



Department of Health & Human Services

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Office of  
Inspector  
General

# Work Plan

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**OIG**

Office of Inspector General

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# A Message From the Office of Inspector General

We are pleased to present the *Office of Inspector General Work Plan for Fiscal Year 2011*. This publication provides brief descriptions of activities that the Office of Inspector General (OIG) plans to initiate or continue with respect to the programs and operations of the Department of Health & Human Services (HHS) in fiscal year (FY) 2011. 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, 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.

## Core Values

- Integrity:** Acting with independence and objectivity.
- Credibility:** Building on a tradition of excellence and accountability.
- Impact:** Yielding results that are tangible and relevant.

## Organization

Following are descriptions of the OIG components that carry out our audit, evaluation, investigation, enforcement, and compliance activities.

- The Office of Audit Services (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

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reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

- The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs. OEI reports also present practical recommendations for improving program operations.
- The Office of Investigations (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 civil monetary penalties.
- The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support 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 civil monetary penalty 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.

The organizational entities described above are supported by the Immediate Office of the Inspector General and the Office of Management and Policy.

### **Program Integrity Resources**

OIG's program integrity resources derive from multiple sources, including a single discretionary appropriation<sup>1</sup> and multiple statutory funding streams provided through other legislation. For the past several years, OIG's discretionary appropriation has represented on average about 20 percent of our total annual funding, while separate statutory funding streams that are mandated for our oversight of Medicare and Medicaid have provided about 80 percent. Our annual budget is devoted largely to oversight of Medicare and Medicaid, consistent with our statutory mandates.

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<sup>1</sup> 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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## 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 year ahead considering 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 work plan proposals, we consider a number of factors, including:

- 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 *Work Plan*, effective as of October 2010, describes for each review the subject, primary objective, and criteria related to the topic. The *Work Plan* also provides for each review its internal identification code, the year in which we expect one or more reports to be issued as a result of the review, and indicates whether the work was in progress at the start of the fiscal year or will be a new start during the year. Typically, a review designated as "work in progress" will result in reports issued in FY 2011, but a review slated to begin in FY 2011 ("new start") could result in FY 2011 or FY 2012 reports, depending upon when the assignments are initiated during the year and the complexity and scope of the examinations.

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The body of the *Work Plan* is presented in seven major parts followed by Appendix A, which describes the Office of Inspector General’s oversight of the funding that HHS receives under the American Recovery and Reinvestment Act of 2009 (Recovery Act).

Detailed tables of contents are provided at the beginning of each major part and Appendix A. Appendix B spells out most acronyms and abbreviations of terms, organizations, and laws that are used in the *Work Plan*. If you have questions about the publication, please contact our Office of External Affairs at (202) 619-1343.

An outline of the major parts and appendixes follows.

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## Outline of Major Parts and Appendixes

- Part I: Medicare Part A and Part B
- Part II: Medicare Part C and Part D
- Part III: Medicaid Reviews
- Part IV: Legal and Investigative Activities
- Part V: Public Health Reviews
- Part VI: Human Services Reviews
- Part VII: Departmentwide Issues
- Appendix A: Recovery Act Reviews
- Appendix B: Acronyms and Abbreviations

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# **Work Plan Part I: Medicare Part A and Part B**

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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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## Medicare Part A and Part B

Medicare Part A helps cover inpatient care in hospitals, including critical access hospitals, skilled nursing facilities (excepting custodial or long-term care), hospice care, and some home health care. Medicare Part B helps cover physicians' services and outpatient care. It also covers designated other medical services that Part A does not cover, such as some physical and occupational therapy services and home health care.

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 skilled nursing facilities (SNF) and the carriers processing claims for Medicare Part B (including for physicians', laboratories', and other services). The Centers for Medicare & Medicaid Services (CMS) also engages contractors that perform specific fee-for-service (FFS) business functions. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 911, 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 claims. The reform plan includes specialty MACs that will service suppliers of durable medical equipment (DME).

Descriptions of our work in progress and planned reviews of Medicare Part A and Part B payments and services for fiscal year (FY) 2011 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. *(OAS; W-00-09-35300; W-00-10-35300; various reviews; expected issue date: FY 2011; 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. Pursuant to 42 CFR § 413.65(d), Medicare may permit hospitals that own and operate multiple provider-based facilities or departments in different sites to operate as a single entity, so long as specific requirements are met. Hospitals that receive this "provider-based status" 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

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disproportionate share hospital (DSH) payments, upper payment limit (UPL) payments, or graduate medical education payments for which they would not normally be eligible. 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 the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities.

*(OAS; W-00-10-35424; W-00-11-35424; various reviews; expected issue date: FY 2011; 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, inpatient prospective payment system (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. 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 Office of Inspector General (OIG) work in this area found significant numbers of improper claims.

*(OAS; W-00-10-35436; various reports; expected issue date: FY 2011; work in progress)*

### **Noninpatient Prospective Payment System Hospital Payments for Nonphysician Outpatient Services**

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 non-IPPS hospitals. Pursuant to the Social Security Act, § 1886(a)(4), payments to non-IPPS hospitals for inpatient claims should include diagnostic services and other services related to admission provided during 1 day immediately preceding the date of the patient's admission. For nonphysician services provided to inpatients, CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, §§ 40.3 B and 40.3 C, prohibits submissions of additional claims to Part B for outpatient diagnostic services and admission-related nondiagnostic services rendered up to 1 day before and on the date of admission.

*(OAS; W-00-11-35450; various reviews; expected issue date: FY 2011; new start)*

### **Critical Access Hospitals**

We will review payments 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

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designation criteria in the Social Security Act, § 1820(c)(2)(B), and conditions of participation (CoP) at 42 CFR pt. 485, subpart F, and whether payments to CAHs were in accordance with Medicare requirements.

*(OAS; W-00-10-35101; W-00-11-35101; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Excessive Payments**

We will review Medicare claims with high payments to determine whether they were appropriate. Our prior work has shown that claims with unusually high payments may be incorrect for various reasons. Pursuant to CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 4, § 20.4, hospitals are required to report units of service as the number of times that a service or procedure was performed. Our work will include certain outpatient claims in which payments exceeded charges and selected Healthcare Common Procedure Coding System (HCPCS) codes for which billings appear to be aberrant. We will also review the effectiveness of the claims processing edits used to identify excessive payments.

