Part D Plans

We will review the appropriateness of Part D sponsors' documentation supporting investment income included in their annual bid proposals to CMS. Pursuant to Federal regulations at 42 CFR § 423.265(c)(1), Part D sponsors are required to submit bids for the costs of providing

prescription drug coverage, including returns on investment and profits. Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. (OAS; W-00-10-35507; various reviews; expected issue date: FY 2011; new start)

Part D Pharmaceutical Manufacturer Rebates

We will review contracted pharmaceutical manufacturer rebates collected by Part D sponsors and PBMs. Under the payment methodology in 42 CFR pt. 423, subpart G, Part D reinsurance and risk corridor payments are calculated based on amounts actually paid by the Part D sponsors, net of DIR, which include all rebates, subsidies, and other price concessions from sources (including but not limited to manufacturers and pharmacies) that serve to decrease the costs incurred by Part D sponsors for Part D drugs. The term "risk corridor" relates to triggers that are set to protect prescription drug plans from unexpected losses and that allow the Government to share in unexpected gains. In its guidance on reporting requirements, CMS requires that Part D sponsors submit DIR reports for use in the Part D payment reconciliation process. We will identify rebate amounts negotiated between Part D sponsors/PBMs and pharmaceutical manufacturers, compare them with the actual rebates paid, and analyze any discrepancies.

(OAS; W-00-10-35508; various reviews; expected issue date: FY 2011; new start)

Alternative Calculation of Part D Rebates

We will apply the Medicaid percentage rebate amount (such as the higher of 15 percent of AMP or Best Price required by the Medicaid drug rebate program) to Medicare Part D covered brand-name drugs to determine the amount that could be saved if the Part D program required drug manufacturers to pay a similar standard percentage rebate compared to the DIR reported. The Social Security Act, § 1860D-2(d)(2), requires Part D sponsors to disclose aggregate price concessions made available to sponsors by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies. In addition, sponsors must report to CMS all price concessions received for use in the annual reconciliation process.

(OAS; W-00-10-35509; various reviews; expected issue date: FY 2011; new start)

Drug Costs Paid by Part D Sponsors Under Retail Discount Generic Programs

We will review drug costs for specific Part D covered drugs on PDE records to determine whether contracted prices between pharmacies and Part D sponsors were accurately reflected. Sponsors contract with pharmacies to dispense drugs to eligible Medicare beneficiaries and pay negotiated rates for drugs dispensed to these beneficiaries. The Social Security Act, § 1860D-4(b), states that "A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan." We will also review contracts between sponsors and pharmacies and PDE records to determine the extent to which sponsors and the Federal Government have benefited from retail discount generic programs.

(OAS; W-00-10-35510; various reviews; expected issue date: FY 2011; new start)

Medicare Part D Program Audit Overview

We will review CMS's Medicare Part D program audits performed since the program's inception in 2006 to determine the extent to which they uncovered violations that resulted in corrective action. The Social Security Act, § 1860D-12(b)(3)(C), added by the MMA, governs audit

authority for Medicare Part D. This review is part of a series of OIG reviews examining CMS's performance of Part D program, bid, financial, and compliance audits.
(*OEI; 03-09-00330; expected issue date: FY 2010; work in progress*)

Audits of Part D Sponsors' Financial Records

We will review CMS's audits of Part D sponsors' financial records to determine whether they were conducted in accordance with Federal regulations. The Social Security Act, § 1860D-12(b)(3)(c), and Federal regulations at 42 CFR § 423.504(d)(1) require that CMS annually audit financial records (including but not limited to data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs, low-income subsidies, and other costs) of at least one-third of Part D sponsors offering Part D drug plans. We will determine whether CMS has met Federal regulations in conducting Part D audits. We will also examine CMS's audit guide, the timeliness of its audits, and actions taken to address audit findings. This review is part of a series of OIG reviews examining CMS performance of required Part D program, bid, financial, and compliance audits.

(*OAS; W-00-10-35511; various reviews; expected issue date: FY 2011; new start*)

Medicare Part D Sponsors' Internal Controls for Fraud, Waste, and Abuse

We will review the reliability of Medicare Part D sponsors' internal controls to guard against fraud, waste, and abuse. The MMA added a requirement in the Social Security Act, § 1864D-4(c), that Part D sponsors have programs to control fraud, waste, and abuse. In addition, Federal regulations at 42 CFR § 423.504(b)(4)(vi)(H) require Part D sponsors to have in place compliance plans that include comprehensive plans to detect, correct, and prevent fraud, waste, and abuse. CMS has issued additional guidance to Part D sponsors in its "Prescription Drug Benefit Manual," Pub. No. 100-18, ch. 9, that provides both interpretive rules and guidelines for Part D sponsors for implementing the regulatory requirements at 42 CFR § 423.504(b)(4)(vi)(H).

(*OAS; W-00-10-35512; various reviews; expected issue date: FY 2010; new start*)

Medicare Part D Price Concessions

We will review the extent to which Part D sponsors receive price concessions. We will also assess how these Part D sponsors report price concessions to CMS. The Social Security Act, § 1860D-2(d)(1)(A), requires a Part D sponsor to provide its enrollees with access to negotiated prices for covered Part D drugs. Regulations at 42 CFR § 423.100 define negotiated prices as prices for covered Part D drugs that 1) are available to beneficiaries at the point of sale at network pharmacies; 2) 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 3) 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.

(*OEI-02-08-00050; expected issue date: FY 2010; work in progress*)

Medicaid Program

The Federal and State governments jointly fund Medicaid, a program that provides medical assistance to certain low-income individuals. Overall, HHS estimated that the Federal Government's share of medical assistance payments in FY 2009 will be approximately 57 percent. The Federal share of a State's expenditures is called the Federal medical assistance percentage (FMAP). The FMAP has a floor rate of 50 percent, and for FY 2009, the highest FMAP is 75.84 percent. States have considerable flexibility in structuring their Medicaid programs within broad Federal guidelines governing eligibility, provider payment levels, and benefits. As a result, Medicaid programs vary widely from State to State.

Our ongoing and new reviews of Medicaid in FY 2009 address payments related to hospitals, long-term and community care, prescription drugs, other services, Medicaid administration, and information systems controls. We are also continuing to review issues related to Medicaid payments and costs related to the Gulf Coast hurricanes.

Medicaid Hospitals

State Medicaid Agency Policies to Deny Payment for Hospital-Acquired Conditions

We will review policies adopted by State Medicaid programs related to adverse events, including events designated in CMS's list of hospital-acquired conditions. Section 5001(c) of the DRA mandated that the Medicare program deny hospitals higher payment for discharges that are complicated by hospital-acquired conditions designated by CMS. In July 2008, CMS provided guidance in its State Medicaid Directors Letter No. 08-004 encouraging State Medicaid programs to implement their own payment policies regarding adverse events. The guidance outlined options that States could consider, including adopting Medicare's policy or developing alternative policies. We will examine the characteristics and implementation of State policies and explore their potential impact on the Medicaid program and its beneficiaries.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Hospital Outlier Payments

We will review State Medicaid payments for hospital outliers, which are cases that incur extraordinarily high costs. 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. The Social Security Act, § 1886(d)(5)(A), provides for supplemental Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for outlier cases. We will determine whether similar vulnerabilities exist in Medicaid State agencies' methods of computing inpatient hospital cost outlier payments. This is a followup to work previously performed involving Medicaid outlier payments.

(OAS; W-00-09-31069; W-00-10-31069; various reviews; expected issue date: FY 2010; work in progress)

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 medical equipment and supplies 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-00-10-31301; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Disproportionate Share Hospital Payment Distribution

We will review the Medicaid inpatient utilization rate used to determine eligibility for Medicaid DSH payments. The Social Security Act, § 1923(d)(3), 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 appropriateness of this threshold and, if appropriate, recommend changes to the program.

(OAS; W-00-09-31302; W-00-10-31302; various reviews; expected issue date: FY 2010; work in progress)

Supplemental Payments to Private Hospitals

We will review Medicaid supplemental payments made by States to private hospitals. States are permitted to make payments under their approved plans to hospitals up to the applicable aggregate UPL, and many States use this flexibility to make lump-sum supplemental payments based on the difference between the ordinary rate and the UPL. Federal regulations at 42 CFR § 447.272 define the UPL for inpatient hospital services as 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. In addition, 42 CFR § 447.253(i) requires the Medicaid agency to pay “for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.” Prior OIG work involving supplemental payments to public facilities identified errors. We will determine whether errors exist involving supplemental payments to private facilities.

(OAS; W-00-10-31126; various reviews; expected issue date: FY 2010; work in progress)

Potentially Excessive Medicaid Payments for Inpatient and Outpatient Services

We will review State controls to detect potentially excessive Medicaid payments to institutional providers for inpatient and outpatient services. OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Att. A, § C.1.a, states that to be allowable, costs must be necessary and reasonable for the proper and efficient performance and administration of Federal awards. Further, section C.1.c of the circular states that costs must be authorized, or not prohibited, under State or local laws or regulations. The Social Security Act, § 1903(d)(2)(A), and the regulations at 42 CFR pt. 433, subpart E, provide for the adjustment of quarterly payments to States by CMS to account for overpayments and underpayments made by States to providers. Prior OIG work involving Medicare inpatient and outpatient claims found that many claims resulting in excessive payments to the hospitals were attributable to billing errors on the submitted claims, such as inaccuracies in the diagnosis codes, admission codes, discharge codes, procedure codes, charges, Healthcare Common Procedure Coding System (HCPCS) codes, and

number of units billed. We will determine whether similar vulnerabilities exist in State agencies' controls for detecting potentially excessive Medicaid payments.

(OAS; W-00-09-31127; W-00-10-31127; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Home, Community, and Nursing Home Care

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 (FFP). OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, establishes cost principles for State and local governments. Attachment A, § C.1.c., of the circular 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 a community residence.

(OAS; W-00-08-31087; W-00-09-31087; W-00-10-31087; various reviews; expected issue date: FY 2010; work in progress)

Targeted Case Management

We will review Medicaid payments made for targeted case management services. The Social Security Act, § 1915(g)(2), 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-00-08-31082; W-00-09-31082; W-00-10-31082; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Payments to Continuing Day Treatment Providers

We will review Medicaid payments made to continuing day treatment (CDT) providers in one State. CDT providers render an array of services to persons with mental illness on a relatively long-term basis. A CDT provider bills Medicaid based on the number of service hours rendered to a beneficiary. OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Att. A, § C.1.c., states that to be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. One State's regulations require that a billing for a visit/service hour be supported by documentation indicating the nature and extent of services provided. A State commission found that more than 50 percent of the service hours billed by CDT providers could not be substantiated. We will follow up on the commission's

findings and determine whether Medicaid payments made to CDT providers in that State are adequately supported.

(OAS; W-00-09-31128; W-00-10-31128; various reviews; expected issue date: FY 2010; work in progress)

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 42 CFR pt. 484 set forth standards and conditions for HHAs' 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 that care. The care must include intermittent (not full-time) skilled nursing care and may include physical therapy or speech-language pathology services.

(OAS; W-00-09-31304; W-00-10-31304; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Payments for Personal Care Services

We will review Medicaid payments for personal care services to determine whether States have appropriately claimed FFP. Pursuant to the Social Security Act, § 1905(a)(24), Medicaid covers personal care services only for individuals who are not inpatients or residents of hospitals, nursing facilities, institutions for mental diseases (IMD), or intermediate care facilities for persons with mental retardation. Personal care services must be authorized for the individual by a physician or (at the option of the State) otherwise authorized for the individual 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-00-08-31035; W-00-09-31035; W-00-10-31035; various reviews; expected issue date: FY 2010; work in progress)

Compliance With States' Requirements for Medicaid-Funded Personal Care Service Attendants

We will review the extent to which States made erroneous Medicaid payments for personal care services provided by attendants who were not in compliance with State-established requirements. CMS's "State Medicaid Manual," Pub. No. 45, pt. 4, §§ 4442.4 and 4480, requires States to develop qualifications for providers of personal care services and establish mechanisms for monitoring the quality of the services. Pursuant to the Social Security Act, §§ 1902 and 1915, States may receive FFP for personal care services only if the providers have met State-established qualifications. A 2005 OIG review found that requirements for attendants often differed among various State plan and waiver programs. In selected States, we will determine whether attendants' qualifications have met their States' requirements.

(OEI; 07-08-00430; expected issue date: FY 2010; 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 the Social Security Act, § 1902(a)(10)(D), States are required to offer home health services to Medicaid beneficiaries who meet the States' criteria for nursing home coverage. Under § 1902(a)(25), Medicaid is the payer of last resort, paying only after Medicare has met its legal obligation to pay. We will determine in selected States 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.

(OAS; W-00-09-31305; W-00-10-31305; various reviews; expected issue date: FY 2010; work in progress)

State and Federal Oversight of Home- and Community-Based Services in Assisted Living Facilities

We will determine the extent to which assisted living facilities (ALF) provide home- and community-based services (HCBS) to Medicaid beneficiaries residing in the facilities. These facilities may receive Medicaid funding through the HCBS waiver program under the Social Security Act, § 1915(c). Under 42 CFR § 441.302, States are required to provide CMS with assurances that necessary safeguards have been taken to protect the health and welfare of HCBS beneficiaries. We will determine how States and CMS ensure that ALFs are meeting provider standards, that plans of care are established and followed by ALFs, and that ALFs meet other Federal requirements for HCBS services.

(OEI; 09-08-00360; expected issue date: FY 2010; work in progress)

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

We will review States' and CMS's oversight of 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, a 2003 GAO review found that CMS and the States did not provide adequate oversight of HCBS waivers. We will determine the extent to which States are complying with Federal regulations for HCBS waiver programs. We will also review CMS's processes for monitoring States' compliance with these requirements.

(OEI; 02-08-00170; expected issue date: FY 2010; work in progress)

Medicaid Adult Day Health Service Payments for Ineligible and Absent Beneficiaries

We will review the appropriateness of Medicaid payments for adult day health services. The Social Security Act, § 1915(c)(4)(B), allows Medicaid payments for adult health services through home- and community-based waiver programs. Previous OIG 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 also determine whether medical records at selected adult day health centers are complete and accurate.

(OEI; 09-07-00500; expected issue date: FY 2010; work in progress)

Oversight of Nursing Home Minimum Data Set Data

We will review CMS's oversight of Minimum Data Set (MDS) data submitted by nursing homes certified to participate in Medicare or Medicaid. The Social Security Act, §§ 1819(b)(3)(A)(iii) and 1819(e)(5), and corresponding sections of Title XIX of the Social Security Act require nursing homes to conduct accurate comprehensive assessments for residents using a resident assessment instrument that includes the MDS. Regulations at 42 CFR § 483.20 specify the requirements of the assessment instrument. MDS data include the residents' physical and cognitive functioning, health status and diagnoses, preferences, and life care wishes. CMS implemented a SNF PPS based on MDS data in July 1998 and began posting MDS-based quality performance information on its Nursing Home Compare Web site in 2002. Approximately half of the States also use MDS data as the basis of their Medicaid payment systems. We will review CMS's processes for ensuring that nursing homes submit accurate and complete MDS data.
(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Transparency Within Nursing Facility Ownership

We will review ownership structures at investor-owned nursing homes. Nursing facilities are increasingly being purchased by private equity or other for-profit investor firms. Prior OIG work showed that after the facility purchase, in some cases, new owners created a complex web of ownership that essentially left the operators of the nursing facility with no assets. Determination of which entity is legally liable for patient care can be made difficult because of the ownership structure. In addition, after the facility purchase, in some cases, new owners have reduced staffing levels and taken other cost-cutting measures that increase profit at the expense of quality of care. We will determine which entities are benefiting from the Medicaid reimbursement and study the effects of these types of ownership changes on the care received by beneficiaries in nursing homes.

(OAS; W-00-10-31130; various reviews; expected issue date: FY 2010; work in progress)

States' Administration and Use of Civil Monetary Penalty Funds in Medicaid Nursing Homes

We will examine how States administer and use civil monetary penalties (CMP) imposed on nursing homes that fail to meet Medicare and Medicaid health and safety requirements. The Social Security Act, § 1919(h)(2)(A)(ii), requires that States use the CMP funds they collect to ensure the safety of residents of the penalized nursing homes. We will identify the amounts that States have received as a result of imposing CMPs, determine what policies and procedures States have to ensure that CMP funds are allocated appropriately to meet Federal requirements, and determine how and to what extent CMS oversees States' use of CMP funds.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Medicaid Nursing Home Patients: Quality of Care

We will review Medicaid data to identify nursing facilities that may have provided substandard care resulting in or contributing to beneficiaries' subsequent hospital admissions, including those for diagnoses of pressure sores, infections, or both. Federal regulations at 42 CFR § 483.25 require facilities to provide beneficiaries necessary care and services to attain the highest practicable physical well-being in accordance with comprehensive assessments and plans of care and to ensure, for example, that no pressure sores develop unless such sores are clinically

unavoidable. OIG work has identified instances when nursing home residents covered by Medicaid were admitted to hospitals with conditions that reflect poor quality of care.
(OAS; W-00-10-31330; various reviews; expected issue date: FY 2010; new start)

Medicaid Incentive Payments for Nursing Facility Quality-of-Care Performance Measures

We will review Medicaid incentive payments that States have made to nursing facilities based on the facilities' quality-of-care performance measures. The Social Security Act, § 1919(h)(2)(F), authorizes States to establish programs to reward nursing facilities—through public recognition, incentive payments, or both—that provide the highest quality care to their Medicaid-eligible residents. We will determine whether States have sufficient controls to assess nursing facilities' quality-of-care performance measures and determine whether States have made incentive payments in accordance with program requirements.
(OAS; W-00-10-31331; various reviews; expected issue date: FY 2010; new start)

Medicaid Waiver Administrative Costs

We will review the reasonableness of Medicaid HCBS waiver program administrative costs. The Federal share of Medicaid matches most administrative expenditures at the 50-percent rate if the expenditures are for the “proper and efficient” administration of the Medicaid program. The Social Security Act, § 1915(c), authorizes the HCBS waiver program, which permits States to furnish arrays of services that assist Medicaid beneficiaries to live in the community and avoid institutionalization. Some States have contracted with nonprofit groups to administer waiver programs. Because CMS's methodology for reviewing waiver applications does not examine administrative costs, it may be possible that States have claimed the Federal share of contracted administrative costs at amounts in excess of Medicaid's actual average administrative costs. We will determine whether States' contractual arrangements with nonprofit entities for administration of HCBS waiver programs are economical.
(OAS; W-00-10-31332; various reviews; expected issue date: FY 2010; new start)

Medicaid Prescription Drugs

Timely Submission of Average Manufacturer Price Data

We will review whether drug manufacturers have reported AMPs to CMS in a timely manner. The Social Security Act, § 1927(b)(3), requires manufacturers to report AMP data to CMS within 30 days of the close of each quarter. Section 6001(b) of the DRA expands the reporting obligations by requiring manufacturers to report AMP data on a monthly basis. AMPs are necessary to calculate the ceiling price under section 340B of the PHS Act and, in the future, may be used to establish Medicaid Federal Upper Limits (FUL) (the maximum amount that federally funded programs may pay for certain drugs) pursuant to section 6001 of the DRA. If AMPs are not reported within the required timelines, the 340B program and CMS will not have complete data on which to base 340B prices and FUL amounts, thereby causing both programs potentially to overpay for prescription drugs. In a previous OIG report, we found that for almost 14 percent of drugs, AMP data were missing, thus preventing the calculation of the 340B ceiling

price. We will assess the timeliness of drug manufacturers' reporting of AMPs to CMS during 2008.