*(OAS; W-00-10-35518; W-00-11-35518; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Disproportionate Share Payments**

We will review Medicare DSH payments to hospitals. Pursuant to 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 in accordance with Medicare methodology 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-00-10-35402; W-00-11-35402; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Outlier Payments**

We will review Medicare outlier payments to determine whether CMS appropriately reconciled the payments. Outliers are additional payments made for beneficiaries who incur unusually high costs. Pursuant to Federal regulations at 42 CFR § 412.84(i)(4), outlier payment reconciliations must be based on the most recent cost-to-charge ratio from the cost report to properly determine outlier payments. Outlier payments also may be adjusted to reflect the time value of money for overpayments and underpayments.

*(OAS; W-00-11-35451; various reviews; expected issue date: FY 2011; new start)*

### **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 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)

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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; W-00-11-35432; various reviews; expected issue date: FY 2011; work in progress)*

### **Hospital Occupational Mix Data Used To Calculate Inpatient Hospital Wage Indexes**

We will determine whether hospitals reported occupational-mix data used to calculate inpatient wage indexes in compliance with Medicare regulations. Hospitals must accurately report data every 3 years on the occupational mix of their employees in accordance with the Social Security Act, § 1886 (d)(3)(E). CMS uses data from the occupational-mix survey to construct an occupational-mix adjustment to its hospital wage indexes. Accurate wage indexes are essential elements of the Medicare prospective payment system (PPS) for hospitals. We will determine the effect on the Medicare program of inaccurate reporting of occupational-mix data.

*(OAS; W-00-11-35452; various reviews; expected issue date: FY 2011; new start)*

### **Medicare Secondary Payer/Other Insurance Coverage**

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 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-00-11-35317; various reviews; expected issue date: FY 2011; new start)*

### **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 the 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-00-11-35438; various reviews; expected issue date: FY 2011; new start)*

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## **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 (DRG) payment and should combine the original and subsequent stays into a single claim. Providers are permitted to override the 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 (QIO) 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-00-10-35439; W-00-11-35439; various reviews; expected issue date: FY 2011; work in progress)*

## **Hospital Admissions With Conditions Coded Present-on-Admission**

We will review Medicare claims to determine which types of facilities are most frequently transferring patients with certain diagnoses that were coded as being present when patients were admitted, referred to as present on admission (POA). Pursuant to the Social Security Act, § 1886(d)(4)(D), and CMS's *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. For certain diagnoses specified by CMS, hospitals receive a lower payment if the specified diagnoses were acquired in the hospital. We will also determine whether specific providers transferred a high number of patients to hospitals with POA diagnoses.

*(OAS; W-00-10-35500; W-00-11-35500; various reviews; expected issue date: FY 2011; work in progress)*

## **Early Implementation of Medicare's Policy for Hospital-Acquired Conditions**

We will review the early implementation of CMS's hospital-acquired conditions (HAC) policy. Pursuant to section 5001(c) of the DRA, CMS implemented the HAC policy on October 1, 2008. The HAC policy prevents additional payment under Medicare's hospital IPPS for certain conditions or complications that are determined to be reasonably preventable. We will review Medicare claims data to identify the number of beneficiary stays associated with HACs and determine their impact on reimbursement. We will also verify the accuracy of POA indicators, which are used for identifying HACs.

*(OEI; 06-09-00310; expected issue date: FY 2011; work in progress)*

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## **Responses to Adverse Events in Hospitals by Medicare Oversight Entities**

We will review responses of State survey-and-certification agencies, Medicare accreditors, and CMS to allegations of adverse events in hospitals. An “adverse event” is defined as harm to a patient as a result of medical care. Various Medicare oversight entities have authority to investigate adverse events in hospitals to determine whether those hospitals have taken corrective actions and are in compliance with Medicare standards. 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 2011; work in progress)*

## **Hospital Reporting for Adverse Events**

We will review the type of information hospitals’ internal incident-reporting systems capture about adverse events. Most hospitals have incident-reporting systems that enable medical and hospital staff members to report information about patient safety incidents when they occur and to use reported information to prevent recurrence, hold staff members accountable, and notify families. Using data collected for a 2010 OIG study examining the national incidence of adverse events among hospitalized Medicare beneficiaries, we will determine the extent to which hospital systems captured adverse events and reported the information to external patient-safety oversight entities.

*(OEI; 06-09-00091; expected issue date: FY 2011; work in progress)*

## **Hospital Reporting for Restraint- and Seclusion-Related Deaths**

We will review hospital-reported restraint and seclusion-related deaths to determine the volume of reports and their outcome. The Patient’s Rights Hospital Condition of Participation rule at 42 CFR § 482.13(g) requires that hospitals report to CMS each death that occurs while a patient is in restraint or seclusion, as well as each death that occurs within 24 hours after a patient has been removed from restraint or seclusion. CMS regional staff members determine whether a death requires an investigation by a State agency. A 2006 OIG report found problems with the restraint- and seclusion-reporting process and stated that the reporting requirements and reporting process may hinder the effectiveness of CMS’s and State agencies’ efforts to identify and respond to restraint- and seclusion-related deaths. We will also determine the outcome of State investigations of restraint and seclusion deaths and the action the State agencies took against hospitals.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Medicare Brachytherapy Reimbursement**

We will review payments for brachytherapy, a form of radiotherapy where a radiation source is placed inside or next to the area requiring treatment, to determine whether the payments are in compliance with Medicare requirements. Pursuant to the Social Security Act, § 1833 (t)(16)(C), as amended by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 142, Medicare pays for radioactive source devices used in treatment of certain forms of cancer.



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*(OAS; W-00-10-35520; W-00-11-35520; various reviews; expected issue date: FY 2011; work in progress)*

### **Payments for Diagnostic Radiology Services in Hospital Emergency Departments**

We will review Medicare Part B paid claims and medical records for interpretations and reports of diagnostic radiology services (x-rays, CTs, and MRIs) performed in hospital emergency departments to determine the appropriateness of payments. Interpretations and reports furnished by physicians are reimbursed according to 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. In its March 2005 testimony before Congress, the Medicare Payment Advisory Commission (MedPAC), reported concerns about the increasing cost of imaging services for Medicare beneficiaries and potential overuse of diagnostic radiology services. In 2008, Medicare reimbursed physicians about \$227 million for imaging interpretations performed in emergency departments. We will determine whether diagnostic radiology interpretations and reports contributed to the diagnoses and treatment of beneficiaries receiving care in emergency departments.

*(OEI; 07-09-00450; expected issue date: FY 2011; work in progress)*

### **Hospitals' Compliance With Medicare Conditions of Participation for Intensity-Modulated and Image-Guided Radiation Therapy Services**

We will review hospitals' compliance with Medicare requirements concerning the safety and quality of intensity modulated radiation therapy (IMRT) and image-guided radiation therapy (IGRT) services. Pursuant to 42 CFR § 482.26, therapeutic radiological services, such as IMRT and IGRT, must meet professionally approved standards for safety and personnel qualification. Hospitals must maintain appropriate radiologic services to ensure safety for patients and personnel in compliance with Medicare CoP. We will also assess CMS's oversight of IMRT and IGRT services provided in hospitals.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicare Inpatient and Outpatient Hospital Claims for the Replacement of Medical Devices**

We will determine whether hospitals submitted inpatient and outpatient claims that included procedures for the insertion of replacement medical devices in compliance with Medicare regulations. The Social Security Act, §1862(a)(2), excludes from Medicare coverage an item or a service for which neither the beneficiary nor anyone on his or her behalf has an obligation to pay. Medicare is not responsible for the full cost of the replaced medical device if the hospital receives a partial or full credit from the manufacturer either because the manufacturer recalled the device or because the device is covered under warranty. Hospitals are required to use modifiers on their inpatient and outpatient claims when they receive credit from the manufacturer of 50 percent or more for a replacement device.

*(OAS; W-00-10-35516; W-00-11-35516; various reviews; expected issue date: FY 2011; work in progress)*

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## **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 2012; new start)*

## **Hospital Inpatient Outlier Payments**

We will review hospital inpatient outlier payments. Medicare typically reimburses hospitals for inpatient services based on a predetermined per-discharge amount, regardless of the actual costs incurred. The Social Security Act, § 1886(d)(5)(A)(ii), allows Medicare to pay hospitals supplemental, or outlier, payments for patients incurring extraordinarily high costs. In 2009, outlier payments represented about 5 percent of total Medicare inpatient payments, or about \$6 billion per year. Recent whistleblower lawsuits have resulted in millions of dollars in settlements from hospitals charged with inflating Medicare claims to qualify for outlier payments. We will examine trends of outlier payments nationally and identify characteristics of hospitals with high or increasing rates of outlier payments.

*(OEI; 06-10-00520; expected issue date: FY 2011; work in progress)*

## **Inpatient Rehabilitation Facility Transmission of Patient Assessment Instruments**

We will determine whether inpatient rehabilitation facilities (IRF) received reduced payments for claims with patient assessment instruments that were transmitted to CMS's National Assessment Collection Database more than 27 days after the beneficiaries' discharges. The patient assessment instrument is used to gather data to determine payment for each Medicare patient admitted to an IRF. Federal regulations for IRF payments at 42 CFR § 412.614(d)(2) provide that if patient assessments are not encoded and transmitted within defined time limits, payments be reduced. If an IRF transmits the instrument more than 27 calendar days from (and including) the beneficiary's discharge date, the IRF's payment rate should be reduced by 25 percent.

*(OAS; W-00-10-35522; various reviews; expected issue date: FY 2011; 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 home health agency (HHA) prospective payments. The Social Security Act, §§ 1832(a)(1) and 1842(b)(6)(F), require that in

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the case of home health services furnished under a plan of care of an HHA, payment for those services be to the HHA, including payment for services and supplies provided under arrangements by outside suppliers. We will identify Part B payments 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-00-10-35108; W-00-11-35418; various reviews; expected issue date: FY 2011; work in progress)*

### **Home Health Agencies' Claims for Medicare Home Health Resource Groups**

We will review Medicare claims submitted by HHAs to determine the extent to which the claims meet Medicare coverage requirements. Federal regulations at 42 CFR § 409.42 provide that beneficiaries receiving home health services must (1) be homebound; (2) need intermittent skilled nursing care, physical or speech therapy, or occupational therapy; (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician. The Social Security Act, § 1895, governs the payment basis and reimbursement for claims submitted by HHAs. On a prospective basis, Medicare reimburses for home health episodes using a system that categorizes beneficiaries into groups that are based on care and resource needs and that are referred to as Home Health Resource Groups (HHRGs). HHRGs are calculated using beneficiary assessment data collected by an HHA, and each HHRG has an assigned weight that affects the payment rate. We will assess the accuracy of HHRGs submitted for Medicare home health claims in 2008 and identify characteristics of miscoded HHRGs.

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

### **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 helping 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 the fall of 2003; and conducted a home health pay-for-performance demonstration based on OASIS data during 2008 and 2009. We will review CMS's process for ensuring that HHAs submit accurate and complete OASIS data.

*(OEI; 01-10-00460; expected issue date: FY 2011; 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,

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the home health PPS was implemented in October 2000. Since that time, total payments to HHAs have increased substantially 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-00-11-35501; various reviews; expected issue date: FY 2011; 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-00-10-35428; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Home Health Agency Enrollment**

We will review the program integrity efforts of CMS, its contractors, and State agencies during the HHA enrollment process. Pursuant to 42 CFR part 424, subpart P, each HHA provider must submit an accurate and complete enrollment application to CMS and adhere to a series of requirements to participate in the Medicare program. Previous work by OIG found that DME suppliers omitted or provided inaccurate information on enrollment applications, which resulted in improper enrollment, and that these suppliers were often associated with HHAs through shared owners and/or managers. We will determine whether the program integrity efforts of CMS, its contractors, and States identify and prevent the enrollment of questionable HHA applicants.

*(OEI; 06-10-00400; expected issue date: FY 2011; work in progress)*

## **Nursing Facilities**

### **Medicare Part A Payments to Skilled Nursing Facilities**

We will review the extent to which payments to SNFs meet Medicare coverage requirements. The Social Security Act, § 1888(e), establishes the amount paid to SNFs for all covered services. Medicare pays Part A SNF stays using a system that categorizes each beneficiary into a group based on care and resource needs. The groups are referred to as Resource Utilization Groups (RUGs). In a prior report, OIG found that 26 percent of claims had RUGs that were not supported by patients' medical records. The percentage represented \$542 million in potential overpayments for FY 2002. We will conduct a medical review to determine whether claims were medically necessary, sufficiently documented, and coded correctly during calendar year (CY) 2009.

*(OEI; 02-09-00200; expected issue date: FY 2012; work in progress)*

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## **Medicare Requirements for Quality of Care in Skilled Nursing Facilities**

We will review how SNFs have addressed certain Federal requirements related to quality of care. 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 the plans of care, and (3) planned for beneficiaries' discharges. Pursuant to the Social Security Act, §§ 1819(b)(3) and 1919(b)(3), nursing homes participating in the Medicare or Medicaid program are required to use the Resident Assessment Instrument (RAI) to assess each nursing home resident's strengths and needs. Prior OIG reports revealed that about a quarter of residents' needs for care, as identified through the RAI, were not reflected in care plans and that nursing home residents did not receive all the psychosocial services identified in care plans. We will also review SNFs' use of the RAI to develop nursing home residents' plans of care.