(OEI; 03-09-00060; expected issue date: FY 2010; work in progress)

Calculation of Average Manufacturer Prices

We will review selected drug manufacturers to evaluate the methodologies that they use to calculate their AMPs and the best price for the Medicaid drug rebate program and for Medicaid drug reimbursement purposes. We will determine whether the methodologies are consistent with applicable statutes, regulations, manufacturers' 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 that will affect the amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program and affect the FUL for drug reimbursement. CMS uses the AMP and the best price to determine a unit rebate amount (URA). Manufacturers must pay rebates to States based on the URAs.

(OAS; W-00-10-31202; various reviews; expected issue date: FY 2011; new start)

Recalculation of Base Date Average Manufacturer Prices

We will review changes to base date AMP and assess the impact of these changes on Medicaid rebates. Section 6001 of the DRA made numerous changes and clarifications to the definition and use of AMP. Section 1927(c) mandates an additional rebate to be paid by manufacturers for single-source drugs, which is based on the difference between AMP and the base date AMP adjusted for inflation. To ensure that the rebate would not increase because of the changes in the AMP, Federal regulations at 42 CFR § 447.510(c) allow manufacturers to revise the base date AMPs against which these inflationary measures are indexed. Because these additional rebates paid by manufacturers are an integral and statutorily required aspect of the Medicaid drug rebate program, we will examine manufacturers' rationale and supporting data for making changes to base date AMPs.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

States' Medicaid Drug Claims

We will review the accuracy of States' submission of Medicaid drug claims to CMS for reimbursement. Pursuant to the Social Security Act, § 1927(a)(1), 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 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 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 States are correct and supported for the drugs claimed.

(OAS; W-00-10-31203; various reviews; expected issue date: FY 2010; work in progress)

Federal Upper Payment Limit Drugs

We will review prescription drug claims to determine whether pharmacies have altered prescriptions to maximize reimbursements by avoiding certain dosage forms for drugs that have FULs on reimbursements. The Social Security Act, § 1927(e)(4), establishes Federal upper limits for all multiple-source drugs. As a result of whistleblowers' actions, several pharmacies

have admitted to changing dosage forms for some commonly prescribed Medicaid drugs, thereby inflating reimbursements by avoiding the FULs established on other dosage forms. We will determine whether there has been manipulation of the FULs.

(OAS; W-00-10-31333; various reviews; expected issue date: FY 2011; new start)

Pharmacy Prescription Drug Claims

We will review the appropriateness of Medicaid pharmacy prescription drug claims for selected State Medicaid agencies. CMS's "State Medicaid Manual," Pub. No. 45, pt. 2, §§ 2497 and 2500, requires that States report actual expenditures on the Medicaid Quarterly Expenditure Report (Form CMS-64) and maintain supporting documentation. We will determine whether States accurately reported Medicaid expenditures for prescription drugs and whether the claims related to the expenditures were adequately supported by pharmacy records.

(OAS; W-00-09-31318; various reviews; expected issue date: FY 2011; work in progress)

Medicaid Payments for Drugs Not Approved for Use by Children

We will review Medicaid paid claims to determine whether payments were made for drugs that are not approved for children by FDA. The Social Security Act, §1905(a), provides that State Medicaid plans may cover prescription drugs. Pursuant to the Social Security Act, §§ 1927(k)(3) and 1927(k)(6), Medicaid will pay for an outpatient drug if it is prescribed for indications approved by FDA or supported by the drug compendia listed in 1927(g)(1). We will examine drug services paid for children under the age of 18 in 2007 by reviewing States' Medicaid and CHIP paid claims files.

(OAS; W-00-10-31131; various reviews; expected issue date: FY 2011; new start)

Medicaid Third-Party Liability for Prescription Drug Payments

We will review a State's controls to determine whether third-party providers are billed for Medicaid fee-for-service (FFS) prescription drug claims before Medicaid pays. Pursuant to the Social Security Act, § 1902(a)(25), participating States must "take reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the [Medicaid] plan." In this regard, the Office of the Auditor General for one State identified almost \$30 million in drug claims during a 2-year period that may have been the responsibility of a third-party insurance payer. We will review the State's process for identifying and billing third-party payers.

(OAS; W-00-10-31134; various reviews; expected issue date: FY 2010; work in progress)

Compound Drugs

We will review whether a State agency's Medicaid claims for compound drugs (custom-blended by pharmacists from bulk ingredients based on doctors' prescriptions) and the drugs' components complied with Federal requirements for reimbursement and collection of rebates. The Social Security Act, § 1927, generally requires manufacturers to have a rebate agreement with CMS for States to claim FFP and report drug utilization to the manufacturers for rebates. The CMS Medicaid Drug Rebate Program State Release No. 130 requires States to use the CMS drug tape, which lists all drugs covered by rebate agreements pursuant to the Social Security Act, § 1927(a)(1), to determine whether drugs they purchase are eligible for Medicaid coverage. CMS Medicaid Drug Rebate Program State Release No. 19 outlines States' responsibility for preventing claims for terminated drugs. We will identify claimed drug components that are not

eligible for Medicaid coverage and determine whether accountability and controls were established for collecting eligible drug component rebates.

(OAS; W-00-08-31317; W-00-09-31317; W-00-10-31317; various reviews; expected issue date: FY 2010; 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. Section 4401 of the Omnibus Budget Reconciliation Act of 1990, 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 best price data provided by drug manufacturers.

(OAS; W-00-09-31306; W-00-10-31306; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Reimbursement for Unapproved Drugs

We will review whether Medicaid pays for drugs that have not been approved by FDA. The Social Security Act, § 1905(a), provides that State Medicaid plans may cover prescription drugs. For the purposes of section 1905(a), Medicaid will pay for an outpatient drug only if FDA has approved it. Preliminary analysis of Medicaid payment data indicates that the program may be paying for drugs that have not received FDA approval. We will determine how State Medicaid agencies use FDA databases to identify unapproved drugs.

(OEI; 03-08-00500; expected issue date: FY 2010; work in progress)

The Deficit Reduction Act of 2005: Impact on Medicaid Rebates for Authorized Generic Drugs

We will review required drug-pricing and rebate data reported by drug manufacturers to State Medicaid agencies to determine the extent to which manufacturers are reporting pricing data and paying rebates for authorized generic drugs. Authorized generics are defined in 42 CFR § 447.506 as versions of brand-name drugs produced and/or marketed with the consent of the original brand manufacturers and marketed under the brand manufacturers' original drug applications. The rebates due to States from drug manufacturers under the Social Security Act, § 1927, are based in part on the difference between the AMP of a drug and the best price of the drug. Section 6001 of the DRA clarified the definition of "best price" to include "the lowest price available to any entity for any such drug that is sold under a new drug application." CMS stated in its 2007 final rule on Medicaid prescription drugs that best price calculations must now include the prices available to secondary manufacturers of authorized generic drugs. This definitional change has the potential to increase the amount of rebates due from single-source drugs' primary manufacturers. We will also determine to what extent Medicaid rebates have changed since the implementation of the DRA and whether the number of new authorized generics changed after the implementation of these DRA provisions.

(OEI; 00-00-00000; expected issue date: FY 2010; 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 § 433.32 require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. During our follow-up reviews, we will review State Medicaid agencies' collection of brand-name drug manufacturer rebates for physician-administered drugs since the passage of the DRA. Pursuant to section 6002 of the DRA, States are required to collect data necessary to enable them to collect rebates on physician-administered drugs. Previous OIG work found that the majority of States were not collecting Medicaid rebates for physician-administered drugs and that most States had weaknesses in accountability and internal controls over their drug rebate programs. We will determine whether States have established adequate internal controls over their Medicaid drug rebate programs. We will also determine whether State Medicaid agencies followed Federal regulations when collecting brand-name drug manufacturer rebates for physician-administered drugs.

(OAS; W-00-08-31205; W-00-09-31205; W-00-10-31205; various reviews; expected issue date: FY 2010; work in progress)

Update of States' Collection of Medicaid Rebates for Physician-Administered Drugs

We will review State Medicaid agencies' policies and practices to determine the extent to which they are collecting drug manufacturers' rebates for physician-administered drugs and estimate the savings that could result if all States collected these rebates. Pursuant to section 6002 of the DRA, States are required to collect utilization and coding information for single-source drugs and 20 multiple-source drugs that have the highest dollar volume of physician-administered drugs dispensed. States must collect such information as is necessary to obtain the manufacturers' rebates. Previous OIG work determined that most States had not collected rebates for physician-administered drugs.

(OEI; 03-09-00410; expected issue date: FY 2010; work in progress)

Medicaid Claims for Drugs Purchased Under Retail Discount Generic Programs

We will review Medicaid claims for generic drugs to determine the extent to which large chain pharmacies are billing Medicaid the usual and customary charges for drugs provided under their retail discount generic programs. These discount programs typically offer selected generic drugs to anyone with a prescription for \$4 for a 30-day supply or \$10 for a 90-day supply. Federal regulations at 42 CFR § 447.512 require, with certain exceptions, that each State Medicaid agency's reimbursement for covered generic outpatient drugs without established upper limits may not exceed (in the aggregate) the lower of the estimated acquisition cost for drugs, plus a reasonable dispensing fee, or the provider's usual and customary charge to the public for the drugs. We will also examine CMS's policies and procedures for ensuring that Medicaid is billed properly under retail discount generic programs.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Review of Medicaid Reimbursement to 340B Entities

We will review State Medicaid agencies' reimbursements under the 340B Drug Pricing Program, which provides for sales of drugs at or below established ceiling prices to covered entities (340B entities) that provide health care to certain disadvantaged individuals. Pursuant

to section 340B(a)(5)(A) of the PHS Act, when using the 340B program to purchase drugs for individuals who are Medicaid beneficiaries, 340B entities are required to bill State Medicaid programs for reimbursement at their actual acquisition costs to prevent duplicate Federal discounts on drug purchases. We will determine whether such entities have billed Medicaid their actual acquisition costs and, if not, how much Medicaid could save if all 340B entities were to bill Medicaid their actual acquisition costs. We will also determine the cost to Medicaid if 340B entities were reimbursed for all Medicaid drug purchases at the standard Medicaid reimbursement rates.

(OEI; 05-09-00320; expected issue date: FY 2010; work in progress)

High-Cost HIV/AIDS Drugs

We will review Medicaid payments for high-cost human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) drugs to determine the amount Medicaid could save by using centralized purchasing and dispensing programs. During recent audits of the Federal AIDS Drug Assistance Program (ADAP), we identified one State that had purchased all ADAP drugs through a single contracted wholesale drug company and dispensed the drugs to ADAP-eligible participants through State-contracted pharmacies. Our preliminary analysis indicates that this centralized approach produced significant savings.

(OAS; W-00-10-31334; various reviews; expected issue date: FY 2011; new start)

Pharmacy Benefit “Carve Out”

We will review pharmacy benefit costs to determine how much States’ Medicaid programs could save if their pharmacy benefit programs for providing prescription drugs to beneficiaries were “carved-out” of Medicaid Managed Care and administered entirely under the States’ FFS programs. The Social Security Act, § 1927(a)(1), requires drug manufacturers to enter into national rebate agreements with CMS for States to receive Federal funding for drugs dispensed to Medicaid beneficiaries under the States’ FFS programs. However, the Social Security Act, § 1927(j), excludes from the Drug Rebate Program drugs dispensed under Medicaid Managed Care; i.e., managed care organizations (MCO) that administer Medicaid pharmacy benefit programs do not receive manufacturer rebates. We will determine the extent to which States are not realizing potential cost savings because of allowing MCOs to administer their pharmacy benefit programs.

(OAS; W-00-10-31335; various reviews; expected issue date: FY 2011; new start)

Reporting Lowest Accepted Reimbursement Rates

We will review one State’s use of a provision in its prescription drug reimbursement agreements that requires pharmacies to report their lowest accepted reimbursement rates from nongovernmental payers for each drug. The State’s Medicaid program then reimburses pharmacies at the lower of those rates or 11 percent below the average wholesale price (AWP) for the each drug. We will determine whether the State’s use of this provision has resulted in significant savings for the State’s Medicaid program and whether other State Medicaid programs could benefit from implementing similar provisions in their reimbursement agreements.

(OAS; W-00-10-31336; various reviews; expected issue date: FY 2011; new start)

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

We will review States' use of AMPs to set Medicaid pharmacy reimbursement amounts. Although States are not required to use AMPs as a basis for their reimbursements to pharmacies, the use of AMP is expected to result in reimbursements that are more accurate and reduce Medicaid prescription drug expenditures. Based on State data and actuarial adjustments, CMS estimated in its FY 2009 budget justification that Federal payments for Medicaid prescription drugs will be about \$10.7 billion in FY 2009, after offsetting rebates. Section 6001(b) of the DRA requires CMS to provide States with the manufacturer-reported AMP data on a monthly basis. However, a court injunction imposed in December 2007 has enjoined CMS from disclosing AMP data. Our previous work found that as of October 2006, most States had not yet decided whether to use AMP data. If the injunction is resolved in a manner that would allow CMS's implementation of the DRA requirement, we will conduct this follow-up review to provide an update on States' use of AMPs in setting reimbursement and examine the factors States consider in their decisions regarding AMPs.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Zero-Dollar Unit Rebate Amounts for Drugs in Medicaid's Drug Rebate Program

We will review whether States are effectively collecting drug rebates from manufacturers for drugs with zero-dollar URAs. At the end of every quarter, CMS calculates a URA for each drug included in the Medicaid drug rebate program and provides this amount to State Medicaid agencies. These URAs are based on pricing data reported by drug manufacturers. Previous OIG work found that States may not be collecting all possible drug rebates from manufacturers for drugs when CMS is unable to calculate the URA. This occurs if and when a manufacturer has not reported the necessary data for the calculation. In these cases, the URA for a product is listed as \$0, i.e., a zero-dollar URA. However, States are still required to work with manufacturers to determine the appropriate rebate for this drug.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Other Medicaid Services

Medicaid Dental Services

We will review Medicaid payments for dental services to determine whether States have properly claimed FFP. Pursuant to the Social Security Act, §§ 1905(a)(4)(B) and 1905(r), dental services are required for most Medicaid-eligible individuals under the age of 21 as a component of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services benefit. Federal regulations at 42 CFR § 440.100 define dental services as diagnostic, preventative, or corrective procedures provided by or under the supervision of a dentist. Services include the treatment of the teeth and associated structure of the oral cavity and disease, injury, or impairment that may affect the oral cavity or general health of the recipient. In 2007, Medicaid costs for dental services totaled more than \$3 billion.

(OAS; W-00-09-31135; W-00-10-31335; various reviews; expected issue date: FY 2010; work in progress)

Family Planning Services

We will review family planning services in several States to determine whether enhanced Federal funding was improperly claimed for such services and the resulting financial impact on the Medicaid program. Pursuant to the Social Security Act, § 1903(a)(5), States may claim Medicaid reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. Prior OIG work identified improper claims for enhanced funds for family planning services.

(OAS; W-00-09-31078; W-00-10-31078; various reviews; expected issue date: FY 2010; 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. We will determine the appropriateness of State Medicaid agencies' payments for transportation services.

(OAS; W-00-08-31121; W-00-09-31121; W-00-10-31121; various reviews; expected issue date: FY 2010; work in progress)

Early and Periodic Screening, Diagnostic, and Treatment Services

We will review the extent to which Medicaid-eligible children receive appropriate EPSDT services. The Social Security Act, §§ 1905(a)(4) and 1905(r), provides for periodic screening for vision, dental, hearing, and other necessary health services to Medicaid-eligible individuals under the age of 21. The EPSDT program is designed to screen at periodic intervals and diagnose and treat medical conditions that might otherwise go undetected or untreated. This study will also describe States' efforts to increase children's participation in EPSDT screenings.

(OEI; 05-08-00520; expected issue date: FY 2010; work in progress)

Payments to Terminated and/or Excluded Medicaid Providers and Suppliers

We will review Medicaid payments to providers and suppliers to determine the extent to which payments were for services provided during periods of termination or exclusion from the Medicaid program. Pursuant to the Social Security Act, §§ 1128 and 1128A, excluded and/or terminated providers and suppliers are not permitted to receive payments for services provided after their effective program termination date or during periods of exclusion.

(OAS; W-00-10-31337; various reviews; expected issue date: FY 2010; new start)

Medicaid Claims With Inactive or Invalid Physician Identifier Numbers

We will review Medicaid claims to determine the extent to which State agencies have controls in place to identify claims associated with inactive or invalid UPINs, including claims for services allegedly provided after the dates of the referring physicians' deaths. In a prior OIG review, we identified instances when Medicare had paid DME claims with inactive or invalid UPINs for the referring physicians. In 2009, the Senate Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, reported that a substantial volume of Medicare-paid DME claims contained UPINs of deceased physicians. Given the vulnerabilities identified in the Medicare program, we will review State Medicaid

programs to determine whether States have controls in place to identify claims with inactive or invalid UPINs.

(OAS; W-00-10-31338; various reviews; expected issue date: FY 2010; new start)

Rehabilitative Services

We will review claims for rehabilitative services to determine whether the services met Federal reimbursement requirements. The Social Security Act, § 1905(a)(13), defines rehabilitative services as any medical or remedial services provided in a facility, a home, or other setting. The services must be recommended by a physician or other licensed practitioner of the healing arts for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level. Previous OIG reviews found a significant number of services claimed that were not eligible for reimbursement.

(OAS; W-00-08-31028; W-00-10-31028; various reviews; expected issue date: FY 2010; 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 the Social Security Act, § 1903(v), 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-00-07-31108; W-00-08-31108; W-00-09-31108; W-00-10-31108; various reviews, expected issued date: FY 2010; work in progress)

Medicaid Payments for Personal Emergency Response Services

We will review one State's Medicaid payments made to providers of personal emergency response services (PERS) to determine the allowability of those payments for Federal matching. PERS, which are electronic devices designed to enable individuals to summon help in emergencies, are provided to Medicaid beneficiaries in conjunction with either personal care or home health care services. Providers of PERS bill Medicaid based on the installation and monthly use of the PERS equipment. The State has promulgated Medicaid reimbursement regulations related to PERS setting forth the conditions under which PERS are available and requiring that PERS be authorized by physicians. We will determine whether Medicaid payments made by the State to PERS providers met Federal and State requirements.