*(OEI; 02-09-00201; expected issue date: FY 2012; work in progress)*

## **Assessment and Monitoring of Nursing Home Residents Receiving Atypical Antipsychotic Drugs**

We will review the extent to which nursing facilities comply with assessment and care-planning requirements for residents receiving atypical antipsychotic drugs. Federal regulations at 42 CFR § 483.20 require nursing facilities to develop resident care plans based on periodic resident assessments. Facilities are required to use the Minimum Data Set (MDS), a standardized assessment tool that includes measures of a resident's health and functional status. Previous OIG studies have found that some MDS data items were inaccurate. We will also examine the extent to which nursing homes used CMS's Resident Assessment Protocol for Psychotropic Drugs to develop residents' care plans.

*(OEI; 07-08-00151; expected issue date: FY 2011; 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 that beneficiaries received in poorly performing nursing homes and evaluate the performance of these nursing homes. The Social Security Act, §§ 1819(g) and 1864, established a survey-and-certification process, including an enforcement process, to ensure that nursing homes meet Federal standards for participation in the Medicare and Medicaid programs. We will examine enforcement decisions resulting from survey-and-certification (S&C) inspections, 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 2012; new start)*

## **Hospitalizations of Nursing Home Residents**

We will review the extent of hospitalizations of Medicare beneficiaries residing in nursing homes. Hospitalizations of nursing home residents are costly to the Medicare program and may be indicative of quality-of-care problems at nursing homes. A 2007 OIG study found that 35 percent of hospitalizations during a SNF stay were caused by poor quality of care or

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unnecessary fragmentation of services. We will also assess CMS's oversight of nursing homes whose residents have high rates of hospitalization.

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

### **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 their implementation of the plans. Federal regulations at 42 CFR § 483.75(m), require that Medicare- and Medicaid-certified nursing homes 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 members 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, such as hurricanes, floods, and wildfires.

*(OEI; 06-09-00270; expected issue date: FY 2011; work in progress)*

### **Criminal Background Checks for Nursing Facility Employees**

We will determine whether and the extent to which nursing facilities have employed individuals who have 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. We will categorize the types of crimes, if any are found, for which nursing facilities' employees have been convicted. We will also identify the number of States requiring criminal background checks.

*(OEI; 07-09-00110; expected issue date: FY 2011; work in progress)*

### **Program for National and State Background Checks for Long-Term-Care Employees**

We will review the program of national and State background checks for prospective long-term-care employees mandated by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), § 6201, which requires the Secretary of HHS to implement a nationwide program to identify efficient, effective, and economical procedures for long-term-care facilities or providers to conduct background checks on prospective employees who will have direct patient access. The Affordable Care Act requires OIG to evaluate the program, to include a review of the procedures implemented by participating States for long-term-care facilities or providers to conduct background checks and an assessment of the costs of conducting such background checks.

*(OEI; 07-10-00420; expected issue date: FY 2012; work in progress)*

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## **Medicare Part B Services During Non-Part A Nursing Home Stays: 2008 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 Part B services provided during a Part A SNF stay, most of which must be billed to Medicare directly by the SNF in accordance with consolidated billing requirements, most Part B services provided during a non-Part A stay may be 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. We will also assess patterns of billing for Part B services among nursing homes and providers.

*(OEI; 06-07-00580; expected issue date: FY 2011; work in progress)*

## **Other Providers and Suppliers**

### **Hospice Utilization in Nursing Facilities**

We will review Medicare Part A hospice claims and data from the MDS to describe hospice utilization in nursing facilities. We will examine the characteristics of nursing facilities with high utilization patterns of Medicare hospice care and the characteristics of the hospices that serve them. The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) created the Medicare hospice benefit for eligible beneficiaries under Medicare Part A. In a recent report, OIG found that 82 percent of hospice claims for beneficiaries in nursing facilities did not meet Medicare coverage requirements. MedPAC, which is an independent Congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program, has noted that hospices and nursing facilities have incentives to admit patients likely to have long stays. We will also assess the business relationships between nursing facilities and hospices and assess the marketing practices and materials of hospices associated with high utilization patterns.

*(OEI; 02-10-00070; expected issue date: FY 2011; work in progress)*

### **Services Provided to Hospice Beneficiaries Residing in Nursing Facilities**

We will review the services that hospices and nursing facilities provide to hospice beneficiaries residing in nursing facilities, including services by hospice-based home health aides. Federal regulations address Medicare CoPs for hospice at 42 CFR part 418, and SNF requirements at 42 CFR 483. We will review hospice and nursing facility medical records, including plans of care. We will determine the extent to which hospices and nursing facilities coordinate care and identify service and payment arrangements between them. We will also assess the appropriateness of hospices' general inpatient care claims.

*(OEI; 02-10-00490; expected issue date: FY 2012; work in progress)*

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### **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 § 414.32 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 2011; 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-00-10-35423; W-00-11-35423; various reviews; expected issue date: FY 2011; work in progress)*

### **Coding of Evaluation and Management Services**

We will review evaluation and management (E&M) claims to identify trends in the coding of E&M services. Medicare paid \$25 billion for E&M services in 2009, representing 19 percent of all Medicare Part B payments. Pursuant to CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 30.6.1, providers are responsible for ensuring that the codes they submit accurately reflect the services they provide. E&M codes represent the type, setting, and complexity of services provided and the patient status, such as new or established. We will review E&M claims to determine whether coding patterns vary by provider characteristics.

*(OEI; 04-10-00180; expected issue date: FY 2011; work in progress)*

### **Payments for Evaluation and Management Services**

We will review the extent of potentially inappropriate payments for E&M services and the consistency of E&M medical review determinations. CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 30.6.1 instructs providers to "select the code for the service based upon the content of the service" and says that "documentation should support the level of service reported." Medicare contractors have noted an increased frequency of medical records with identical documentation across services. We will also review multiple E&M services for the same providers and beneficiaries to identify electronic health records (EHR) documentation practices associated with potentially improper payments.

*(OEI; 04-10-00181; 04-10-00182; expected issue date: FY 2012; work in progress)*



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## **Evaluation and Management Services During Global Surgery Periods**

We will review industry practices related to the number of 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 that are 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; various reviews; expected issue date: FY 2011; 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 payments reflect the expenses incurred and whether the utilization rates reflect industry practices.

*(OAS; W-00-11-35219; various reviews; expected issue date: FY 2011; new start)*

## **Billing of Portable X-Ray Suppliers**

We will review providers of portable x-ray services with unusual claims patterns and identify Medicare claims that are questionable. Payment for the services provided by portable x-ray suppliers are governed by Federal regulations at 42 CFR § 486.100 through § 486.110. CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 13, § 90, says that diagnostic imaging services furnished by portable x-ray suppliers have as many as four components. In addition to paying suppliers for the technical and professional components of a test, Medicare pays these suppliers a setup component and transportation component. We will examine the billing patterns of portable x-ray suppliers to identify those that merit additional scrutiny.

*(OEI; 12-10-00190; expected issue date: FY 2011; work in progress)*

## **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 CSWs 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

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in inpatient facilities were separately billed to Medicare Part B.  
(OAS; W-00-11-35405; various reviews; expected issue date: FY 2011; new start)

### **Partial Hospitalization Program Services**

We will review the appropriateness of Medicare payments for partial hospitalization program (PHP) psychiatric services. The Social Security Act, § 1832(a)(2)(J), provides for coverage of PHP services, and conditions for payment are in CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 4, § 260, and at 42 CFR §§ 410.43 and 424.24(e). A PHP is an intensive outpatient program of psychiatric services that hospitals may provide to individuals in lieu of inpatient psychiatric care. The program is to provide individuals who have mental health conditions with an individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. Medicare spending for PHP services has increased over the years. We will determine whether Medicare payments for PHP psychiatric services in hospital outpatient departments and freestanding community mental health centers met Medicare requirements based on documentation supporting psychiatric services, including patient plans of care, and physician supervision and certification requirements.

(OAS; W-00-11-35453; various reviews; expected issue date: FY 2011; 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-00-11-35220; various reviews; expected issue date: FY 2011; new start)

### **Questionable Billing for Medicare Outpatient Therapy Services**

We will review paid claims data for Medicare outpatient therapy services from 2009 and identify questionable billing patterns. We will identify counties with high utilization and compare utilization in these counties to national averages. We will also determine the extent to which billing characteristics in high-utilization counties, including questionable characteristics that may indicate fraud, differed from billing characteristics nationwide..

(OEI; 04-09-00540; expected issue date: FY 2011; work in progress)

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### **Appropriateness of Medicare Payments for Polysomnography**

We will review the appropriateness of Medicare payments for sleep studies. Sleep studies are reimbursable for patients who have 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 \$235 million in 2009, and coverage was also recently expanded. 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 2012; new start)*

### **Medicare Payments for Sleep Testing**

We will review the appropriateness of Medicare payments for sleep test procedures provided at sleep disorder clinics. 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, § 70, provides CMS’s requirements for coverage of sleep tests under Part B. A preliminary OIG review identified improper payments when certain modifiers are not reported with sleep test procedures. We will examine Medicare payments to physicians and independent diagnostic testing facilities for sleep test procedures to determine whether they were in accordance with Medicare requirements.

*(OAS; W-00-10-35521; W-00-11-35521; various reviews; expected issue date: FY 2011; work in progress)*

### **Excessive Payments for Diagnostic Tests**

We will review Medicare payments for high-cost diagnostic tests to determine whether they were medically necessary. 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.” We will determine the extent to which the same diagnostic tests are ordered for a beneficiary by primary care physicians and physician specialists for the same treatment.

*(OAS; W-00-11-35454; various reviews; 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 CMS’s *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

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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-00-11-35222; various reviews; expected issue date: FY 2011; new start)*

### **Medicare Part B Payments for Glycated Hemoglobin A1C Tests**

We will review Medicare contractors' procedures for screening the frequency of clinical laboratory claims for glycated hemoglobin A1C tests. CMS's *Medicare National Coverage Determinations Manual*, Pub. 100-03, Ch. 1, pt. 3, § 190.21, states that it is not considered reasonable and necessary to perform a glycated hemoglobin test more often than every 3 months on a controlled diabetic patient unless documentation supports the medical necessity of testing in excess of national coverage determinations guidelines. Preliminary OIG work at two Medicare contractors showed variations in the contractors' procedures for screening the frequency of glycated hemoglobin A1C tests. We will determine the appropriateness of Medicare payments for glycated hemoglobin A1C tests.

*(OAS; W-00-11-35455; various reviews; expected issue date: FY 2011; new start)*

### **Trends in Laboratory Utilization**

We will review trends in laboratory utilization under the Medicare program. Pursuant to 42 CFR § 410.32(a), Medicare pays only for laboratory tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary. In 2008, Medicare paid about \$7 billion for clinical laboratory services, which represents a 92 percent increase from 1998. Much of the growth in laboratory spending was the result of increased volume of ordered services. We will examine the types of laboratory tests and the number of laboratory tests ordered. We will also examine how physician specialty, diagnosis, and geographic difference in the practice of medicine affect laboratory test ordering.

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

### **Lab Test Payments: Comparison of Medicare with Other Public Payers**

We will review the extent to which Medicare payment rates for laboratory tests vary from other public payers. Excessive payment rates for laboratory tests can be costly for the Medicare program. In 2009, Medicare paid nearly \$10 billion for lab tests. We will compare Medicare laboratory payment rates for the 10 most utilized lab tests with those of other public payers, including the Department of Veterans Affairs (VA) and State Medicaid programs.

*(OEI; 00-00-00000; expected issue date: FY 2012; 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). IDTFs are facilities that perform diagnostic procedures and are independent of physicians' offices or hospitals. An IDTF may have a fixed location or be a mobile entity, and the practitioner performing the procedures may be a

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nonphysician. IDTFs must meet regulatory 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. We will also examine billing patterns in areas with a high density of IDTFs.

*(OEI; 09-09-00380; expected issue date: FY 2011; work in progress)*

### **Independent Diagnostic Testing Facilities' Compliance With Medicare Standards**

We will review selected IDTFs enrolled in Medicare to determine the extent to which they comply with selected Medicare standards. IDTFs received payments of about \$860 million in 2009. Federal regulations at 42 CFR § 410.33, require IDTFs to certify on their enrollment applications that they comply with 17 standards. Such standards include requirements that IDTFs comply with all of the Federal and State licensure and regulatory requirements that are applicable to the health and safety of patients, provide complete and accurate information on their enrollment applications, and have on duty technical staff members who hold appropriate credentials to perform tests. We will also identify billing patterns associated with IDTFs that were not compliant with selected Medicare standards.