(OAS; W-00-10-31339; various reviews; expected issue date: FY 2010; new start)

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 under Medicare were medically unnecessary, were billed incorrectly, or were rendered by unqualified providers. Through a medical review, we will determine whether Medicaid has similar program integrity issues.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

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, "Cost Principles for State, Local, and Indian Tribal Governments," 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-00-07-31045; W-00-08-31045; W-00-09-31045; W-00-10-31045; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Payments for Services 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 the Social Security Act, § 1915(b), 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 evaluate the actuarial soundness of the managed care capitation rates.

(OAS; W-00-08-31125; W-00-09-31125; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Managed Care Fraud and Abuse Safeguards

We will review State Medicaid agencies' oversight plans and procedures to determine the extent to which States monitor MCOs' fraud and abuse program safeguards for compliance with Federal requirements. Pursuant to 42 CFR § 438.608, Medicaid MCOs must have administrative and management arrangements or procedures, including mandatory compliance plans, that are designed to guard against fraud and abuse. We will also review CMS's plans and procedures for overseeing States' compliance with these requirements.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Medicaid Managed Care Marketing Practices

We will review State Medicaid agencies' oversight policies, procedures, and activities to determine the extent to which States monitor MCOs' marketing practices and compliance with Federal and State contractual marketing requirements. The Social Security Act, § 1932(d)(2), provides that no marketing materials may be distributed by Medicaid MCOs without first obtaining States' approval. Under 42 CFR § 438.104, States may impose additional requirements in their contracts with MCOs regarding marketing activities. We will also

determine the extent to which CMS ensures States' compliance with Federal requirements involving Medicaid managed care marketing practices.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

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 section 1915(b) waivers are also known as managed care/freedom of choice waivers, and section 1915(c) waivers are also 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; W-00-10-31309; various reviews; expected issue date: FY 2010; work in progress)

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 the Social Security Act, § 1915(c) waiver authority, CMS may authorize States to expand the term "medical assistance" to include HCBS pursuant to written plans of care. Such services can include both traditional medical services and support services, e.g., respite care and case management. In addition, the waivers allow family members to provide services if they meet certain requirements.

(OAS; W-00-09-31124; W-00-10-31124; various reviews; expected issue date: FY 2010; work in progress)

Enrollment of Excluded Medicaid Providers

We will review States' processes for enrolling Medicaid providers. Specifically, we will focus on a subset of Medicaid providers who were subsequently excluded from participating in Federal health care programs. Pursuant to 42 CFR pt. 455, subpart B, States are required to collect information from providers regarding the ownership of health care entities and criminal convictions as part of the enrollment process for participating in Federal health care programs. However, there is no corresponding requirement that States verify the information. Previous GAO and OIG reviews found that most States had not verified information that providers submitted in their applications nor required periodic reenrollment. We will assess the prevalence of judgments, tax liens, and criminal convictions among a population of excluded Medicaid providers and the extent to which States had checked providers' backgrounds both before and after enrollment. We will also determine how much States reimbursed these providers when they were active.

(OEI; 09-08-00330; expected issue date: FY 2010; work in progress)

State Agencies' Redeterminations of Medicaid Eligibility

We will review the State agencies' procedures for redetermining the eligibility status of Medicaid beneficiaries. During recent audits of Medicaid payments for services provided to

beneficiaries with concurrent eligibility in two States, we found that eligibility status reviews were not always performed in a timely manner. Federal regulations at 42 CFR § 435.916 require that State agencies redetermine the eligibility of Medicaid beneficiaries, with respect to circumstances that may change, at least every 12 months. We will determine the amount of unallowable payments associated with beneficiaries who did not receive the required Medicaid eligibility redeterminations.

(OAS; W-00-09-31140; W-00-10-31140; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Administrative Costs

We will review administrative costs claimed by several States. The Social Security Act, § 1903(a)(7), provides 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, “Cost Principles for State, Local, and Indian Tribal Governments,” and State requirements.

(OAS; W-00-08-31123; W-00-10-31123; various reviews; expected issue date: FY 2010; work in progress)

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, the Social Security Act, § 1862(b), and 42 CFR pt. 411 require participating providers to furnish information about payments made to them and to refund any moneys incorrectly paid. For Medicaid, the Social Security Act, § 1902(a)(25); regulations at 42 CFR pt. 433, subpart D; and various State laws require that Medicaid be the payer of last resort and that providers identify and refund overpayments received. Prior OIG work has identified Medicare and Medicaid overpayments in patients’ accounts with credit balances.

(OAS; W-00-09-31311; W-00-10-31311; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Management Information System Costs

We will review Medicaid Management Information System (MMIS) costs in selected States to determine whether costs allocated to Medicaid are allowable. The Social Security Act, § 1903(a)(3), as implemented by 42 CFR pt. 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; W-00-09-31312; W-00-10-31312; various reviews; expected issue date: FY 2010; work in progress)

State Buy-In of Medicare Coverage

We will review States’ Medicaid buy-in programs of Medicare Part B. States may enroll dual-eligible beneficiaries in the Medicare Part B program. The Social Security Act, § 1843, and 42 CFR §§ 407.40 through 407.42 require States that operate buy-in programs to pay the Medicare Part B premium for each dual-eligible individual that they enroll in the Medicare

Part B program. We will determine whether States have adequate controls to ensure that Medicare premiums are paid only for individuals eligible for State buy-in coverage of Medicare services.

(OAS; W-00-09-31220; W-00-10-31220; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Services to Incarcerated Juveniles

We will review States' compliance with Federal rules that exclude Federal funding for medical services to incarcerated juveniles. The Social Security Act, § 1905(a)(28)(A), specifically excludes Federal funding for services provided to inmates of a public institution (except patients in medical institutions). Further, 42 CFR § 435.1010 defines an inmate of a public institution as "a person who is living in a public institution." It defines "public institution" as "an institution that is the responsibility of a governmental unit over which a governmental unit exercises administrative control." Previous work had identified unallowable claims in this area. We will determine whether States have improperly claimed Federal funding for medical services provided to incarcerated juveniles.

(OAS; W-00-07-31222; W-00-10-31222; various reviews; expected issue date: FY 2010; work in progress)

Medicaid's All-Inclusive Rate for Reimbursement to the Indian Health Service

We will review IHS's calculation of the all-inclusive rate (AIR). Pursuant to section 402 of the Indian Health Care Improvement Act of 1976 (IHCA), Medicaid programs reimburse IHS and tribal facilities for outpatient services provided to Medicaid beneficiaries. Medicaid programs reimburse the facilities using the AIR, which is derived from hospital cost reports and is published annually in the Federal Register. However, the types of outpatient services billed to Medicaid at the AIR vary by State. We will also examine CMS's oversight of AIR.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

States' Effort To Improve Third-Party Liability Payment Collections in Medicaid

We will review States' procedures for identifying and collecting third-party payments for services provided to Medicaid beneficiaries to determine the extent to which States' efforts have improved since our last review in 2006. The Social Security Act, § 1902(a)(25), requires States to take all reasonable measures to ascertain the legal liabilities of third parties with respect to health care items and services. Section 6035 of the DRA clarified this provision for entities defined as third-party payers. Many Medicaid beneficiaries may have additional health insurance through third-party sources, such as employer-sponsored health insurance. Previous OIG work detailed problems experienced by State Medicaid agencies with identifying and collecting third-party payments. We will identify changes made to State laws and Medicaid procedures and determine whether such changes have improved States' identification of third-party liabilities.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

States' Use of the Public Assistance Reporting Information System to Reduce Medicaid Benefits Received From More Than One State

We will review eligibility data from the Public Assistance Reporting Information System (PARIS) to determine the extent to which States use PARIS to identify Medicaid recipients who are simultaneously receiving Medicaid benefits in more than one State. PARIS is a computer

matching and information exchange system operated by the Administration for Children and Families (ACF). Using States' eligibility data, PARIS identifies individuals who are concurrently receiving benefits from Medicaid and other means-tested programs, such as Food Stamps, in more than one State. The QI Program Supplemental Funding Act of 2008 amended the Social Security Act, § 1903, to require that States' Medicaid eligibility determination systems provide data matching through PARIS by October 1, 2009. We will also determine the extent to which States investigate instances in which recipients are receiving Medicaid benefits in more than one State simultaneously and recover Medicaid payments for recipients determined to be ineligible.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

States' Compliance With Estate Recovery Provisions of the Social Security Act

We will review States' compliance with requirements for recoveries from deceased Medicaid beneficiaries' estates. Pursuant to the Social Security Act, § 1917(b)(1), States must, with certain exceptions, recoup medical assistance costs from the estates of deceased beneficiaries who were institutionalized. States generally can recover medical assistance costs of inpatient stays at nursing facilities, intermediate care facilities for the mentally retarded, or other medical institutions. In addition, States may opt to recover costs of other services covered under the States' Medicaid plans if the individuals were 55 or older when the services were provided. Pursuant to the Social Security Act, § 1917(b)(4), States at a minimum must recover assets that pass through probates governed by States' laws. CMS's "State Medicaid Manual," Pub. No. 45, pt. 2, § 2500.1, requires that the amounts collected from deceased Medicaid beneficiaries' estates be reported on the Medicaid Quarterly Expenditure Report (Form CMS-64) as reductions to total Medicaid expenditures. We will determine whether States complied with applicable requirements in making estate recoveries and properly reported any such recoveries on the Form CMS-64.

(OAS; W-00-09-31113; W-00-10-31113; various reviews; expected issue date: FY 2010; work in progress)

Medicaid Claims That Exceed Timely Filing Requirements

We will review Medicaid payments to determine whether States have improperly received Federal Medicaid reimbursement for claims that exceeded timely filing requirements. Federal regulations at 42 CFR § 447.45(d) provide that State Medicaid agencies require providers to submit all claims no later than 12 months from the dates of services. An OIG review in one State identified Medicaid claims that exceeded the 12-month filing requirement and therefore should not have been submitted.

(OAS; W-00-10-31340; various reviews; expected issue date: FY 2010; new start)

State Medicaid Agencies' Reclassification of Non-Federal Claims

We will review Medicaid payments to determine whether State Medicaid agencies are reclassifying non-Federal claims as federally participating, thus claiming Federal matching funds for non-Medicaid services and beneficiaries. State Medicaid agencies use their MMISs to process and pay claims for non-Federal as well as federally participating programs. In a prior OIG review, we reported that one State had improperly designated non-Federal claims as Medicaid, resulting in unallowable claims for Federal matching funds.

(OAS; W-00-10-31341; various reviews; expected issue date: FY 2010; new start)

Feasibility of Applying Medicare National Correct Coding Initiative Edits to Medicaid Claims

We will apply Medicare National Correct Coding Initiative (CCI) edits to Medicaid outpatient claims to estimate the amount that could be saved if State Medicaid agencies implemented CCI edits. CCI edits are not required for Medicaid claims. Previous OIG work on this issue determined that 39 States paid \$54 million for services that would have been denied based on CCI edits.

(OAS; W-00-10-31342; various reviews; expected issue date: FY 2010; new start)

States' Efforts in Medicaid Enrollment, Outreach, and Retention

We will review States' implementation of the Medicaid enrollment, outreach, and retention provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) to determine whether implementing these provisions has resulted in increased Medicaid enrollment. Section 104 of CHIPRA provides bonuses based on the number of new enrollees to States that adopt at least five of eight listed enrollment policies. We will compare trends in Medicaid enrollment before and after implementation of CHIPRA.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Medicare and Medicaid Information Systems and Data Security

OIG reviews the design, development, and maintenance of HHS computer-based systems by performing comprehensive audits of general and applications controls in accordance with applicable control requirements. Our work in progress and planned reviews deal with standards, security, controls, and oversight of the information systems that support Medicare and Medicaid payments and operations. This section describes reviews involving the controls, security, and oversight aspects of Medicare and Medicaid systems and data.

Medicare Annual Reports to Congress on Contractor Information Systems Security Programs

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and MACs. Section 912 of the MMA requires annual independent evaluations of security programs of FIs, carriers, and MACs and subsequent OIG assessment of these evaluations. OIG is required to annually report the results of its assessments to Congress. Our report to Congress will include our assessment of the scope and sufficiency of the evaluations performed and will summarize the results of independent evaluations.

(OAS; W-00-10-41010; expected issue date: FY 2010; 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 information technology closeout audits at Medicare contractors that left the program during FYs 2007 and 2008 to assess compliance with applicable Federal requirements. Section 911 of the MMA requires the Secretary 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. 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 Common Working File (CWF) system, and Medicare banking records need to be terminated as soon as the contractors' performance periods end.

(OAS; W-00-10-41011; various reviews; expected issue date: FY 2010; new start)

Medicare Part D Selected Controls for Systems Tracking True Out-of-Pocket Costs

We will review selected Medicare Part D general and application controls at the CMS contractor, known as the TrOOP facilitator, 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 controls related to software development changes. We will also review application controls, including ensuring the accuracy and completeness of standard transactions generated by the TrOOP facilitator for covered prescriptions and documenting payers that are secondary to Medicare. The transactions are transmitted by the TrOOP facilitator to the plans, which use them to compute beneficiary TrOOP for covered prescription drugs. We will follow up on issues identified in a prior audit of a TrOOP facilitator.

(OAS; W-00-10-41012; expected issue date: FY 2010; new start)

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

We will review implementation of systems to support the Part D prescription drug benefit plan and expansion of beneficiary choices at MA plans, small- to medium-size Part D sponsors, and other Part D sponsors 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 systems supporting key Part D components, such as beneficiary enrollment, coordination of benefits TrOOP costs, and PDE operations. We will follow up on issues identified in prior reviews of larger plans.

(OAS; W-00-10-41013; various reviews; expected issue date: FY 2010; new start)

Medicare and Medicaid Security of Portable Devices Containing Personal Health Information at Contractors and Hospitals

We will review security controls implemented by Medicare and Medicaid contractors as well as hospitals to prevent the loss of protected health information stored on portable devices and media, such as laptops, jump drives, backup tapes, and equipment considered for disposal. Recent breaches related to Federal computers, including one involving a CMS contractor, have heightened concerns about protecting sensitive information. OMB Memorandum M-06-16, issued June 23, 2006, recommended that all Federal departments and agencies take action to

protect sensitive information by following the National Institute of Standards and Technology's Special Publications 800-53 and 800-53A. We will assess and test contractors' and hospitals' policies and procedures pertaining to electronic health information protections, access, storage, and transport.

(OAS; W-00-10-41014; various reviews; expected issue date: FY 2010; new start)

Medicare and Medicaid Health Information Data Privacy

We will review HIPAA-covered Medicare and Medicaid program providers' compliance with the HIPAA Privacy Rule requirements defined in 45 CFR § 160.103. The standards to protect the privacy of individually identifiable health information required under 45 CFR parts 160 and 164 are known as the HIPAA Privacy Rule. The standards apply to HIPAA "covered entities," including Medicare and Medicaid providers. OCR is responsible for overseeing compliance with and enforcement of this regulation. We will review the adequacy of OCR's oversight of the HIPAA Privacy Rule.

(OEI; 00-00-00000; various reviews; expected issue date: FY 2011; new start)

Medicaid Management Information Systems Business Associate Agreements

We will review CMS's oversight activities related to data security requirements of States' MMISs, which 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 are among the covered entities that must comply with HIPAA Security Final Rules, which stipulate minimum requirements that must be included in contracts with business associates to protect the privacy and security of certain electronic personally identifiable health information. We will determine whether business associate agreements have been properly executed to protect beneficiary information, including safeguards implemented pursuant to HIPAA standards.

(OAS; W-00-10-41015; various reviews; expected issue date: FY 2010; new start)

Medicaid Security Controls Over State Web-Based Applications

We will review States' security controls over Web-based applications that allow Medicaid providers to electronically submit claims. The electronic transactions may contain protected health information as defined under HIPAA. The regulation at 45 CFR § 160.103 includes Medicaid programs within the meaning of "health plans" that must comply with the security standards set forth in 45 CFR § 164.306, pt. 164, subpart C, of the HIPAA Security Rule. Using an application security assessment tool, we will determine whether States' Web-based applications contain any vulnerabilities that would potentially affect the confidentiality, integrity, and availability of the Medicaid claims' protected health information.

(OAS; W-00-10-41016; various reviews; expected issue date: FY 2010; new start)

Medicaid Security Controls at the Mainframe Data Center That Processes States' Claims Data

We will review security controls at CMS's mainframe data center that processes Medicaid claims data received from States. OMB Circular A-130, "Management of Federal Information Resources," Appendix III, paragraph A.3, states that agencies shall implement and maintain programs to ensure that adequate security is provided for all agency information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. The Appendix also establishes a minimum set of controls to be included in Federal

automated information security programs. We will focus on security controls over CMS's mainframe computer, such as access controls over the mainframe operating system and security software. In addition, we will review some limited general controls, such as disaster recovery plans and physical security.

(OAS; W-00-07-40019; expected issue date: FY 2009; work in progress)

Children's Health Insurance Program

CHIP is a partnership between Federal and State governments that helps provide low-income children with health insurance coverage. The program improves access to health care and quality of life for millions of vulnerable children under 19 years of age. CHIP reaches children whose families have incomes too high to qualify for Medicaid, but too low to afford private health insurance. States with approved CHIP plans are eligible for Federal matching payments. Our reviews typically focus on eligibility and payment issues, administrative costs, and error rate measurement.

Medicaid and Children's Health Insurance Program Citizenship Requirements

We will review the eligibility status of Medicaid beneficiaries to ensure that States are meeting the new citizenship requirements. As of July 1, 2006, all individuals who apply for Medicaid or renew their Medicaid eligibility must prove their citizenship by presenting, among other possible documents, a U.S. passport or the combination of a U.S. birth certificate and an identification document. States that provide Medicaid eligibility to individuals who have not proven their citizenship may not claim Federal matching funds for Medicaid-covered services to those individuals. The new requirement was mandated by section 6036 of the DRA. As of April 1, 2009, CHIPRA gave States a new option to provide legal immigrant children and pregnant women Medicaid and CHIP coverage during their first five years in the country and requires new verification of legal residence requirements be met when they renew their Medicaid and CHIP eligibility. We will determine whether States implemented the citizenship requirement and document the amount of payments made on behalf of individuals not meeting the new citizenship requirements.

(OAS; W-00-09-31224; W-00-10-31224; various reviews; expected issue date: FY 2010; work in progress)

Children's Health Insurance Program Administrative Costs

We will review States' CHIP compliance with the 10-percent cap on administrative costs. The Social Security Act, § 2105(c)(2)(A), establishes a limit on administrative funds that are eligible for Federal matching equal to 10 percent of the amounts expended to provide child health assistance. Administrative expenditures include expenditures related to administration, outreach, and other child health assistance and initiatives. We will determine whether States have appropriately claimed administrative costs.

(OAS; W-00-09-31226; W-00-10-31226; various reviews; expected issue date: FY 2010; work in progress)

Dually Enrolled Beneficiaries in a State

We will review a State's claims for FFP under the State's CHIP program for individuals who were enrolled in the State's Medicaid program to determine the appropriateness of these claims. Pursuant to the Social Security Act, § 2105(c)(6)(B), no payment shall be made to a State for expenditures for child health assistance provided for a targeted low-income child under its plan to the extent that payment has been made or can reasonably be expected to be made promptly under any other federally operated or financial health care insurance program. A previous OIG review of CHIP eligibility in one State for the first 6 months of 2005 indicated that the State had made some CHIP payments on behalf of individuals who were also enrolled in the Medicaid program.

(OAS; W-00-10-31314; various reviews; expected issue date: FY 2010; work in progress)

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

We will review CMS's Payment Error Rate Measurement (PERM) process to determine whether the PERM has produced valid and reliable error rate estimates for Medicaid and CHIP FFS, managed care, and eligibility. The IPIA and OMB's implementation of that act in memorandum M-06-23 require Federal agencies annually to develop statistically valid estimates of improper payments made under programs with a significant risk of erroneous payments. Medicaid and CHIP have been identified as programs with significant risks and programs for which OMB has requested improper payment information. To comply with the IPIA, CMS developed the PERM, which was to be fully implemented in FY 2008. The PERM process includes conducting fee-for-service, managed care, and eligibility reviews pursuant to 42 CFR pt. 431, subpart Q. As part of OIG's oversight and monitoring responsibilities of CMS's error rate process, we will review CMS's implementation of the PERM process for Medicaid and CHIP. We will also review the physical and data security of health information that is transmitted by States or contractors for use in the PERM process to assess compliance with OMB Memorandums M-06-16 and M-07-16, which provide guidance on protecting sensitive information and reporting incidents involving potential and confirmed breaches of personally identifiable information.

(OAS; W-00-10-40036; various reviews; expected issue date: FY 2010; new start)

Compliance With Payment Error Rate Measurement Program: Medicaid and Children's Health Insurance Program Eligibility Determinations

We will review compliance in one State with PERM requirements for reviewing eligibility in its Medicaid and CHIP programs. The IPIA of 2002 and OMB's implementations of that act in memorandum M-06-23 require Federal agencies annually to develop statistically valid estimates of improper payments made under programs with significant risk of erroneous payments. To comply with the IPIA, CMS developed the PERM program, which was to be fully implemented in FY 2008. The PERM process includes conducting FFS, managed care, and eligibility reviews pursuant to 42 CFR Part 431, subpart Q. As part of the PERM program, CMS requires States to have an independent review performed of Medicaid and CHIP eligibility determinations to assess whether the State is in compliance with the State's eligibility requirements and has properly documented its eligibility determinations. As part of OIG's oversight and monitoring responsibilities under the Chief Financial Officers Act of 1990 related to CMS's error rate

process, we will review implementation of the PERM process for Medicaid and CHIP in one State.

(OAS; W-00-10-40038; expected issue date: FY 2010; new start)

Investigative and Legal Activities Related to Centers for Medicare & Medicaid Services Programs and Operations

OIG conducts investigations of fraud and misconduct to safeguard HHS's programs and to protect the beneficiaries of those programs. Investigations are designed to detect and prevent waste, fraud, and abuse in HHS programs. Our investigations result in criminal prosecutions 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 our attention for review, investigation, and appropriate resolution. The nature and volume of complaints cannot be predicted. Our Work Plan identifies investigative focus areas on which we will concentrate our resources, subject to the demands of current complaint referrals. In addition to meeting our programmatic requirements, we will continue to review and investigate allegations of misconduct and wrongdoing within HHS. We carry out this responsibility to ensure that HHS personnel and contractors uphold the highest level of integrity.

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 CMPs and assessments. OCIG also negotiates and monitors corporate integrity agreements (CIA). OCIG issues special fraud alerts, special advisory bulletins, and advisory opinions regarding the application of our sanction authorities and is responsible for developing OIG regulations, including new safe harbor regulations under the anti-kickback statute, and compliance program guidance.

Our health care investigations and legal activities span the Medicare and Medicaid programs. Following are some examples of where we will continue to focus attention.

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 entities, such as the Federal Bureau of Investigation, the United States Postal Inspection Service, the Internal Revenue Service, and State Medicaid Fraud Control Units (MFCU).

We 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 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 also conduct investigations specifically related to the Medicare Part D drug benefit and assist CMS in identifying program vulnerabilities. We are currently investigating matters involving enrollment and marketing schemes; prescription shorting (dispensing fewer doses of a drug than prescribed, charging the full amount, and instructing the customer to return to pick up the remainder); and health care fraud. Working with other law enforcement partners at the Federal, State, and local levels, we 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 Strike Force work related to fraudulent DME. The Strike Force model brings together a multiorganizational, multidisciplinary Task Force project that uses real-time analysis of Medicare billing data, as well as findings from earlier investigations, to identify, investigate, and prosecute individuals and companies that have committed DME fraud. Strike Forces have been used in South Florida, Detroit, Houston, and Los Angeles. The Strike Force model will be applied to other regions when circumstances are favorable to the use of this approach in combating health care fraud.

We will continue to examine quality-of-care issues in nursing facilities and other care settings to detect and prevent fraud and abuse perpetrated against beneficiaries and the Medicare and Medicaid programs. We will investigate instances in which the programs may have been billed for medically unnecessary services or 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 continue to investigate allegations of patient abuse or neglect and work with the MFCUs to provide assistance in this area.

We will continue to conduct investigations related to false claims submitted to Medicaid, such as those for services not rendered, for substandard care provided to nursing home residents, or when payment codes were manipulated in an effort to inflate reimbursement amounts. We will continue to strengthen coordination between the Office of Investigations and organizations such as the National Association of Medicaid Fraud Control Units and National Association for Medicaid Program Integrity.

Exclusions From Program Participation

OIG has authority to exclude individuals and entities from participation in Medicare, Medicaid, and all other 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. We impose exclusions based on referrals 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. In FY 2008, we reported exclusions of 3,129 individuals and entities from Federal health care programs and anticipate reviewing and implementing the exclusion of

additional providers in FY 2010. As appropriate, the Office of Investigations and OCIG expect to initiate program exclusions against individuals and entities that submitted false or fraudulent claims; failed to provide services that met professionally recognized standards of care; or otherwise engaged in conduct actionable under the Social Security Act, § 1128, 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, we 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 us. 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. In a 2006 Open Letter to Health Care Providers, we encouraged providers to disclose improper arrangements under the physician self-referral law (42 U.S.C. § 1395nn) and committed, in appropriate cases, to settling liability under OIG's authorities, generally for an amount near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred. On April 15, 2008, we issued an additional open letter that discussed certain refinements and clarifications to OIG's policies to increase the efficiency of the self-disclosure protocol and benefit providers that self-disclose.

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.

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

When adequate evidence of violations exists, OIG staff will continue to work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal false claims cases against individuals and entities that defraud the Government. Authorities relevant to this work come from the False Claims Amendments Act of 1986. 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 our 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 us, 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, on providers that breach their integrity agreement obligations.

Advisory Opinions, Fraud Alerts, and Other Industry Guidance

As part of our 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. For example, In FY 2008, we issued a revised supplemental compliance program guidance (CPG) for nursing facilities, updating the original CPG published in 2000 to reflect OIG's focus on quality of care issues, including staffing, care plan development, and patient neglect and abuse.

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 the Social Security Act, § 1128B(b); violations of EMTALA; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

Public Health and Human Service Programs and Departmentwide Issues

Based on our available resources during each fiscal year (FY), we allocate about 20 percent of our appropriations to oversight of approximately 300 Department of Health and Human Services (HHS) public health and human service programs and certain departmentwide issues. This part of the Work Plan describes our ongoing and planned activities in public health and human services, categorized by agency, and summarizes our work on departmentwide issues.

Public Health Programs

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 HHS include the following:

- Centers for Disease Control and Prevention (CDC). CDC operates a system of health surveillance to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.
- Food and Drug Administration (FDA). FDA is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.
- Health Resources and Services Administration (HRSA). 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.
- Indian Health Service (IHS). IHS provides or funds health care services for 1.6 million American Indians and Alaska Natives.
- National Institutes of Health (NIH). NIH supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).
- Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds services to improve the lives of people with or at risk for mental and substance abuse disorders.

In addition, 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, 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. The Office of Human Research Protections oversees the protection of volunteers involved in research. The following sections describe the reviews that are planned with regard to the Office of Inspector General's (OIG) oversight of public health programs.

Agency for Healthcare Research and Quality

Bioterrorism Epidemic Outbreak Response Model

We will survey State and local governments to determine the extent to which they are aware of and use the Bioterrorism Epidemic Outbreak Response Model (BERM) and "Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness" (the planning guide). The Pandemic and All-Hazards Preparedness Act established ASPR within HHS and provided new authorities for a number of preparedness and response activities, including the development of guidance for States and localities to use when preparing for large-scale public health emergencies. In 2001, AHRQ developed the BERM at ASPR's request and BERM model 2.0 was re-released in 2005. ASPR's predecessor funded the planning guide in 2004. We will also assess whether BERM and the planning guide meet States' and localities' needs for planning for medical surge (medical evaluation and care during events that exceed the limits of the normal medical infrastructure of an affected community) and community-based mass prophylaxis (measures designed to preserve health or prevent the spread of disease).
(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Centers for Disease Control and Prevention

Monitoring of Subrecipient Emergency Preparedness Expenditures

We will review the adequacy of one State's monitoring of subrecipient expenditures charged to the Public Health Emergency Preparedness (PHEP) program. The purpose of this program is to upgrade and integrate State and local public health jurisdictions' preparedness for and response to terrorism and other public health emergencies. Pursuant to Office of Management and Budget (OMB) Circular A-87, "Cost Principles for State, Local, and Indian Tribal Governments," App. B, § h(3) (in the Code of Federal Regulations (CFR) at 2 CFR pt. 225), State grantees of the PHEP program are required to provide time and effort certifications for employees who are expected to work solely on that Federal award. Under 45 CFR § 92.40, grantees must also manage and monitor day-to-day operations of their subgrantees to ensure compliance with Federal requirements. A prior review disclosed that one State was not able to provide the required certifications for its employees who charged 100 percent of their time and effort to the PHEP program. We will determine whether similar salary charges have been made at the

subrecipient level and assess the adequacy of the State's subrecipient expenditure-monitoring process.

(OAS; W-00-10-58140; expected issue date: FY 2010; new start)

States' 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 the United States Code (U.S.C.), 42 U.S.C. §§ 247d-3 and 247d-3a, CDC funds PHEP 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 urgent disease and public health emergency reporting systems 24 hours per day, 7 days per week (24/7 systems). These 24/7 systems 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. We will evaluate States' 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 2011; new start)

Fraud and Abuse Safeguards for the Vaccines for Children Program

We will review Vaccines for Children (VFC) grantees' compliance with CDC's fraud and abuse program safeguard requirements. The Social Security Act, § 1902(a)(62), requires that a program for vaccinating eligible children be included in each State's Medicaid eligibility plan. The Social Security Act, § 1928, provides for the Federal Government to purchase vaccines on behalf of States as part of the vaccination program. CDC requires VFC grantees to develop and implement comprehensive fraud and abuse policies. Specifically, grantees must submit written fraud and abuse policies to CDC annually. We will also review the adequacy of CDC's oversight of VFC grantees' fraud and abuse activities.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Community Health Centers Adoption of Recommendations for Human Immunodeficiency Virus Testing in Health Care Settings

We will review the extent to which health care providers in community health centers are aware of and have adopted CDC's recommendations for HIV testing in health care settings. Each year, 56,300 people in the United States become infected with HIV. CDC's recommendations, issued on September 22, 2006, aim to make HIV testing a routine part of medical and prenatal care and are a key strategy in CDC's effort to reduce the number of new HIV infections in the United States by 50 percent. Intended for all health care providers in the public and private sectors, CDC's recommendations include the following: HIV screening for all patients ages 13 to 64 in a health care setting; inclusion of HIV screening in the routine panel of prenatal tests for all pregnant women, unless the patient declines; and incorporation of HIV screening into the general consent for medical care rather than requiring a separate consent. We will also review activities CDC has undertaken to encourage community health centers to adopt CDC's HIV guidelines.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Grantees' Implementation of National Breast and Cervical Cancer Early Detection Program Management Guidance

We will review the extent to which grantees of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) have implemented NBCCEDP program components and assess CDC oversight of grantees' program management activities. Through State grantees, NBCCEDP funds breast and cervical cancer screening and diagnostic services for low-income, uninsured, and other women who have difficulty gaining access to health care. The Breast and Cervical Cancer Mortality Prevention Act of 1990 outlines required grantee activities (e.g., providing screening, treatment referrals, education, and conducting self-evaluation). We will also determine the extent to which CDC ensures that NBCCEDP grantees develop workplans, implement program components, and evaluate their performance on these components in accordance with CDC recommendations.

(OEI; 04-09-00400; expected issue date: FY 2010; work in progress)

Deemed Exports

We will review CDC's compliance with the Department of Commerce's (DOC) Export Administration Regulations at 15 CFR, Chapter VII, subchapter C, for foreign nationals working at CDC and having 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 (EAA) and Executive Order 13222 (August 17, 2001). DOC 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 worked at CDC and had access to covered equipment.

(OAS; W-00-10-58130; expected issue date: FY 2010; new start)

Contracting Procedures

We will review CDC's contracting procedures to determine whether applicable criteria and regulations have been followed. In its contracting activities, CDC is required to follow the Federal Acquisition Regulation (FAR) and the HHS Acquisition Regulation (HHSAR) at Title 48 of the CFR.

(OAS; W-00-10-58141; expected issue date: FY 2010; new start)

Food and Drug Administration

Food Facility Inspections

We will review FDA's food facility inspection process and its methods for selecting facilities for inspection. FDA monitors the safety of domestic food primarily through inspections of farms, warehouses, manufacturers, packers, and other types of food establishments. The Food, Drug, and Cosmetic Act of 1938 (FDCA), § 704(a), 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 offices, with guidance from FDA headquarters, determine the

number, type, and specific facilities FDA will inspect. We will also determine the extent to which FDA identifies and addresses food facility violations.

(OEI; 02-08-00080; expected issue date: FY 2010; work in progress)

Oversight of State Food Facility Inspections

We will review FDA's oversight of food facility inspections conducted on behalf of FDA by States through contracts and partnership agreements. Section 704(a) of the FDCA authorizes FDA to conduct inspections to enforce the provisions of that statute and other applicable laws. This review will update OIG's 2000 review, which found that FDA's oversight of both the contracts and partnership agreements with States was insufficient to ensure the quality of State food firm inspections carried out on its behalf. This followup review will determine whether FDA has improved its performance. We will also determine how FDA uses the information from State inspections.

(OEI; 02-09-00430; expected issue date: FY 2010; work in progress)

Oversight of Food Safety Operations

We will review FDA's oversight and operations related to imported pet food and feed products. Specifically, we will review the extent of FDA's enforcement authorities, its procedures to implement those authorities, the way in which FDA is carrying out the activities called for in its procedures, and the sufficiency of the authorities. We will review FDA's policies to determine whether it requires imported pet food and feed to be produced under the same safety standards as those under which they 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.

(OAS; W-00-08-51002; expected issue date: FY 2010; work in progress)

Complaint Investigation Process

We will review the adequacy of FDA's complaint investigation process, upon which the agency relies in its efforts to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Specifically, we will determine whether complaints are properly recorded in the Consumer Complaint System and investigated in an expeditious manner as required by FDA's "Investigations Operation Manual," Chapter 8, § 8.2. In addition, we will review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries.

(OAS; W-00-10-51010; expected issue date: FY 2010; new start)

Foreign Clinical Trials

We will review the extent to which drug manufacturers use foreign clinical trials to support new drug applications (NDA) and biological licensing agreements (BLA) submitted to FDA. Section 505(i) of the FDCA and regulations at 21 CFR pt. 312 provide for FDA oversight of clinical trials of new drugs. Sponsors may submit data from foreign clinical trials if they meet criteria set forth in 21 CFR § 312.120 related to the qualifications of clinical investigators and participating sites. FDA is prohibited from disqualifying foreign trial data if the trials are conducted in accordance with principles acceptable to the world community regarding ethical treatment of subjects. FDA officials interviewed for a 2007 OIG report estimated that 20 percent to 30 percent of data used in NDAs come from foreign clinical trials. FDA stated that it is often unaware that foreign trials have been conducted until after the results are submitted in NDAs.

We will also examine how FDA reviews data from foreign clinical trials submitted to support NDAs and BLAs.

(OEI; OEI-01-08-00510; expected issue date: FY 2010; work in progress)

The Food and Drug Administration's Oversight of Investigational New Drug Applications

We will review FDA's process for evaluating investigational new drug (IND) applications. Section 505(i) of the FDCA governs FDA's authority to oversee INDs used in clinical trials to assess their safety and effectiveness. Drug sponsors submit IND applications to FDA for review, and the agency has 30 days from receipt of the applications to review them, after which the sponsors may start clinical trials without FDA's approval. We will assess FDA's timeliness and identify challenges to the IND review process.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Oversight of Blood Establishments

We will review the extent to which the FDA oversees blood establishments to ensure the safety of the Nation's blood supply. Under the FDCA, codified at 21 U.S.C. § 301, FDA is charged with ensuring the safety of our Nation's blood supply by overseeing blood establishments. FDA is required to issue licenses to manufacturers of biological products, and manufacturers are required to report to FDA biological product deviations in manufacturing that may affect the safety, purity, or potency of a product. In 2000, FDA published a Final Rule, 21 CFR, Parts 600 and 606, requiring all unlicensed registered blood establishments, as well as licensed blood establishments, to report product deviations in manufacturing, for distributed products only, within a 45-day period. We will determine whether FDA's inspections of licensed blood establishments and monitoring of blood deviations meet statutory requirements.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Health Resources and Services Administration

Ryan White CARE Act Payer of Last Resort Provision

We will review States' compliance with the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) payer of last resort requirement in the administration of the AIDS Drugs Assistance Program (ADAP) funds. Title II of the 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 PHS 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; various reviews; expected issue date: FY 2010; work in progress)

Oversight of the Ryan White Core Medical Services Requirement

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 this Act, grantees must spend at least 75 percent of funds for Ryan White Parts A–C 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 this Act. Grantees seeking a waiver self-certify that core medical services are otherwise available. We will also determine the extent to which grantees spent Ryan White funds on core medical services.