*(OEI; 05-09-00560; expected issue date: FY 2011; work in progress)*

### **Comprehensive Outpatient Rehabilitation Facilities**

We will review national Medicare utilization patterns for Comprehensive Outpatient Rehabilitation Facility (CORF) services and identify CORFs in high-utilization areas. Medicare paid about \$61 million for 35,000 beneficiaries who received CORF services in 2009. Previous OIG work identified CORF services that did not meet Medicare reimbursement standards because they were not medically necessary or lacked documentation that they were provided. OIG has also raised concern about potentially inappropriate rental arrangements between physician landlords and CORFs. Federal regulations at 42 CFR § 485.62, require that CORFs maintain locations that provide safe and sufficient space for the scope of all services offered. We will conduct site visits to determine whether CORFs in high-utilization areas meet basic Medicare requirements. We will also identify differences in billing patterns of CORFs that met selected Medicare requirements and those that did not.

*(OEI; 05-10-00090; expected issue date: FY 2011; work in progress)*

### **Medicare Providers' Compliance With Assignment Rules**

We will review the extent to which providers comply with assignment rules and determine whether 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 allow the physician or other supplier to request direct payment from Medicare for covered Part B services, equipment, and supplies by assigning the claim to the

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physician or supplier. The physician or other supplier in return agrees to accept the Medicare-allowed amount indicated 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 2012; new start)

### **Medicare Payments for Claims Deemed Not Reasonable and Necessary**

We will review Medicare payments for Part B claims in 2009 that providers note as not reasonable and necessary on claim submissions. The CMS *Claims Processing Manual* states that providers may use GA or GZ modifiers on claims they expect Medicare to deny as not reasonable and necessary. A recent OIG study found that Medicare paid for 72 percent of pressure-reducing support surface claims with GA or GZ modifiers, amounting to \$4 million in potentially inappropriate payments. We will determine the extent to which Medicare paid for Part B claims with these modifiers, as well as the types of providers and the types of services associated with these claims. We will also assess the policies and practices that Medicare contractors have in place with regard to these claims.  
(OEI; 02-10-00160; expected issue date: FY 2011; work in progress)

### **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 give beneficiaries advance notice of charges for services that are excluded from Medicare by statute. As a result, beneficiaries may unknowingly acquire large medical bills for which they are responsible. 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 2012; 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. Pursuant to the Social Security Act, §§ 1128 and 1156, and 42 CFR § 1001.1901, no payment shall be made for any items or services furnished, ordered, or prescribed by an excluded individual or entity. We will examine CMS's 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 2012; new start)

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### **Payments for ESRD Beneficiaries Entitled to Medicare Under Special Provisions**

We will review claims for end stage renal disease (ESRD) beneficiaries entitled to Medicare coverage only because of special circumstances. Individuals who are medically determined to have ESRD may become eligible for Medicare benefits regardless of age. The Social Security Act, § 226A(b)(2), limits Medicare coverage to the 36th month after the month in which such individual receives a kidney transplant or the 12th month after the month in which such course of dialysis is terminated in the case of an individual who has not received a kidney transplant and no longer requires a regular course of dialysis. Our preliminary analysis identified ESRD-eligible beneficiaries who were still receiving Medicare benefits beyond the 36-month timeframe. We will determine the extent to which beneficiaries who are eligible for Medicare benefits because of special provisions continue to obtain Medicare benefits after their coverage should have ended.

*(OAS; W-00-11-35456; various reviews; expected issue date: FY 2011; new start)*

### **Error-Prone Providers: Medicare Part A and Part B**

We will review Medicare Part A and Part B claims submitted by error-prone providers. CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 requires providers to submit accurate claims for services provided to Medicare beneficiaries. Previous OIG work illustrated a methodology for identifying error-prone providers using CMS's Comprehensive Error Rate Testing (CERT) Program data. Using this methodology, we identified providers that consistently submitted claims found to be in error in a 4-year period. We will select the top error-prone providers based on expected dollar error amounts and match selected providers against the National Claims History file to determine the total dollar amount of claims paid. We will then conduct a medical review on a sample of claims to determine their validity, project our results to each provider's population of claims, and request refunds on projected overpayments.

*(OAS; W-00-11-40044; various reviews; expected issue date: FY 2011; new start)*

### **Comprehensive Error Rate Testing Program: FY 2010 Error Rate Oversight**

The Improper Payments Information Act of 2002 (IPIA) requires the head of a Federal agency with any program or activity that may be susceptible to significant improper payments to report to Congress the agency's estimate of improper payments. For any program or activity with estimated improper payments exceeding \$10 million, the agency must report to Congress the actions that the agency is taking to reduce those payments. OMB identified CMS as an agency with high-profile programs that are susceptible to significant improper payments. In November 2003, CMS assumed responsibility for estimating and reporting improper Medicare fee-for-service payments and national error rates. The CERT Program, implemented in CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 12, was established by CMS to meet the requirements of the IPIA and to monitor the accuracy with which Medicare claims are billed and paid. Effective August 1, 2008, the CERT program also samples inpatient records replacing the Hospital Payment Monitoring Program (HPMP). Through CERT, national, contractor-specific, , and service-type error rates are computed. The CERT program's national estimated

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improper payments for FY 2009 were \$24.1 billion (7.8 percent error rate). We will review certain aspects of the CERT Program to evaluate CMS's efforts to ensure the accuracy of the FY 2010 error rate and to reduce improper payments.

*(OAS; W-00-11-40048; various reviews; expected issue date: FY 2011; 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 FFS payments. Pursuant to 42 CFR § 407.27(a), 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. CMS's *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 Federal regulations at 31 CFR § 901.1, requires the recovery of overpayments.

*(OAS: W-00-09-35435; W-00-10-35435; various reviews; expected issue date: FY 2011; work in progress)*

## **Medical Equipment and Supplies**

### **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 in accordance with Medicare requirements.

*(OAS; W-00-10-35223; W-00-11-35223; various reviews; expected issue date: FY 2011; work in progress)*

### **Frequency of Replacement Supplies for Durable Medical Equipment**

We will review the compliance of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) with Medicare requirements for frequently replaced DME supplies. The Social Security Act, § 1862(a)(1)(A), requires that Medicare not pay for items or services that are "not reasonable and necessary for the diagnosis and treatment of illness or



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injury or to improve the functioning of a malformed body member.” CMS’s *Medicare Program Integrity Manual*, Pub. 100-08, ch. 5, §§ 2.3 and 5.9, states that for DME supplies and accessories used on a periodic basis, the order or Certificate of Medical Necessity must specify the type of supplies needed and the frequency with which they must be replaced, used, or consumed. CMS’s *Medicare Claims Processing Manual*, Pub. 100-04, ch. 20, § 200, states that a beneficiary or a beneficiary’s caregiver must specifically request refills of repetitive services and/or supplies before a supplier dispenses them. It further states that a supplier may not initiate a refill of an order and that a supplier must not automatically dispense a quantity of supplies on a predetermined regular basis. Preliminary OIG work showed that suppliers automatically shipped continuous positive airway pressure system and respiratory-assist device supplies when no physician order for refills was in effect. We will select a sample of claims for frequently replaced supplies to determine whether payments to DME suppliers met Medicare requirements.