(OEI; 07-08-00240; expected issue date: FY 2010; work in progress)

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 health centers. We will also 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 2010; work in progress)

Reporting Adverse Actions to the Healthcare Integrity and Protection Data Bank

We will review the extent to which HHS agencies have reported adverse actions to the Healthcare Integrity and Protection Data Bank (HIPDB). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) directed the Secretary, acting through OIG and the Attorney General, to create HIPDB to help combat fraud and abuse in health care delivery. The HIPDB, operated by HRSA under a memorandum of agreement with OIG, is a national data bank containing "adverse actions" taken against health care practitioners, providers, and suppliers, including OIG exclusions, criminal convictions, and civil judgments related to health care. As such, adverse actions taken by the Centers for Medicare & Medicaid Services (CMS), FDA, IHS, HRSA, NIH, and OIG are required to be reported to the HIPDB. We will determine whether the HIPDB contains all HHS-imposed actions and whether there are any impediments to reporting such actions.

(OEI; 07-09-00290; expected issue date: FY 2010; work in progress)

Health Education Assistance Loan Program Defaulters

We will review whether individuals who have defaulted on Health Education Assistance Loans (HEAL) have earned income while in default on their HEAL loans. Authorized under the Public Health Service Act (PHS Act), §§ 701 – 720, the HEAL program was implemented by HRSA in 1978 to help eligible graduate students finance their health profession education. No new HEAL loans have been issued since September 30, 1998; however, HRSA continues to insure prior loans made by participating lenders. We will determine the income that HEAL defaulters earned from October 2007 through September 2008.

(OEI; 03-09-00100; expected issue date: FY 2010; work in progress)

Indian Health Service

Provision of Dialysis and Mental Health Services at Indian Health Services Facilities

We will assess the provision of dialysis and mental health services at IHS facilities. Mortality rates for many illnesses, including alcoholism, diabetes, and suicide, are significantly higher among American Indians and Alaska Natives than among other Americans. Provision of dialysis and mental health services poses particular challenges because of the need for specialized equipment and/or staff. If services are not provided at a local IHS facility, patients may need to travel a significant distance to receive services. Additionally, when services are not provided at an IHS facility, patients may rely on contract health services, which are purchased pursuant to 42 CFR pt. 136, subpart C, from other public and private providers. Funding for contract health services is limited and may be exhausted before the end of each year. We will determine the availability of dialysis and mental health services at IHS facilities as well as the distance patients must travel for these services.

(OEI; 09-08-00580 and 09-08-00581; expected issue date: FY 2010; work in progress)

Accounting for Medication Inventory

We will review IHS's accounting for medication inventory. 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; various reviews; expected issue date: FY 2010; work in progress)

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. 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-00-10-50020; various reviews; expected issue date: FY 2010; new start)

Indian Health Service Loan and Repayment Programs

We will review the internal controls that IHS has in place for its scholarship and loan repayment programs. The IPIA authorizes IHS funding to recruit and retain health professionals who provide health care services to the Indian population. Several of these programs require that the recipients of these funds enter into contracts with IHS whereby they are required to fulfill service obligations or repay the funds if the obligations are not fulfilled. We will determine whether IHS has adequate internal controls to monitor recipients' compliance with their scholarship and loan repayment program requirements.

(OAS; W-00-10-50021; expected issue date: FY 2010; new start)

Tribal Governments' Third-Party Collections in Emergency Medical Services Programs

We will evaluate tribal governments' efforts to collect third-party payments for their emergency medical services (EMS) programs. IHS is a payor of last resort, meaning that it pays the remainder after Medicare, Medicaid, or private insurance pay their shares. IHS's "Revenue Operations Manual," July 2006, describes the responsibilities of providers and facilities for billing third-party insurance and details the process that IHS, tribal governments, and tribal health care facilities should use in doing so. Third-party collections are important to IHS and tribal governments because these funds augment congressional appropriations. Funds collected from third-party reimbursement can represent up to 50 percent of the operating budget for some health care facilities. Tribal governments began direct billing of third-party payers in 2002, and IHS has had no reliable data on actual tribal third-party collections for any tribally operated programs, including the EMS program.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

National Institutes of Health

Superfund Financial Activities for Fiscal Year 2009

We will review the payments, obligations, reimbursements, and other uses of Superfund moneys by NIH's National Institute of Environmental Health Sciences (NIEHS). A provision of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), codified at 42 U.S.C. § 9611(k), requires that OIG 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-00-10-50035; expected issue date: FY 2010; new start)

National Institute of Environmental Health Science's Grant Process

We will review issues related to grants made by NIEHS to determine whether it complied with the HHS "Grants Administration Manual" and whether FY 2005 to 2007 expenses incurred by its Director's office were in accordance with NIH policies.

(OAS; W-00-10-50036; expected issue date: FY 2010; new start)

Colleges' and Universities' Compliance With Cost Principles

We will review colleges' and universities' compliance with selected cost principles issued by OMB Circular A-21, Cost Principles for Educational Institutions. 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 Resources and Technology (ASRT) and the Assistant Secretary for Administration and Management (ASAM).

(OAS; W-00-10-50037; various reviews; expected issue date: FY 2010; new start)

Use of Data and Safety Monitoring Boards in Clinical Trials

We will review the extent to which Data and Safety Monitoring Boards (DSMB) monitor data 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 also determine how and to what extent NIH is ensuring that grantees comply with the NIH policy for DSMBs in multisite clinical trials.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

National Center for Research Resources’ Oversight of Clinical and Translational Science Awards

We will review the National Center for Research Resources (NCRR) process for overseeing Clinical and Translational Science Award (CTSA) grantees. The CTSA program began in 2006 to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at various medical colleges and universities. The CTSA program awards 5-year grants to 12 academic health centers annually. When fully implemented in 2012, the CTSA program will consist of a consortium of 60 institutions that facilitates the creation of translational science networks and biomedical informatics tools. NCRR oversees this program and its milestones for compliance with CTSA program objectives and HHS grant administration requirements at 45 CFR pt. 74. Congress awarded over \$300 million during the first 2 years of this program, with funding of the full CTSA initiative expected to exceed \$500 million annually by 2012. We will also examine the types of innovative information-sharing techniques developed through the CTSA program.

(OEI; 07-09-00300; expected issue date: FY 2010; work in progress)

National Institute of Allergy and Infectious Diseases’ Oversight of Project BioShield Grants

We will review the processes that the National Institute of Allergy and Infectious Diseases (NIAID) uses to monitor Project BioShield grantees’ compliance with Federal laws, regulations, and policies. Project BioShield, created by the Project BioShield Act of 2004, authorizes the Federal Government to research, develop, and procure medical countermeasures, such as vaccines, therapeutics, and diagnostics. It has lead responsibility for research and development of such medical countermeasures. From FY 2005 to FY 2008, NIAID awarded over \$60 million in grants and contracts for Project BioShield-related medical countermeasure research and development and provided grant support to over 50 grantees. NIAID is required to follow HHS rules regarding grants oversight and monitoring, including periodic review and approval of progress and financial reports. We will review NIAID’s oversight of grantees that have received awards under NIAID’s Project BioShield funding. We will also examine how NIAID ensures that grantees are aware of required security measures as well as the consequences of noncompliance with the requirements during the research and development of Project BioShield products.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Financial Interests Held by Institutions Receiving National Institutes of Health Research Grants

We will determine if and to what extent grantee institutions receiving NIH grants have financial interests that could be affected by the research. Current Federal regulations at section 493A of the PHS Act added by Public Law 103-43 allow the Secretary to establish regulations regarding researcher and institutional financial conflicts of interest in federally funded research and outline how grantee institutions should identify, report, and address financial conflicts of interest among researchers. However, as of 2009, there are no Federal regulations to provide guidance on the handling of financial conflicts of interest that may exist within grantee institutions. Our previous work has identified instances where grantee institutions were receiving financial payments from the same companies that they believed created a conflict for the researchers. We will identify and quantify financial interests that grantee institutions have that are related to research being conducted at these institutions.

(OEI; 03-09-00450; expected issue date: FY 2010; ongoing)

Substance Abuse and Mental Health Services Administration

Substance Abuse Prevention and Treatment Block Grants

We will review one State's expenditures of SAMHSA-funded Prevention and Treatment Block Grants (SAPTBG) for State FYs 2003 through 2007. The State has reported expenditures that exceeded its awards for at least one previous year. SAMHSA requested that OIG perform this review to determine whether the State had adequate controls over its expenditure of SAPTBG funds and can meet applicable Federal requirements specified in 42 U.S.C. § 300x-30 and 45 CFR § 96.134.

(OAS; W-00-09-57205; A-04-09-03526; expected issue date: FY 2010; work in progress)

Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program

We will assess SAMHSA's progress in identifying performance goals for the Substance Abuse Treatment Block Grant program. The goal of the block grant is to improve access, reduce barriers, and promote effective treatment and recovery services for people with alcohol and drug abuse problems. The Government Performance and Results Act of 1993 (GPRA) requires Federal agencies to develop long-term strategic plans defining goals and objectives for their programs. We will also assess the extent to which States are reporting and meeting performance goals for this program.

(OEI; 00-00-00000; expected issue date: FY 2010; new start)

Cross-Cutting Public Health Activities

Oversight of Federal Advisory Committee Special Government Employee Conflicts of Interest

We will review HHS officials' monitoring of conflicts of interest reported by special Government employees (SGE) who serve on Federal advisory committees. Pursuant to 5 CFR pt. 2634, the HHS Designated Agency Ethics Official and Deputy Ethics Counselors

oversee submission and review of financial reports required of all employees in HHS, including special Government employees. SGEs are temporarily appointed subject matter experts who become employees in the executive branch of the Federal Government. SGEs serve with or without compensation, for a period not to exceed 130 days at a time. For Federal advisory committees' advice, recommendations, and guidance to be credible, it is important that special Government employees be free from conflicts of interest that may impair their independence. We will also assess HHS's documentation of required ethics training for special Government employees.

(OEI; 04-09-00390; various reviews; expected issue date: FY 2010; work in progress and new start)

Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation

We will review States' use of the Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. The program, authorized under sections 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2 of the PHS Act, provides funding to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. States may not use Federal funds to compensate State employees for non-Federal services that States have provided in the immediately prior years. We will determine whether States have inappropriately used program funding to compensate State employees.

(OAS; W-00-10-57228; various reviews; expected issue date: FY 2010; new start)

Pandemic Influenza Planning

We will review HHS's implementation of high-risk areas of its pandemic influenza plan. The plan is HHS's blueprint for responding to the next pandemic that has the potential to overwhelm current public health and medical care capabilities. We will review areas pertaining to appropriate morbidity and mortality rates; supplies of pre-pandemic vaccines, post-pandemic vaccines, and antivirals; reliance on vaccine policies; and vaccine and antiviral distribution. We will also assess the extent to which States are reporting and meeting performance goals.

(OAS; W-00-10-57229; expected issue date: FY 2010; new start)

Rollup of Departmental Laboratories' Implementation of Select Agent Regulations

We will consolidate results of individual reviews of CDC, NIH, and FDA laboratories' compliance with select agent regulations and contrast our results with those from the CDC's Division of Select Agents and Transfers, an oversight body that conducts onsite evaluations of compliance using the same regulations. Select agents regulated by CDC are biological agents or toxins that have the potential to pose severe threats to public health and safety. The rollup will address compliance with select agent Federal regulations at 42 CFR Part 73 regarding security plans, accountability, and access.

(OAS; W-00-10-58200; expected issue date: FY 2010; new start)

Public Health Investigations

Violations of Select Agent Requirements

OIG continues to receive requests for information on and investigations of alleged terrorist and bioterrorist activities relating to select agents (biological agents and toxins that have the potential to pose a severe threat to public health). On March 18, 2005, HHS issued a final regulation at 42 CFR pt. 73 on possession, use, and transfer of select agents and toxins, 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 (CMP) against individuals or entities for violations of these requirements. As of May 2009, OIG had settled 13 cases involving violations of the select agent regulations and had collected a total of \$1,997,000 in CMPs. 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.

Public Health Legal Activities

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 fraud cases and promotes compliance measures by recipients of HHS 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 Federal False Claims Act (FCA) 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.

Human Service Programs

Several HHS agencies support human services to assist vulnerable individuals of all ages, including: the Administration on Aging (AoA), which 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; and the Administration for Children and Families (ACF), which operates over 30 programs that promote the economic and social well-being of children, families, and communities, including Temporary Assistance for Needy Families (TANF); the national child support enforcement (CSE) system; the Head Start program for preschool children; and assistance for child care, foster care, and adoption services.

Our planned reviews of human service programs follow.

Administration on Aging

Aging Programs in One State

We will review one State's aging program grants. Pursuant to Title III of the Older Americans Act of 1965 (OAA), HHS 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 one State complied with Federal requirements.

(OAS; W-00-10-26002; expected issue date: FY 2011; new start)

Performance Data for the Senior Medicare Patrol Projects

We will collect and report on Medicare and Medicaid monetary recoveries attributable to the Senior Medicare Patrol Projects. This information will support AoA's efforts to evaluate and improve the performance of these projects. Beginning in 1997, pursuant to Congressional recommendations in a report accompanying the Omnibus Consolidated Appropriations Act of 1997 (OCAA) (PL 104-368), AoA established demonstration projects that recruit retired professionals to serve as educators and counselors to help beneficiaries detect fraud, waste, and abuse in the Medicare and Medicaid programs. We will review documentation for actual amounts attributable to the projects that were recovered for the Medicare and Medicaid programs, beneficiaries, and others.

(OEI; 00-00-00000; various reviews; expected issue date: FY 2010; new start)

Administration for Children and Families

Foster Care and Adoption Assistance Training Costs and Administrative Costs

We will review foster care and adoption assistance training costs and other administrative costs claimed under Title IV-E of the Social Security Act. The Social Security Act, §§ 474(a)(3)(A) – (B) and 474(a)(3)(E), provides for Federal reimbursement of training and administrative costs, respectively. Title IV-E training costs and other administrative costs have increased dramatically in relation to maintenance payments in recent years. Prior OIG reviews in three States 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 States' cost allocation plans.

(OAS; W-00-08-24100; various reviews; expected issue date: FY 2010; work in progress and new start)

Foster Care Per Diem Rates

We will review foster care maintenance payments claimed under Title IV-E of the Social Security Act on behalf of children. The Social Security Act, § 475(4)(A), 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 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 2010; work in progress and new start)

Costs Billed by Child-Placing Agencies

We will review child-placing agencies' maintenance payments and administrative costs claimed under Title IV-E of the Social Security Act. Under the Social Security Act, § 475(4)(A), 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 States have received duplicate reimbursement for the administrative costs of child-placing agencies.

(OAS; W-00-10-24110; expected issue date: FY 2010; new start)

Group Home and Foster Family Agency Rate Classification

We will review one 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 of foster care maintenance payments and that States must review the amount of the payments to ensure the continued appropriateness of the amounts. The auditee State's Code provides that rates be established by classifying each group home program and applying the standardized schedule of rates. The foster care payment amount correlates with the rate classification level. Payments are initially established at a provisional rate; the State subsequently conducts audits 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 in the State were accurate.

(OAS; W-00-10-24111; expected issue date: FY 2010; new start)

Adoption Assistance Subsidies

We will review States' claims for Federal reimbursement of adoption assistance subsidies to determine compliance with eligibility requirements. Adoption assistance eligibility requirements were established by the Social Security Act, §§ 473(a) and 473(c). Federal subsidy payments are 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 one State's adoption assistance subsidies identified payments to families that did not meet eligibility requirements.

(OAS; W-00-08-24009; expected issued date: FY 2010; work in progress and 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 of the Social Security Act for the placement of delinquent children. Pursuant to the Social Security Act, § 475(4)(A), maintenance costs include room and board payments to licensed foster parents, group homes, and residential child care facilities for children who meet Title IV-E program requirements. A prior OIG review found that claims were submitted for ineligible children,

some services were not provided, and some services were ineligible. 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; various reviews; expected issue date: FY 2010; work in progress and new start)

Foster Care Preplacement/Candidacy Costs

We will review State claims for foster care candidate costs. The Social Security Act, § 472(i)(2), allows States to claim administrative costs for allowable preplacement activities on behalf of foster care candidates. A candidate for foster care is a child who is at imminent 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 candidates under Title IV-E of the Social Security Act. In several States, we will determine whether costs for candidates were properly claimed.

(OAS; W-00-10-24112; expected issue date: FY 2010; new start)

Foster Children Over 19 Years Old

We will review foster care maintenance payments made on behalf of children age 19 and over. Children age 19 and over are ineligible for foster care maintenance payments. The Social Security Act, § 472, limits 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 19 years old or over 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-00-10-24113; various reviews; expected issue date: FY 2010; new start)

Oversight of System Design of Statewide Automated Child Welfare Information Systems

We will review ACF's oversight of and guidance and assistance to States directed to ensuring that States' new Statewide Automated Child Welfare Information System (SACWIS) initiatives are appropriately focused and successfully implemented with potential risks minimized. Federal regulations at 45 CFR § 95.621 require that ACF continually review, assess, and inspect the planning, design, and operation of SACWIS systems to determine how such systems meet the requirements imposed by law, regulations, and guidelines. Pursuant to 45 CFR § 1355.52, States may receive 50-percent Federal Financial Participation (FFP) for the costs of planning, design, development, and installation of a statewide child welfare information system. In addition, we will determine whether the costs claimed by States for the systems are allowable.

(OAS; W-00-10-25040; expected issue date: FY 2010; new start)

Foster Care Program Collection and Reporting of Child Support Payments

We will review and reconcile States' records of children in foster care with corresponding States' collections of child support. Federal regulations at 45 CFR 302.52 require that States' collections of child support payments for children in foster care be used to offset Foster Care program costs instead of being sent to individuals who no longer have custody of the children. To facilitate offsets, Foster Care program agencies are required to report identifying information for children in foster care to States' CSE agencies. We will determine the extent to which

prompt and accurate reporting takes place, reconcile the reports with corresponding offsets, and identify the causes of any discrepancies.

(OAS; W-00-10-25041; expected issue date: FY 2010; new start)

Services for Recently Arrived Refugees

We will review grantee compliance with terms and conditions for grants and contracts awarded under the Refugee Act of 1980, § 412(c), which allows the Director of Refugee Resettlement to make grants to, and enter into contracts with, public or private nonprofit agencies for projects specifically designed to assist refugees in obtaining the skills necessary for economic self-sufficiency; to provide training in English where necessary; and to provide health, social, educational, and other services. We will determine whether agencies have met the terms and conditions of their respective grants and contracts.