*(OAS; W-00-11-35240; various reviews; expected issue date: FY 2011; new start)*

### **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 the claims were medically necessary. 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, which covers DME. The Social Security Act, § 1862(a)(1), says that items provided under Part B 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 supported the medical necessity of the power wheelchairs and whether this was consistent with documentation from the physicians who ordered the power wheelchairs.

*(OEI; 04-09-00260; expected issue date: FY 2011; 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 MACs found that suppliers had little or no documentation to support their claims, suggesting 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 met Medicare requirements.

*(OAS; W-00-09-35305; W-00-10-35305; W-00-11-35305; various reviews; expected issue date: FY 2011; work in progress)*

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### **Competitive Bidding Process for Medical Equipment and Supplies**

We will review the process CMS used to conduct competitive bidding and subsequent pricing determinations for certain DMEPOS items and services in selected competitive bidding areas under rounds 1 and 2 of the competitive bidding program. Section 154(a)(1)(E) of the MIPPA requires OIG to conduct postaward audits to assess the process used by CMS for competitive bidding and subsequent pricing determinations under rounds 1 and 2 of the competitive bidding program.

*(OAS; W-00-11-35241; various reviews; expected issued date: FY 2011; 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 the Social Security Act, § 1847, CMS is required to establish a competitive bidding process for the purchase of selected DME items, which Congress subsequently delayed until 2011. Section 1847 requires that OIG conduct reviews (including this evaluation) examining the competitive bidding process. We will also examine billing patterns to identify changes resulting from competitive bidding.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicare Pricing for Parenteral Nutrition**

We will review Medicare's fee schedule for parenteral nutrition, compared 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 2009, Medicare paid more than \$137 million for parenteral nutrition supplies. 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 also identify reimbursement amounts paid by public and private payers for parenteral nutrition services.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicare Part B Payments for Home Blood Glucose Testing Supplies**

We will review Medicare Part B payments 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 coverage determinations (LCD) 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 LCDs require that the supplier add a modifier to identify when a patient is treated with insulin or not treated with insulin. The amount of supplies

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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; W-00-11-35407; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Market Shares of Mail-Order Diabetic Testing Strips**

We will determine the brands and models of diabetic testing strips reimbursed by Medicare. The Social Security Act, § 1847(b)(10)(B), requires OIG to complete a study of diabetic testing strip products and submit it to the Secretary before January 1, 2011. CMS may use the results of this study in future rounds of competitive bidding for mail-order diabetic testing strips to ensure that suppliers that submit winning bids are able to provide beneficiaries' preferred types of testing strips. We will also determine the market shares of diabetic testing strips that Medicare beneficiaries receive by mail order.

*(OEI; 04-10-00130; expected issue date: FY 2011; work in progress)*

### **Medicare Enrollment and Monitoring for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**

We will review Medicare contractors' processes for enrolling and monitoring suppliers of DMEPOS. Pursuant to CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 10, § 1.3, Medicare contractors must conduct prescreening, verification, validation, and final processing of Medicare provider enrollment applications. A recent OIG study found that suppliers 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 applicants that pose fraud risks to Medicare and the extent to which applicants omitted ownership information on enrollment applications.

*(OEI; 06-09-00230; expected issue date: FY 2011; work in progress)*

### **Medicare Qualifications of Orthotists and Prosthetists**

We will review the extent to which Medicare claims for orthotics and prosthetics were paid to unqualified practitioners in 2009. We will also assess whether CMS provided guidance to State licensing boards and industry on how to define a "qualified practitioner" of orthotics and prosthetics. Pursuant to the Social Security Act, § 1834(h)(1)(F), "Special Payment Rules for Certain Prosthetics and Custom-Fabricated Orthotics," no payment will be made for such items unless provided by a qualified practitioner as defined in the statute. Previous OIG work found that miscoded orthotics represented \$33 million in inappropriate Medicare payments in 1998 because the device did not meet the specifications billed, the device was not custom-fabricated, or the part billed was already included in the base code for a larger device. OIG concluded that the qualifications of orthotic suppliers varied, with noncertified suppliers most likely to provide inappropriate devices and services. We will review the credentials of a sample of providers submitting orthotic and prosthetic claims and determine the extent to

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which CMS provides oversight of credentialing of orthotists and prosthetists.  
(OEI; 07-10-00410; expected issue date: FY 2011; work in progress)

### **Medicare Part B Payments for Lower-Limb Prostheses in 2009**

We will review Medicare payments for lower-limb prostheses in 2009. In 2009, Medicare paid about \$655 million for lower-limb prostheses, which represented 82 percent of Medicare Part B payments for all prostheses. Over the last 5 years, payments for lower-limb prostheses increased by 27 percent. We will also assess the policies and practices that Medicare contractors have in place for lower-limb prosthetic claims to prevent fraud, waste, and abuse.

(OEI; 02-10-00170; expected issue date: FY 2011; work in progress)

## **Part B Payments for Prescription Drugs**

### **Comparing Average Sales Prices to Average Manufacturer Prices**

We will periodically review Medicare Part B drug prices by comparing average sales prices (ASP) 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), requires 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 2011; new start)

### **Comparison of Average Sales Prices to Widely Available Market Prices for Selected Drugs**

We will periodically review widely available market prices (WAMP) for selected prescription drugs covered by Part B and compare them to ASPs 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), requires OIG to conduct studies that compare ASPs to WAMPs for Part B-covered drugs. If OIG finds that the ASP of a drug exceeds the WAMP by a certain threshold (now 5 percent), CMS is required to base payment for the drug on the lesser of the WAMP or 103 percent of the AMP. This study will estimate the WAMPs of prescription drugs that have been identified in earlier OIG reports and compare the WAMPs to the drugs' ASPs.