(OAS; W-00-10-25042; expected issue date: FY 2010; new start)

Licensing Standards and Health and Safety Monitoring at Child Care Facilities

We will review licensing, health, and safety standards at selected child care facilities that received Federal Head Start funding and/or Federal funding from the Child Care and Development Fund (CCDF). Federal regulations for the CCDF at 45 CFR § 98.15(b)(4)-(6) require States to certify that they have licensing and health and safety requirements applicable to child care services pursuant to 45 CFR §§ 98.40 and 98.41. A previous OIG review of one Head Start grantee that also provided CCDF day care services found several instances in which child care facilities did not comply with the applicable health and safety requirements. Federal Head Start performance standards at 45 CFR §§ 1304 and 1308 require that Head Start facilities comply with State and local child care licensing requirements. If States do not have licensing requirements or the States' requirements are less stringent than Federal standards, the facilities must comply with the Head Start health and safety requirements found at 45 CFR §1304.53(a). We will determine the extent to which Head Start grantees and States have demonstrated that child care facilities receiving Federal funds have complied with applicable requirements.

(OAS; W-00-10-22005; various reviews; expected issue date: FY 2010; new start.

OEI; 00-00-0000; expected issue date: FY 2010; new start)

Federal Employers' Payment Submissions to Child Support State Disbursement Units

We will assess the procedural accuracy of Federal employers' payment submissions to Child Support State Disbursement Units. In a 2000 OIG review of State Disbursement Units, managers of these units reported that child support payments from Federal agencies were often labeled poorly or delivered incorrectly, which caused delays in States' disbursement of payments to families. OIG recommended that the Office of Child Support Enforcement (OCSE) work with Federal employers to improve payment practices. This follow-up review will determine whether these problems have been corrected. Specifically, we will determine whether Federal payers accurately label and submitted payments, identify barriers to proper labeling and submission, and assess the impact on agencies and families of deficient practices on the part of Federal payers.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

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 program expenditures under Title IV-D of the Social Security Act. 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-00-08-23080; various reviews; expected issue date: FY 2010; work in progress)

Interest Earned on Child Support Enforcement Funds

We will review interest earned by local government entities that receive CSE funds. Pursuant to 45 CFR § 92.21(i), interest earned on advances, except for interest earned on advances of funds exempt under the Intergovernmental Cooperation Act of 1968, 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-00-10-20031; expected issue date: FY 2010; new start)

Increasing Child Support Collections

We will review States' procedures for collecting child support from self-employed noncustodial parents. A prior review in one State disclosed that the State increased child support collection by more than \$1 million as a result of enacting legislation to identify earnings from self-employed noncustodial parents. We will determine the adequacy of procedures for and extent of increases in child support collections by States that have implemented the necessary legislation to identify earnings and collect child support from self-employed individuals whose families are receiving TANF.
(OAS; W-00-10-20032; expected issue date: FY 2010; new start)

Characteristics of Child Support Arrears

We will review the characteristics of child support arrears and individuals who owe these debts and determine whether specific characteristics are associated with patterns of payment or nonpayment. OCSE within ACF is responsible for ensuring that assistance in obtaining financial and medical support is available to children by locating parents, establishing paternity and support obligations, and enforcing those obligations. All States and territories operate child support enforcement programs that receive Federal funding through Title IV-D of the Social Security Act, § 452, (42 U.S.C. § 652). Nationwide, in FY 2007, noncustodial parents participating in the Title IV-D program owed approximately \$107 billion in arrears on child support payments. We will also assess ACF's efforts to oversee collections of child support arrears.
(OEI; 00-00-00000; expected issue date: FY 2010; new start)

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. As part of Project Save Our Children, OIG reported 98 criminal convictions and approximately \$4.9 million in court-ordered fines, penalties, and restitution for FY 2008. In FY 2010, we plan to continue our efforts to encourage and coordinate enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases.

Departmentwide Issues

Certain financial, performance, and investigative issues cut across HHS programs. OIG's ongoing and planned work addresses departmentwide issues, such as financial statement audits; financial accounting; information systems management; and other departmental issues, including discounted airfares and protections for persons with disabilities in residential settings.

We have discretion in allocating most of our non-Medicare and non-Medicaid resources; a portion, however, is used for mandatory reviews. These include financial statement audits conducted pursuant to the Government Management Reform Act of 1994 (GMRA), § 405(b); the Chief Financial Officers Act of 1990 (CFO Act); and information systems reviews required by the Federal Information Security Management Act of 2002 (FISMA).

The GMRA 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. The GMRA broadened the CFO Act by requiring annual audited financial statements for all accounts and associated activities of HHS and other Federal agencies and components of Federal agencies, including CMS.

Financial Statement Audits

Audits of Fiscal Years 2009 and 2010 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 2009 financial statements are due to OMB by November 16, 2009; for FY 2010, they are due by November 15, 2010.

The following FY 2009 financial statement audits will be completed and reports will be issued during FY 2010:

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- Consolidated HHS – This audit incorporates all operating divisions, including CMS, which will receive a separate audit report (listed below). (OAS; W-00-09-40009; A-17-09-00001)
 - CMS – (OAS; W-00-09-40008; A-17-09-02009)

The following FY 2010 financial statement audits will be completed and reports will be issued during FY 2011:

- Consolidated HHS – This audit will incorporate all operating divisions, including those that will receive separate audit reports (listed below). (OAS; W-00-10-40009)
- CMS – (OAS; W-00-10-40008)

Fiscal Year 2010 Statement on Auditing Standards Examinations

We will review the independent auditor’s workpapers to determine whether the examinations of HHS’s service organizations were conducted in accordance with applicable laws and regulations. These examinations are conducted in accordance with Generally Accepted Government Auditing Standards and the American Institute of Certified Public Accountants’ “Statement on Auditing Standards (SAS) No. 70, Service Organizations,” commonly referred to as SAS 70 examinations. SAS 70 examinations report on the controls of service organizations that may be relevant to the user organizations’ internal control structures. The following SAS 70 examinations of HHS service organizations will support FY 2010 financial statement audits and will be issued during FY 2010:

- Center for Information Technology (NIH Computer Center)
(OAS; W-00-10-40012; A-17-10-00010)
- Payment Management System
(OAS; W-00-10-40012; A-17-10-00009)

Fiscal Years 2009 and 2010 Financial-Related Reviews

The purpose of the financial-related reviews is to fulfill requirements in OMB Bulletin No. 07-04, “Audit Requirements for Federal Financial Statements,” §§ 11 and 13.

The FY 2009 financial-related reviews that will be issued during FY 2010 are:

- Closing-Package Audit Reports for the Governmentwide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports.
(OAS; W-00-09-40009; A-17-09-00006)
- Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the Department of Defense (DOD) OIG in performing the OMB Bulletin 07-04, “Audit Requirements for Federal Financial

Statements,” Section 11, Agreed-Upon Procedures.
(OAS; W-00-09-40009; A-17-09-00008)

The FY 2010 financial-related reviews that will be issued in FY 2011 are:

- Closing-Package Audit Reports for the Governmentwide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports.
(OAS; W-00-10-40009; A-17-10-00006)
- 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 07-04, “Audit Requirements for Federal Financial Statements,” Section 11, Agreed-Upon Procedures.
(OAS; W-00-10-40009; A-17-10-00008)

Other Financial Accounting Reviews

The President’s Emergency Plan for AIDS Relief Funds

We will review the effectiveness of HHS’s accounting for and control of funds received under the President’s Emergency Plan for AIDS Relief (PEPFAR) program. HHS received PEPFAR funds from both the annual HHS/Labor appropriation and the Foreign Operations appropriation. PEPFAR funds support international programs for AIDS prevention, treatment, and care.
(OAS; W-00-10-52300; expected issue date: FY 2011; new start)

Public Welfare Cost Allocation Plan

We will review the cost allocation plan submitted by one State. The State contracted to have its cost allocation plan prepared. ACF has informed us that the plan may be unworkable and that the State has been required to revise it. Federal regulations at 45 CFR pt. 95, subpart E, require that cost allocation plans conform to the accounting principles and standards in OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments. We will determine whether State agency costs have been allocated correctly among various Federal programs and whether claims submitted by the State based on the cost allocation plan were supported and claimed in accordance with Federal criteria pertinent to the State agency.
(OAS; W-00-10-52310; expected issue date: FY 2010; 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 the OIG expresses a conclusion on the reliability of the agency’s assertions in its accounting. We will submit this authentication with respect to HHS’s FY 2009 annual accounting.
(OAS; W-00-10-52312; expected issue date: FY 2010; new start)

Use of Appropriated Funds in Program Support Center Contracting

We will review the appropriateness of the Program Support Center's (PSC) obligation of appropriated funds for services it obtains through contracts to ensure that appropriated funds were used only during their period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and were used only for a bona fide need arising in the FY for which the appropriation was made. Key provisions of the Anti-Deficiency Act prohibit the Government from obligating or expending funds in advance of an appropriation unless authorized by law (31 U.S.C § 1341(a)(1)). In addition, appropriations may be used only for bona fide needs arising in the FY for which the appropriation was made (31 U.S.C. § 1502). We will review contracts and contract modifications issued by PSC during FYs 2004 through 2008 to determine whether appropriated funds were used in accordance with the Anti-Deficiency Act.

(OAS; W-00-10-52313; expected issue date: FY 2010; new start)

Contracting Procedures

We will review HHS's contracting procedures by performing a risk assessment. HHS's contracting procedures are subject to the FAR and the HHSAR. We will determine the scope of HHS contracting for goods and services and determine whether there are risks in this process that would require reviews by OIG.

(OAS; W-00-10-52314; various reviews; expected issue date: FY 2010; new start)

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 moneys that they receive. Our reviews ensure that the audits and reports meet applicable standards, identify any follow-up work needed, and identify issues that may require management attention. As part of our reviews of A-133 audits, we will ensure that the auditors have audited and reported on compliance with provisions of the Recovery Act. OIG also provides 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 HHS managers. Our reviews provide HHS 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 HHS's cognizant responsibility under OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations. To ensure a coordinated Federal approach to audits of colleges, universities, and States, OMB establishes audit cognizance, that is, designates which Federal agency has lead responsibility for audit of all Federal funds the entity receives. Accordingly, HHS OIG has audit cognizance over all State governments and most major research colleges and universities. Agreements are reached with other Federal audit organizations or other Federal agencies to reimburse the HHS OIG as the

cognizant audit organization for audits that HHS OIG performs of non-HHS funds at their request.

(OAS; W-00-10-50012; various reviews; expected issue date: FY 2010; new start)

Requested Audit Services

Throughout the year, Congress, HHS, 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.

Automated Information Systems

Information System Security Audits

We will review the reliability of the Information System Security Program at several operating divisions. HHS 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, several reviews have been conducted to determine compliance with HHS-mandated security program requirements.

(OAS; W-00-10-42000; expected issue date: FY 2010; new start)

Federal Information Security Management Act of 2002 and Critical Infrastructure Protection

We will review various HHS operating divisions' compliance with FISMA and critical infrastructure protection requirements. 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. As part of our review, we will follow up on the unresolved findings from prior reviews of information systems controls.

(OAS; W-00-10-42001; various reviews; expected issue date: FY 2010; new start)

Information Technology Systems' General Controls

We will review the adequacy of information technology security general controls of selected HHS systems using Departmental, OMB, and FISMA guidance and regulations. Recent legislation and OMB directives have focused on safeguards for critical systems' assets and infrastructures.

(OAS; W-00-10-42002; various reviews; expected issue date: FY 2010; new start)

Other Departmental Issues

Use of Discounted Airfares by Employees

We will review HHS employees' use of discounted airfares. Under a General Services Administration (GSA) agreement negotiated with airlines, Government employees traveling on Government business may be eligible for discounted airfares, known as a City Pair With Capacity Limits. Section 301-10.106 of the Federal Travel Regulation (FTR) requires Federal travelers to use a GSA contract carrier when available. According to the results of a prior review, capacity-controlled coach-class fare may not be used as often as mandated by the FTR. We will determine the extent to which HHS's travelers obtain discount airfares and whether there are opportunities to increase the use of the discount airfares.

(OAS; W-00-10-58125; expected issue date: FY 2010; new start)

State Protections for Persons With Disabilities in Residential Settings

We will review actions taken by CMS, ACF, SAMHSA, and FDA on OIG recommendations to work cooperatively to provide information and technical assistance to States for strengthening State protections for persons with disabilities in residential settings. Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid, CMS has established conditions of participation. For facilities not subject to CMS oversight, there are limited Federal standards, partly because of HHS's limited statutory authority.

(OAS; W-00-10-58126; expected issue date: FY 2010; new start)

Classifications of Federal Pass-Through Funding Recipients

We will review the appropriateness of States' classifications of recipients of Federal pass-through funds. State agencies determine whether they are passing through Federal funds in the form of Federal financial assistance to subgrantees or whether they are contracting with vendors. OMB Circular A-133, Subpart B, § 210, provides guidance on distinguishing between subrecipients and vendors. There is an advantage to the recipient of the pass-through funds if the recipient is treated as a vendor. Vendors may enter into fixed-price contracts that allow retention of unused funds, whereas subgrantees must return unspent Federal funds to the State agency. In one State we will examine why the State awarded funds to a university as a vendor when the State had previously treated this university as a subrecipient.

(OAS; W-00-10-58127; expected issue date: FY 2012; new start)

Appendix A: Recovery Act Work Plan

Centers for Medicare & Medicaid Services

Medicare Part A and Part B

Breach Notification and Medical Identity Theft in Medicare

We will review CMS's compliance with new breach notification requirements for personally identifiable information (PII) in the American Recovery and Reinvestment Act of 2009 (Recovery Act) and the Centers for Medicare & Medicaid Services (CMS) oversight measures in cases of medical identity theft within Medicare. Section 13402 of the Recovery Act requires entities covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to notify individuals of breaches of their PII. Such PII includes health information maintained by Medicare providers and contractors. Breaches of PII can facilitate the theft of health-related PII (medical identity theft). We will examine CMS's internal procedures and processes related to the Recovery Act's breach notification requirements. We will assess CMS's oversight of its contractors, plans, and sponsors regarding breach deterrence and notification and determine other steps CMS has taken to deter medical identity theft.

(OEI; 00-00-00000; expected issue date: FY 2011; new start; Recovery Act)

Medicare Incentive Payments for Electronic Health Records

We will review Medicare incentive payments made to eligible health care professionals and hospitals for adopting electronic health records (EHR) and CMS's safeguards against incentive payments made in error. Sections 4101 and 4102 of the Recovery Act authorize incentive payments over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology. Bonus payments are scheduled to begin in 2011 and continue through 2016, with payment reductions to health care professionals who fail to become meaningful users of EHRs (section 4101(b)) beginning in 2015. Bonus payments for hospitals are scheduled to begin in 2011 (section 4102). According to Congressional Budget Office (CBO) estimates, Medicare spending for incentives and payment reductions will total approximately \$18 billion between 2011 and 2019. We will review Medicare incentive payment data from calendar year 2011 to identify incentive payments made in error. If errors are identified, we will also assess CMS's actions to remedy incentive payments made in error and its plans for securing these payments for the duration of the incentive program.

(OEI; 00-00-00000; multiple reviews; expected issue date: FY 2012; new start; Recovery Act)

Medicaid Program

Medicaid Hospitals

Medicaid Disproportionate Share Hospital Payments

We will review disproportionate share hospital (DSH) payments to determine whether expenditures were claimed in accordance with Medicaid requirements. Section 5002 of the Recovery Act provides fiscal relief to States by increasing most States' fiscal years (FY) 2009 and 2010 Medicaid DSH allotments by 2.5 percent. These payments are in addition to the regular payments that DSH hospitals receive for providing care to Medicaid beneficiaries. The Medicaid DSH allotment calculation is based on a statutory formula in the Social Security Act, § 1923. States receive an annual allotment to make payments to DSH hospitals to account for higher costs associated with treating uninsured and low-income patients. For FY 2009, the estimated total Federal Medicaid DSH allotments available to States would increase by \$268 million to approximately \$11.33 billion.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

Medicaid Administration

Medicaid Incentive Payments for Electronic Health Records

We will review Medicaid incentive payments made to providers and hospitals for adopting EHRs and CMS safeguards against incentive payments made in error. Section 4201 of the Recovery Act establishes 100-percent Federal financial participation (FFP) for allowable expenses for eligible Medicaid providers to purchase, implement, and operate certified EHR technology. In addition, section 4201 of the Recovery Act provides a 90-percent Federal match for State administrative expenses related to the adoption of certified EHR technology by Medicaid providers. According to CBO estimates, Medicaid spending for incentives will total approximately \$12 billion between 2011 and 2019. We will review Medicaid incentive payment data from 2011 for a selection of States to identify incentive payments made in error. We will also assess CMS actions to remedy incentive payments made in error and its plans for securing these payments for the duration of the incentive program.

(OEI; 00-00-00000; multiple reviews; expected issue date: FY 2012; new start; Recovery Act and OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Temporary Increases in Federal Medical Assistance Percentages

We will review the calculations for the temporary increases in the Medicaid Federal medical assistance percentages (FMAP) and CMS's controls for ensuring that the provisions of the Recovery Act are correctly implemented. Pursuant to section 5001 of the Recovery Act, each State is eligible for temporary increases of its Medicaid FMAP from October 2008 through December 2010 based on the State's FMAP for the prior FY, the State's unemployment

level, and other factors. We plan to review the calculations of the increased FMAPs for various quarters of FYs 2009 and 2010 for all States and the District of Columbia.

(OAS; W-00-09-31318; various reviews; expected issue date: FY 2010; work in progress, Recovery Act)

States' Compliance With Requirements for Claiming Increased Federal Medical Assistance Percentages

We will review States' compliance with sections 5001(f) and (g) of the Recovery Act. The Recovery Act provides that a State is generally ineligible for an increased FMAP if the State's eligibility standards are more restrictive than those in place on July 1, 2008 (section 5001(f)(1)); if the State fails to comply with prompt payment requirements (section 5001(f)(2)); or if the State requires increased local government contributions toward the non-Federal share of Medicaid payments (section 5001(g)(2)). States must comply with these rules to qualify for their temporary FMAP increases from October 2008 through December 2010.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

States' Use of Increased Recovery Act Funding

We will review States' compliance with section 5001(f)(3) of the Recovery Act, which provides that a State is not eligible for an increased FMAP if any amount attributable (directly or indirectly) to such increase is deposited or credited into any State reserve or rainy day fund. We will determine how selected States expended their increased FMAP funding and whether they used the increased funding to supplement their reserve or rainy day funds.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

State Controls Over Increased Federal Medical Assistance Percentages

We will review States' controls to ensure that expenditures claimed at the increased FMAPs are proper. We will determine whether States have properly accounted for the State and Federal shares of expenditures. Our prior reviews disclosed instances in which States improperly identified the State and Federal shares of expenditures.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

State Medicaid Program Integrity Efforts

We will review State Medicaid agencies' program integrity policies and procedures to determine whether States proactively manage overall program risks at the State agency, payment contractor, and provider levels. The Code of Federal Regulations (CFR) at 42 CFR § 455 sets forth requirements for State fraud detection and investigation programs. With the increased funding provided by the Recovery Act, State program integrity efforts become an even more important factor in the detection of improper payments. We will determine how State agencies prioritize actions to prevent improper payments, how providers and/or payment areas are identified for audit, and whether improper payments are collected and properly reported to CMS.

(OAS; W-00-09-31318; various reviews; expected issue date: FY 2010; work in progress, Recovery Act)

Reconciliation of Expenditure Reports to Claim Data

We will review and reconcile reported line items on the Medicaid quarterly expenditure report (Form CMS-64) in selected States to determine whether the amounts claimed are adequately supported. The amounts reported on Form CMS-64 and its attachments must be actual

expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time a claim is filed. Our prior audit work revealed concerns related to expenditures claimed on Form CMS-64.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

Medicaid High-Risk Providers

We will review claims from selected provider types that have a high risk of claiming improper Medicaid payments. We will analyze claim data to identify provider types and conduct focused reviews of individual providers. We will identify high-risk providers based on our past work in the Medicaid program and on error rates reported under CMS's Payment Error Rate Measurement (PERM) program.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2010; new start, Recovery Act)

Transitional Medical Assistance Programs

We will review States' implementation of the extension of their transitional medical assistance (TMA) programs and the new State option regarding coverage provided by section 5004 of the Recovery Act. TMA programs help low-income families with children transition to jobs by allowing them to keep their Medicaid coverage for a limited period after they find jobs even though their earnings make them ineligible for regular Medicaid coverage. The Recovery Act extends this provision to assist families for 18 months effective July 1, 2009. We will determine whether actual expenditures claimed met Medicaid requirements.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2011; new start, Recovery Act)

Medicaid Qualified Individual Programs

We will review States' expenditures under the Qualifying Individual (QI) program. The Medicaid QI program pays the Medicare Part B premiums of Medicare beneficiaries with incomes between 120 and 135 percent of the Federal poverty level. States receive 100-percent Federal funding for the QI program. Section 5005 of the Recovery Act extends the provision for 100-percent Federal funding for 12 months from December 2009 to December 2010. We will determine whether actual expenditures claimed met Medicaid requirements.

(OAS; W-00-10-31318; various reviews; expected issue date: FY 2011; new start, Recovery Act)

Medicare and Medicaid Information Systems and Data Security

Early Assessment of CMS Oversight of Recovery Act Incentives for Electronic Health Records

We will review CMS's oversight of the implementation and program management of Medicare and Medicaid incentive payments for EHR and describe the procedures in place to prevent and detect duplicate incentive payments. The Recovery Act creates incentives for eligible health care professionals to adopt certified EHR technology in both the Medicare and Medicaid programs (sections 4101 and 4201, respectively). Although incentives are available under Medicare and Medicaid, eligible health care professionals are not allowed to receive incentive payments from both Medicare and Medicaid (section 4201(a)). According to CBO estimates, net Medicare and Medicaid spending for incentives between 2011 and 2019 will total approximately \$30 billion.

We will assess CMS's plan for oversight and implementation of Medicare and Medicaid incentives and determine the extent to which CMS can prevent and detect duplicate incentive payments. We will also assess whether fiscal oversight and reporting mechanisms are established for CMS to determine "meaningful use" of certified EHR technology.
(OEI; 00-00-00000; expected issue date: FY 2011; new start; Recovery Act)

Health Information Technology System Enhancements

We will review health information technology (HIT) enhancements to CMS systems to ensure that they include standards adopted by HHS and that adequate information technology (IT) security controls are in place to protect sensitive EHR and personal information. The Recovery Act provides financial incentives through the Medicare and Medicaid programs to encourage doctors, hospitals, health clinics, and other entities to adopt and use certified EHRs. Medicare incentive payments are being phased out over time and replaced with financial penalties for providers that are not using EHR. CMS systems require modification to manage these new requirements.

(OAS; W-00-10-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Contractor System Enhancements

We will review HIT enhancements to IT systems used by Medicare and Part D contractors to ensure that adequate IT security controls are in place to protect sensitive EHR and personal information that is being added as a result of the Federal HIT initiatives. CMS contractor systems require modification to work with these new requirements.

(OAS; W-00-12-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

Public Health Programs

Centers for Disease Control and Prevention

Controls Over the Cooperative Agreement Award Process

We will review the Centers for Disease Control and Prevention's (CDC) controls over the cooperative agreement award process. The Recovery Act provides \$1 billion for prevention and wellness strategies, including community-based disease prevention, increased immunization activities, and health-care-associated infection reduction. CDC has an aggressive timeline to award these funds, primarily through cooperative agreements. In accordance with the Recovery Act, we will provide oversight of the funds to prevent fraud, waste, and abuse. As part of this oversight role, we will determine whether CDC's internal controls over the cooperative agreement award and administration processes appear to be effective considering the accelerated timeline for disbursement and the increased funds that will be awarded above the annual appropriation.

(OAS; W-00-09-27102; expected issue date: FY 2009; new start, Recovery Act)

Implementation of Controls Over Cooperative Agreements

We will review the implementation of CDC's controls over cooperative agreements awarded with the \$1 billion in increased Recovery Act funds for prevention and wellness strategies. As part of our oversight role in preventing fraud, waste, and abuse, we will assess CDC's implementation of its internal controls over the cooperative agreement award and administration processes and determine whether the controls were effective.

(OAS; W-00-09-27102; expected issue date: FY 2010; new start, Recovery Act)

Recipient Compliance With Cooperative Agreement Requirements

We will review compliance with the Recovery Act and applicable Federal regulations by recipients of CDC's cooperative agreements. The Recovery Act provides \$1 billion, primarily through cooperative agreements, for prevention and wellness strategies. These funds will be awarded and spent in a short period. As part of our oversight role in preventing fraud, waste, and abuse, we will determine whether CDC recipients spent funds in accordance with the terms and conditions set forth in the Recovery Act and applicable Federal regulations.

(OAS; W-00-09-27102; expected issue date: FY 2011; new start, Recovery Act)

Health Resources and Services Administration

Health Information Technology Grants

We will review HIT grant recipients' required reporting documents to assess grantee progress in implementing EHR and other HIT initiatives. During 2007 and 2008, the Health Resources and Services Administration (HRSA) awarded 74 grants totaling \$50 million to health-center-controlled networks and large multisite health centers to implement EHRs and other HIT innovations to improve the safety and quality of health care delivery and cut waste and duplication of care. The Recovery Act provided HRSA with \$1.5 billion for modernization, renovation, and repair of health centers, which includes the acquisition of HIT systems. In accordance with 70 Fed. Reg. § 76463 (Dec. 27, 2005), HRSA's Office of Health Information Technology (OHIT) is charged with promoting the adoption and effective use of HIT through grants and technical assistance. To assist grantees, HRSA collaborated with the Agency for Healthcare Research and Quality (AHRQ) to establish a "Health Information Technology Community" Web site that enables HRSA to provide HIT technical assistance interactively. We will examine HRSA's efforts to promote and oversee grantees' implementation of electronic health records.

(OEI; 00-00-00000; expected issue date: FY 2011; new start; Recovery Act)

Internal Controls for Awarding and Monitoring Grants to Community Health Centers

We will review HRSA's controls over the grant award and monitoring process. The Recovery Act provides \$500 million to community health centers to meet increased demand for services and to establish new access points. As part of the Office of Inspector General's (OIG) oversight role in preventing fraud, waste, and abuse, we will assess HRSA's internal controls over the grant award and monitoring processes to determine whether the controls appear to be effective

considering the accelerated timeline for disbursement and the increased funds that will be awarded above the annual appropriation.

(OAS; W-00-09-27105; expected issue date: FY 2010; new start, Recovery Act)

Recipient Capability Audits

We will determine whether new potentially high-risk recipients of Recovery Act funds for new access points are capable of managing Federal awards. Under the new access points program, 50 of the 126 grantees receiving \$157 million in Recovery Act funds for new service delivery sites are new grantees. For the increased demand for services grants (\$343 million) and the minor capital improvements grants (\$850 million), HRSA requested our assistance in conducting audits of grantees with identified concerns. In light of OIG's oversight role in preventing fraud, waste, and abuse and the increased number of grants, we will conduct modified recipient capability audits to assess grantees' capacity to manage and account for Federal funds and to operate new community health service delivery sites in accordance with Federal regulations.

(OAS; W-00-09-27105; various reviews; expected issue date: FYs 2009 and 2010; new start, Recovery Act)

Construction Grant Award and Monitoring Process

We will review HRSA's controls over the construction grant award and monitoring process. The Recovery Act provides \$1.375 billion to community health centers to fund minor capital improvements (\$850 million) and major capital improvements (\$525 million). Our preliminary analysis indicates that HRSA has not received construction funding other than earmarks in 12 years and is updating limited construction grant guidance. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will assess HRSA's internal controls over the construction grant award and monitoring processes to determine whether the controls appear to be effective considering the accelerated timeline for disbursement and the increased funds that will be awarded above the annual appropriation.

(OAS; W-00-09-27105; expected issue date: FY 2010; new start, Recovery Act)

Award and Monitoring of Grants, Loans, Scholarships, and Service Agreement Contracts for Health Professions Training Programs

We will review HRSA's controls over awarding and monitoring grants, loans, scholarships, and service agreement contracts used to carry out Health Professions Training Programs. The Recovery Act provides \$500 million to address health profession workforce shortages by building on HRSA's programs. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether HRSA's internal controls over the award and monitoring processes appear to be effective considering the volume of applications, the accelerated timeline for disbursement, and the increased funds that will be awarded above the annual appropriation.

(OAS; W-00-10-27105; expected issue date: FY 2010; new start, Recovery Act)

Grant Award System for Health Information Technology Funds

We will review general and application IT security controls for HRSA's grant system to ensure that adequate IT security controls are in place. We will assess whether HRSA's grant award system has sufficient processes in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. HRSA has \$125 million in Recovery Act funding available for HIT systems and network grants to support EHR for health centers. The review will focus on the controls in place to safeguard HIT grant information

pertaining to HRSA's distribution of the grant funds. We will also determine whether HRSA's grant awards require appropriate IT security provisions to protect sensitive EHR or personal information at the grantee level.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Community Health Centers Receiving Health Information Technology Funding

We will review general IT security controls in place for community health center systems funded by HRSA HIT grants to ensure that adequate HIT security controls are in place to protect sensitive EHR and personal information. HRSA will expend \$125 million, of \$1.5 billion in Recovery Act funding, for HIT systems and network grants to support EHR for community health centers. More than 1,000 community health centers are expected to benefit from this funding.

(OAS; W-00-10-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Indian Health Service

Facilities Construction: Bid Proposal Audits

We will review the top bidders for Indian Health Service (IHS) construction contracts to determine whether the proposed costs were supported by current, complete, and accurate cost or pricing data and determine the reasonableness and allowability of proposed costs and will review bid estimation procedures. The Recovery Act provides \$415 million for construction of IHS health care facilities. As part of our oversight role in preventing fraud, waste, and abuse, we will assess the bid proposals to address the risk of unreasonable or unallowable costs or inaccurately priced contracts.

(OAS; W-00-09-27103; expected issue date: FY 2012; new start, Recovery Act)

Facilities Construction: Contingency Fund Management Audits

We will review IHS's management of construction contingency funds and determine whether they were spent on eligible project costs. The Recovery Act provides \$415 million for construction of IHS health care facilities. Our preliminary analysis indicates that 10 to 15 percent of construction funding is usually set aside as a contingency fund for major construction projects. The Recovery Act specifies that funds must be obligated by the end of FY 2010. As part of our oversight role in preventing fraud, waste, and abuse, we will assess IHS's management of contingency funds to determine whether the usage was proper considering the accelerated timeframe to obligate the funds, which will then be used for construction projects lasting for years afterward.

(OAS; W-00-11-27103; expected issue date: FY 2012; new start, Recovery Act)

Internal Controls Over Equipment

We will review IHS's internal controls for property management and monitoring of equipment. The Recovery Act provides \$20 million for IHS to purchase medical equipment, computed tomography scanners, and ambulances. A recent Government Accountability Office (GAO) audit found that millions of dollars worth of IHS property was lost or stolen over the past several years. The audit also found evidence of wasteful spending. As part of OIG's oversight role in

preventing fraud, waste, and abuse, we will assess internal controls and monitoring of IHS property.

(OAS; W-00-11-27103; expected issue date: FY 2012; new start, Recovery Act)

Indian Health Service System Improvements

We will review improvements made by IHS to its applications and network infrastructure to ensure that IT security controls are in place. The Recovery Act provided \$85 million to IHS to make improvements to its HIT environment and to improve service to its constituents. Activities to be funded with this investment include (1) application development and enhancements for the Resource and Patient Management System, which contains patient medical data, history, and payment data, and (2) HIT infrastructure security enhancements to ensure safety of health data and network upgrades to provide enhanced health services to IHS constituents.

(OAS; W-00-10-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

National Institutes of Health

Internal Controls Over Research Awards

We will review the National Institutes of Health's (NIH) internal controls over the research grant award process in light of the extensive funding provided by the Recovery Act and the timeframes in which the funds are to be spent. NIH's scientific research spending plan proposes \$8.2 billion of Recovery Act funds to support previously approved but not funded projects, new applications, and expansion of current projects. The comparative effectiveness research spending plan proposes \$400 million of Recovery Act funds for research that will evaluate the impact of various options for treating a given medical condition. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH's internal controls for processing and monitoring Recovery Act grants are effective and efficient.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Implementation of Internal Controls Over Grant Awards

We will review NIH's internal controls for ensuring that grant awards comply with Recovery Act requirements. The Recovery Act provides \$10.4 billion in new funding to NIH: \$8.6 billion to the Office of the Director for research efforts; \$1.3 billion to the National Center for Research Resources (NCRR) for extramural laboratory construction and purchase of shared instrumentation; and \$500 million to NIH's Intramural Buildings and Facilities program for construction, repairs, and improvements. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH has a system in place to track funds that are received and awarded and to report results in accordance with the terms and conditions of the Recovery Act.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Recipient Capability Audits

We will review selected NIH grantees to determine whether they have the capacity to manage and account for Federal funds and to operate in accordance with Recovery Act requirements. The Recovery Act provides \$10.4 billion in new funding to NIH. We will determine whether

NIH grantees are financially capable of performing as responsible recipients and whether financial management reporting, monitoring, and evaluation systems are adequate to administer federally funded projects.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Implementation of Internal Controls for Grantee Reporting

We will review NIH's internal controls for ensuring that grantee reporting processes comply with the Recovery Act requirements. The Recovery Act provides \$10.4 billion in new funding to NIH. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH has a system in place to ensure that grantees capture and report necessary financial, economic, and grant/contract data in accordance with the terms and conditions of the Recovery Act.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Recipient Compliance With Grant Requirements

We will review NIH grant recipients' compliance with the Recovery Act and applicable Federal regulations. The Recovery Act provides \$10.4 billion in new funding to NIH. We will determine whether NIH grantees spent funds in accordance with the terms and conditions set forth in the Recovery Act and applicable Federal regulations.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Internal Controls for Extramural Construction and Shared Instrumentation

We will review NIH's internal controls for awarding extramural construction and shared instrumentation grants. NIH's extramural construction spending plan proposes \$1 billion of Recovery Act funds for renovations, repairs, improvements, or construction of core research facilities. The shared instrumentation spending plan proposes \$300 million of Recovery Act funds for the purchase of major items of biomedical research equipment. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH's internal controls for the systems used to process and monitor Recovery Act grants are effective and efficient.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

National Institute of Environmental Health Sciences Grant Process

We will review issues related to grants made by the National Institute of Environmental Health Sciences (NIEHS), including grants awarded with Recovery Act funds. NIEHS is expected to receive approximately \$168 million over 2 years for scientific research grants directed to improving the length and quality of lives. We will determine whether NIEHS complied with the terms and conditions of the Recovery Act and applicable Federal regulations. Additionally, we will determine whether the FYs 2005 to 2007 expenses of its Director's office were incurred in accordance with NIH policies. This review was congressionally requested.

(OAS; W-00-09-27102; expected issue date: FY 2010; new start, Recovery Act)

Intramural Construction Bid Proposal Audits

We will review the top bidders for construction contracts to determine whether proposed costs were supported by current, complete, and accurate cost or pricing data and determine the reasonableness and allowability of proposed costs and will evaluate bid estimation procedures. The Recovery Act provides \$500 million to NIH's Intramural Buildings and Facilities program.

As part of our oversight role in preventing fraud, waste, and abuse, we will assess the bid proposals to determine the risk of unreasonable or unallowable costs or inaccurately priced contracts.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Intramural Construction: Contingency Fund Management

We will review NIH's management of construction contingency funds to ensure that they are spent on eligible project costs. The Recovery Act provides \$500 million to NIH's Intramural Buildings and Facilities program. Our preliminary analysis indicates that 10 to 15 percent of construction funding is usually set aside as a contingency fund for major construction projects. The Recovery Act specifies that funds must be obligated by the end of FY 2010. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will assess NIH's management of the contingency funds to determine whether the usage was proper considering the accelerated timeline to obligate the funds, which will then be used for construction projects lasting for years afterward.

(OAS; W-00-11-27101; expected issue date: FY 2012; new start, Recovery Act)

College and University Indirect Costs Claimed as Direct Costs

We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants. Prior audit work identified problems in this area, and a large amount of Recovery Act funds will be used for grants to colleges and universities. We will review administrative and clerical expenses claimed for reimbursement as direct charges to Federal grants and contracts when those costs should have been treated as indirect costs and recovered through negotiated facility and administrative rates. The Office of Management and Budget (OMB) Circular A-21, "Cost Principles for Educational Institutions," provides that such costs usually be treated as indirect costs. However, direct charging of these costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support.

(OAS; W-00-09-27102; expected issue date: FY 2012; new start, Recovery Act)

National Institutes of Health Grant System

We will review general and application IT security controls for NIH's Information for Management, Planning, Analysis, and Coordination (IMPAC) system to ensure that adequate IT security controls are in place. We will assess whether NIH has processes in place or under development that are sufficient to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. The IMPAC system manages the grants at NIH, and its importance has increased since NIH received \$7.4 billion in Recovery Act funding for grants to and cooperative agreements with research entities, including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and individuals. We will also determine whether NIH's grant awards require appropriate IT security provisions to protect sensitive EHR or personal information at the grantee level.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Cross-Cutting Public Health Activities

Recipient Compliance With Reporting Requirements

We will review monitoring by HRSA, NIH, and IHS of award recipients' compliance with the reporting requirements specified in the Recovery Act and OMB guidance. The recipients and uses of Recovery Act funds must be transparent to the public, and the public benefits of these funds must be reported clearly and accurately and in a timely manner. We will review recipients' reports for compliance with the reporting requirements, including accuracy and completeness.

(OAS; W-00-10-27109; various reviews; expected issue date: FY 2010; new start, Recovery Act)

State Compliance With Grant Requirements

We will review security controls implemented by States to safeguard electronic health information exchanges. Under the Public Health Service Act of 1944 (PHS Act), § 3013, as added by section 13301 of the Recovery Act, the Office of the National Coordinator for Health Information Technology (ONC) is authorized to award planning and implementation grants to States to facilitate and expand electronic health information exchanges. To receive an implementation grant, a State must submit a plan describing the activities to be carried out to facilitate and expand electronic health information exchange according to nationally recognized standards and implementation specifications. We will use our body of work in Medicaid reviews of 24 States to identify higher risk States, assess State plans, and determine the adequacy of their security controls.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)

Human Service Programs

Administration for Children and Families

Internal Controls Over Grant Award Process

We will review the Administration for Children and Families' (ACF) internal controls over the grant award and administration process. The Recovery Act appropriates approximately \$10 billion to a variety of ACF programs (Head Start and Early Head Start, Temporary Assistance to Needy Families (TANF), the Child Care and Development Block Grant (CCDBG), and the Community Services Block Grant (CSBG)). As part of OIG's oversight role in preventing fraud, waste, and abuse and in light of the anticipated increase in new applications and time constraints for awarding funds, we will determine whether ACF's internal controls for processing and monitoring Recovery Act grants are effective and efficient.

(OAS; W-00-09-27101; expected issue date: FY 2010; new start, Recovery Act)

Community Service Block Grants

We will review ACF's controls over the grant award and oversight process for CSBG funds. The Recovery Act provides \$1 billion in additional funds for States to alleviate the causes and conditions of poverty in communities. A recent GAO review identified numerous internal

control weaknesses concerning ACF's oversight of the States' use of CSBG funds. As part of our oversight role under the Recovery Act, we will conduct a follow-up review of the grant award and oversight process to determine whether ACF has taken effective corrective actions and to assess other oversight controls.

(OAS; W-00-09-27100; A-01-09-00000; expected issue date: FY 2010; new start, Recovery Act)

Licensing, Health, and Safety Standards at Childcare Facilities

We will review licensing, health, and safety standards at selected childcare facilities that received CCDBG funding, including Recovery Act funds. Federal regulations at 45 CFR § 98.15(b)(4)-(6) for CCDBG require States to certify that they have complied with licensing, health, and safety requirements applicable to childcare services in accordance with 45 CFR §§ 98.40 and 98.41. A previous review of one Head Start grantee that also provided CCDBG daycare services found several instances in which childcare facilities did not comply with applicable health and safety requirements. We will determine the extent to which childcare facilities that received Federal funding, including Recovery Act funds, have complied with applicable requirements.

(OAS; W-00-09-27100; various reviews; expected issue date: FY 2010; new start, Recovery Act)

Licensing, Health, and Safety Standards at Head Start Facilities

We will review licensing, health, and safety standards at selected facilities that received Head Start funding, including Recovery Act funds. The Recovery Act requires that \$1 billion in supplemental funds awarded to Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Head Start performance standards at 45 CFR §§ 1306.30(c) and 1306.35(d) require that Head Start facilities comply with State and local childcare licensing requirements. If States do not have licensing requirements or if State requirements are less stringent than Federal standards, the facilities must comply with the Head Start health and safety requirements found at 45 CFR § 1304.53(a). Our previous reviews of two Head Start grantees found several instances in which the facilities did not comply with applicable health and safety requirements. We will determine the extent to which Head Start grantees have demonstrated that facilities receiving Federal funding, including Recovery Act funds, complied with applicable requirements.

(OAS; W-00-09-27100; various reviews; expected issue date: FY 2010; new start, Recovery Act)

Head Start Matching Costs

We will review Head Start matching claims to determine whether grantees that received Recovery Act funding met the 20-percent match of total costs required for Head Start funding. The Recovery Act requires that the \$1 billion in supplemental funds for Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Regional ACF officials have indicated that grantees might not be meeting the Head Start matching requirement. Federal regulations at 45 CFR §§ 74.23 and 1301.20 establish which costs a grantee may consider to satisfy the required match. We will identify any challenges facing grantees in meeting the matching requirement.

(OAS; W-00-09-27100; various reviews; expected issue date: FY 2012; new start, Recovery Act)

Head Start Agencies' Use of Grant Funds

We will review the use of funds, including Recovery Act funds, by Head Start agencies. The Recovery Act requires that the \$1 billion in supplemental funds for Head Start grantees be

used in a manner consistent with the requirements of the Head Start Act. Recipients of Head Start funds are required to ensure that these funds are used for authorized purposes as required by 45 CFR § 92.20(b)(3). We will determine whether Head Start funds and Recovery Act funds were properly used for the purposes outlined in Federal award letters, approved Head Start agency grant applications, and program requirements.

(OAS; W-00-09-27100; expected issue date: FY 2012; new start, Recovery Act)

Head Start Recipient Capability Audits

We will review Head Start applicants' capacity to manage and account for Federal funds, including Recovery Act funds, and to operate a Head Start program in accordance with Federal regulations. The Recovery Act requires that \$1 billion in supplemental funds awarded to Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Pursuant to 2 CFR § 215.21(a)(3), grantees receiving Head Start funds must ensure that the funds are used for authorized purposes. We will determine whether Head Start applicants are able to adequately manage and account for Federal funds, including Recovery Act funds, and fulfill Head Start program requirements.

(OAS; W-00-09-27100; expected issue date: FY 2010; new start, Recovery Act)

Early Head Start Recipient Capability Audits

We will review Early Head Start applicants' ability to manage and account for Federal funds, including Recovery Act funds, and to operate an Early Head Start program in accordance with Federal regulations. The Recovery Act requires that \$1.1 billion in program expansion funds awarded to Early Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Grantees receiving Early Head Start funds must ensure that the funds are used for authorized purposes pursuant to 2 CFR § 215.21(b)(3). We will determine whether Early Head Start applicants are able to adequately manage and account for Federal funds, including Recovery Act funds, and fulfill Early Head Start program requirements.

(OAS; W-00-09-27100; various reviews; expected issue date: FY 2011; new start, Recovery Act)

Early Head Start Agencies' Use of Grant Funds

We will review the use of funds, including Recovery Act funds, by Early Head Start agencies. The Recovery Act requires that the \$1.1 billion in program expansion funds for Early Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Recipients of Early Head Start funds are required to ensure that these funds are used for authorized purposes as required by 45 CFR § 92.20(b)(3). We will determine whether Early Head Start funds, including Recovery Act funds, were properly used for the purposes outlined in Federal award letters, approved Head Start agency grant applications, and program requirements.

(OAS; W-00-09-27100; expected issue date: FY 2012; new start, Recovery Act)

Administration for Children and Families Grant System

We will review general and application IT security controls for ACF's Grants Administration Tracking Evaluation System (GATES) to determine whether adequate IT security controls are in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. GATES is used by ACF grants officers and specialists to manage their grant programs and process grant applications from receipt through award. ACF received \$10 billion for grants supporting Head Start, Early Head Start, TANF, childcare and development, and Community Services. We will also determine whether ACF's grant awards

require increased IT security provisions to protect sensitive EHR or personal information at the grantee level.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Administration for Children and Families Health Information Technology Grants

We will review general IT security controls for systems funded by ACF HIT grants to determine whether adequate security controls are in place to protect sensitive EHR and personal information. ACF will award HIT grants to State agencies, local governments, nonprofit organizations, and school systems administering Head Start, Early Head Start, TANF, CCDBG and CSBG programs. We will also assess whether ACF grantees receiving HIT funds have sufficient processes in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained.

(OAS; W-00-10-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Departmentwide Issues

Cross-Cutting Investigative Activities

Integrity of Recovery Act Expenditures

We will review and evaluate credible allegations relating to improper expenditures of Recovery Act funds to identify cases in which criminal investigations will be opened and appropriate enforcement actions pursued. The Recovery Act funding will result in a significant increase in the number of grants and contracts awarded by HHS. Accordingly, we anticipate an increase in the number of complaints and referrals of grant- and contract-related fraud allegations. The Recovery Act requires transparency and accountability in the awarding and spending of funds.

(OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)

Enforcement of Whistleblower Protections

We will review and evaluate credible allegations relating to reprisals perpetrated against whistleblowers by entities or individuals receiving Recovery Act funds to identify cases in which criminal investigations will be opened and antireprisal enforcement actions pursued. Section 1553 of the Recovery Act extends whistleblower protection to employees who reasonably believe they are being retaliated against for reporting misuse of Recovery Act funds received by their non-Federal employers.

(OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)

Preaward Screening of Potential Grant Recipients

We will develop and implement a process whereby HHS granting agencies will be able to quickly consult with OIG to determine whether there are any ongoing OIG or other criminal

investigations before making awards. Through this mechanism, we will reinforce HHS's efforts to ensure integrity in the awarding of funds under the Recovery Act.

(OI; expected implementation date: FY 2009; work in progress; Recovery Act)

Health Information Technology Standards

We will review the process used by ONC to develop and recommend HIT standards to the HHS Secretary. Section 3003 of the PHS Act, as added by section 13101 of the Recovery Act, establishes the HIT Standards Committee to recommend to the ONC standards, implementation specifications, and certification criteria for the electronic exchange of health information. ONC is charged with reviewing and recommending to the Secretary whether to propose adoption of these measures through the rulemaking process. Section 3004(b) requires that the Secretary adopt an initial set of standards by December 31, 2009. We will assess the standards adoption process to determine whether IT security controls have been adequately developed and included in the standards recommended for adoption.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Departmentwide Network Improvements

We will review the acquisition of staff, hardware, and software intended to improve IT security at HHS and, where applicable, test modifications to the HHS IT security environment. HHS has allocated \$50 million in Recovery Act funds to improve IT security departmentwide. Recent compromises of systems and data in HHS's Office of the Secretary, as well as at several HHS agencies, require concerted and coordinated action across HHS that is commensurate with the sustained level of sophisticated cyber attacks that have targeted HHS computer systems.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Security Controls for Grants Web Site

We will review general and application IT security controls for the Grants.gov Web site to ensure that adequate IT security controls are in place to protect information. Our assessment will focus on controls for ensuring confidentiality, integrity, and availability of data. Grants.gov is the central grant identification and application portal for more than 1,000 Federal grant programs offered by 26 Federal agencies and organizations. On March 6, 2009, Grants.gov began posting information on specific grant opportunities provided in the Recovery Act. As a result, grant applications filed using Grants.gov have escalated to an unprecedented level, reaching almost 11,500 applications per week, which is about three times the weekly average number of submissions during FY 2008.

(OAS; W-00-09-27109; various reviews; expected issue date: FY 2010; new start; Recovery Act)

Appendix B: Acronyms and Abbreviations

Terms and Titles

The Work Plan refers to the following acronyms and abbreviations for terms and titles. Organization and Public Law acronyms and abbreviations are listed in separate sections that follow.

340B program	section 340B drug pricing program
ADAP	AIDS Drug Assistance Program
AIDS	acquired immunodeficiency syndrome
AIR	all-inclusive rate
ALF	assisted living facility
AMP	average manufacturer price
ASC	ambulatory surgical center
ASP	average sales price
AWP	average wholesale price
BERM	Bioterrorism Epidemic Outbreak Response Model
BLA	biological licensing agreement
CAH	critical access hospital
CAS	Cost Accounting Standards
CCDBG	Child Care and Development Block Grant
CCDF	Child Care and Development Fund
CCI	Medicare National Correct Coding Initiative
CDT	continuing day treatment (providers)
CERT	Comprehensive Error Rate Testing (program)
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CIA	corporate integrity agreement
CMP	civil monetary penalty
CPG	compliance program guidance
CSBG	Community Services Block Grant
CSE	child support enforcement
CSW	clinical social worker
CTSA	Clinical and Translational Science Award (grants)
CWF	Common Working File
CY	calendar year
DGME	direct graduate medical education
DIR	direct and indirect remunerations
DME	durable medical equipment
DRG	diagnosis-related group
DSH	disproportionate share hospital
DSMB	Data and Safety Monitoring Board
DSMT	diabetes self-management training
E&M	evaluation and management (services)
EHR	electronic health records
EMS	emergency medical services
ENT	enteral nutrition therapy
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
ESA	erythropoiesis-stimulating agents (in dialysis)
ESRD	end-stage renal disease

FAR	Federal Acquisition Regulation (CFR, Title 48)
FFP	Federal financial participation
FFS	fee-for-service (payments)
FI	fiscal intermediary
FMAP	Federal medical assistance percentage
FTE	full-time equivalent
FTR	Federal Travel Regulation
FUL	Federal upper limit
FY	fiscal year
GATES	Grants Administration Tracking Evaluation System
HCBS	home- and community-based services
HCFAC	Health Care Fraud and Abuse Control (program)
HCPCS	Healthcare Common Procedure Coding System
HEAL	Health Education Assistance Loan
HHA	home health agency
HHRG	home health resource group
HHSAR	HHS Acquisition Regulation (CFR, Title 48)
HI	Hospital Insurance (trust fund)
HIPDB	Healthcare Integrity and Protection Data Bank
HIT	health information technology
HIV	human immunodeficiency virus
IDTF	independent diagnostic testing facility
IMD	institution for mental diseases
IME	indirect medical education
IMPAC	Information for Management, Planning, Analysis, and Coordination (system)
IND	investigational new drug
IPF	inpatient psychiatric facility
IPPS	inpatient prospective payment system
IRIS	Intern and Resident Information System
IRF	inpatient rehabilitation facility
IT	information technology
LIS	low-income subsidy
LMRP	local medical review policy
LTC	long term care
LTCH	long term care hospital
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MCO	managed care organization
MDS	Minimum Data Set
Medi-Medi	Medicare and Medicaid Data Match Project
MFCU	Medicaid Fraud Control Unit
MMIS	Medicaid Management Information System
MPFS	Medicare physician fee schedule
MS-DRG	Medicare Severity Diagnosis Related Group (system)
MSN	Medicare Summary Notice
MTMP	medication therapy management program
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NDA	new drug application
NPI	national provider identifier
NQF	National Quality Forum
OASIS	Outcome and Assessment Information Set
OPO	organ procurement organization
OPPS	outpatient prospective payment system
PARIS	Public Assistance Reporting Information System
PBM	pharmacy benefit manager
PCA	progressive corrective action

PDE	prescription drug event
PDP	prescription drug plan
PEPFAR	President’s Emergency Plan for AIDS Relief
PERM	Payment Error Rate Measurement (program)
PERS	personal emergency response services
PHEP	Public Health Emergency Preparedness (program)
PII	personally identifiable information
POA	present on admission
PPS	prospective payment system
PSC	Program Safeguard Contractor
QI	Qualifying Individual program
QIO	Quality Improvement Organization
RAC	Recovery Audit Contractor
RAI	Resident Assessment Instrument
RUG	resource utilization group
SACWIS	Statewide Automated Child Welfare Information System
SAPTBG	SAMHSA-Funded Prevention and Treatment Block Grants
SAS	Statement on Auditing Standards
SGE	special Government employees
SMI	Supplemental Medical Insurance (trust fund)
SNF	skilled nursing facility
TANF	Temporary Assistance for Needy Families (program)
TMA	transitional medical assistance
TrOOP	true out-of-pocket costs for Part D
UPIN	unique physician identifier number
URA	unit rebate amount
UPL	upper payment limit
U.S.C.	United States Code
VFC	Vaccines for Children (grants)
WAMP	widely available market price
ZPIC	Zone Program Integrity Contractor

Organizations

The Work Plan refers to the following acronyms and abbreviations for governmental organizations.

ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AoA	Administration on Aging
ASAM	Office of the Assistant Secretary for Administration and Management
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASRT	Office of the Assistant Secretary for Resources and Technology
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
DOC	Department of Commerce
DOD	Department of Defense
DOJ	Department of Justice
FDA	Food and Drug Administration
GAO	Government Accountability Office
GSA	General Services Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IO	Immediate Office of the Inspector General
MedPAC	Medicare Payment Advisory Commission

NCRR	National Center for Research Resources
NIAID	National Institute of Allergy and Infectious Diseases
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OHIT	Office of Health Information Technology
OCR	Office for Civil Rights
OCSE	Office of Child Support Enforcement
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMH	Office of Minority Health
ONC	Office of the National Coordinator for Health Information Technology
ONDACP	Office of National Drug Control Policy
PSC	Program Support Center
SAMHSA	Substance Abuse and Mental Health Services Administration
VA	Department of Veterans Affairs

Public Laws

The Work Plan refers to the following acronyms and abbreviations for Public Laws (P.L.).

Anti-Deficiency Act	Anti-Deficiency Act of 1950, P.L. No. 82-414
BBA	Balanced Budget Act of 1997, P.L. No. 105-33
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, P.L. No. 106-554
CARE Act	Ryan White Comprehensive AIDS Resources Emergency Act of 1990, P.L. No. 101-381
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980, P.L. No. 96-510
CFO Act	Chief Financial Officers Act of 1990, P.L. No. 101-576
CHIPRA	Children’s Health Insurance Program Reauthorization Act of 2009, P. L. No. 111-3
DRA	Deficit Reduction Act of 2005, P.L. No. 109-171
EAA	Export Administration Act of 1979, P.L. No. 96-72
EMTALA	Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272
FCA	False Claims Amendments Act of 1986, P.L. No. 99-562
FCCA	Federal Claims Collection Act of 1966, P. L. No. 89-508
FDCA	Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717
FISMA	Federal Information Security Management Act of 2002, Title III, E-Government Act of 2002, P.L. No. 107-347
GMRA	Government Management Reform Act of 1994, P.L. No. 103-356
GPR	Government Performance and Results Act of 1993, P.L. No. 103-62
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191
IHCIA	Indian Health Care Improvement Act of 1976, P.L. No. 94-437
IPIA	Improper Payments Information Act of 2002, P.L. No. 107-300
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275
OAA	Older Americans Act of 1965, P.L. No. 89-73
OCAA	Omnibus Consolidated Appropriations Act of 1997, P.L. 104-368
PHS Act	Public Health Service Act of 1944
Recovery Act	American Recovery and Reinvestment Act of 2009, P.L. No. 111-5
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, P.L. No. 97-248
TRHCA	Tax Relief and Health Care Act of 2006, P.L. No. 109-432
(Not abbreviated)	Breast and Cervical Cancer Mortality Prevention Act of 1990, P.L. No. 101-354
(Not abbreviated)	Civil Rights Act of 1964, P.L. No. 88-352
(Not abbreviated)	Indian Child Protection and Family Violence Prevention Act, P.L. No. 101-630

(Not abbreviated) Refugee Act of 1980, P.L. No. 96-212
(Not abbreviated) Ryan White HIV/AIDS Treatment Modernization Act of 2006, P.L. No. 109-415
(Not abbreviated) Social Security Act of 1935, P.L. No. 74-271