(OEI; 03-10-00280; expected issue date: FY 2011; work in progress)

### **Fluctuation of Average Sales Price for Medicare Part B Drugs**

We will review trends and variations in quarterly ASPs from the implementation of the payment methodology in 2005 to the present. Section 303(c) of the MMA established the ASP as the basis for reimbursement for Part B-covered drugs. We will determine the degree of fluctuation in ASPs from quarter to quarter and examine the potential monetary impact of ASP

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fluctuation on Part B payments for drugs. We will also determine how these fluctuations compare to price-change indexes developed by the Bureau of Labor Statistics (BLS).  
(OEI; 00-00-00000; expected issue date: FY 2011; new start)

### **Medicare Payments for Part B Drugs**

We will review services associated with Medicare claims for Part B drugs. CMS's *Medicare Benefits Policy Manual*, Pub. No. 100-02, ch. 15, § 50, says that Medicare Part B provides limited benefits for outpatient drugs. Medicare Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. (The term "usually" here means more than 50 percent of the time for all Medicare beneficiaries who use the drug.) We will determine whether Medicare payments for the Part B drugs, where associated with a physician service, were in accordance with Medicare requirements.

(OAS; W-00-11-35242; various reviews; expected issue date: FY 2011; new start)

### **Billing for Immunosuppressive Drugs**

We will review Medicare Part B immunosuppressive drug claims to determine whether they were billed according to their Food and Drug Administration (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 immunosuppressive drugs. The manual also states in 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-00-11-35434; 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 Health & Human Services. Federal regulations at 42 CFR § 414.930(b) established a process for identifying authoritative sources of information. The DrugDex, 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 about \$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

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approved for those indications and, if so, whether there were improvements in the patients' medical conditions before the use of off-label drugs. If the beneficiaries' medical conditions improved before the 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-00-11-35504; various reviews; expected issue date: FY 2011; new start)*

### **Acquisition Costs and Payments for Lucentis and Avastin Used in Treating Wet Age-Related Macular Degeneration**

We will review how physicians' acquisition costs compare to Medicare Part B payments for two drugs used to treat wet age-related macular degeneration (AMD), the leading cause of blindness in the elderly. Lucentis is a drug specifically approved by FDA to treat wet AMD, and Avastin is approved to treat cancer. However, eye doctors have been using smaller doses of Avastin off-label as a treatment for wet AMD. CMS recently enacted and then reversed its decision to pay a lower amount for Avastin when used to treat wet AMD after physicians claimed that the new payments were too low and would require them to prescribe the higher-priced Lucentis. Medicare may subsequently be paying substantially more than the acquisition cost for Avastin when it is used to treat wet AMD. The smaller Avastin dose used to treat wet AMD must be prepared in a sterile environment through a process known as compounding. We will also examine the additional compounding cost for Avastin.

*(OEI; 03-10-00360; expected issue date: FY 2011; work in progress)*

### **Usage Patterns and Payments for Avastin and Lucentis in Treating Wet Age-Related Macular Degeneration**

We will review National Claims History data to identify nationwide usage patterns and payments for two drugs used to treat wet AMD. Pursuant to SSA § 1861(t)(2), CMS's *Medicare Benefits Policy Manual*, Pub No. 100-02, ch. 15, § 50.4.2, says that Medicare Part B may cover drugs that are used for indications other than those listed on the official label if the Medicare contractor determines the use to be medically accepted. Avastin, approved by FDA as a colorectal cancer drug, is also used off-label to treat wet AMD. The FDA has approved the use of Lucentis for AMD. Both drugs are physician administered and are covered under Medicare Part B. MACs have issued LCDs allowing for reimbursement for Avastin use off-label to treat wet AMD. Initial results of the Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) study that compares the safety and efficacy of the two drugs from the National Eye Institute of the National Institutes of Health (NIH) are expected in late 2010 or early 2011. We will determine whether a significant savings can be recognized if either Avastin or Lucentis is used more by ophthalmologists.

*(OAS; W-00-10-35535; various reviews; expected issue date: FY 2011; work in progress)*

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## 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 Office of Management and Budget (OMB) Circular A-122, *Cost Principles for Non-Profit Organizations*. The reports produced by these reviews assist CMS in negotiating favorable and cost-beneficial contract awards.

(OAS; W-00-10-35002; W-00-11-35002; various reviews; expected issue date: FY 2011; 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-00-09-35005; W-00-10-35005; W-00-11-35005; various reviews; expected issue date: FY 2011; 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 2012; 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 about 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 2011; work in progress)

### Quality Improvement Organization's Hospital Quality Improvement Projects

We will review the effectiveness of the quality improvement projects QIOs conducted with hospitals. Among other responsibilities specified in CMS's *Quality Improvement Organization*

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*Manual, Pub. 100-10, Ch. 1, § 1020, QIOs must work with hospitals on projects designed to improve performance on specific quality measures. In the QIOs' most recently completed 3-year contract, the measures focused on acute myocardial infarction, heart failure, pneumonia, and surgical care measures. QIOs are responsible for identifying and recruiting participant hospitals, then working with them on process improvements. We will also determine whether hospitals sustained improvements after their projects concluded.*

*(OEI; 00-00-00000; expected issue date: FY 2011; 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 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 that Medicare contractors use to conduct first-level Medicare appeals.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicare Administrative Law Judge Decisions**

We will review the characteristics of cases brought before Medicare administrative law judges (ALJs) in 2009 and describe how Medicare ALJs conduct hearings and decide cases. We will also describe the extent to which CMS participates in ALJ hearings. There are four levels of the Medicare administrative appeals process within HHS. The third level of appeals consists of ALJ hearings and is governed by the Social Security Act, § 1869(d). The process is administered by the HHS Office of Medicare Hearings and Appeals (OMHA). We will review case files of a sample of recent ALJ hearings as well as interview relevant OMHA and CMS officials.

*(OEI; 02-10-00340; expected issue date: FY 2011; work in progress)*

### **Accuracy of the National Provider Enumeration and Medicare Provider Enrollment Data**

We will review the extent to which national provider identifier (NPI) enumeration data and Medicare Provider Enrollment, Chain and Ownership System (PECOS) data are complete, consistent, and accurate. The Health Insurance Portability and Accountability Act of 1996 (HIPPA) required the Secretary of HHS to establish a standard unique health identifier for each health care provider, health care organization, and health plan for use in the health care system. The Secretary established the NPI to address this requirement. Separately, 42 CFR § 424.505 requires providers to enroll to receive payment from Medicare, and PECOS is the system CMS uses to complete the enrollments online. We will assess CMS's processes for ensuring the completeness, consistency, and accuracy of NPI and PECOS data.

*(OEI; 07-09-00440; expected issue date: FY 2011; work in progress)*

### **Medicare Secondary Payer Recovery Contractor: Early Implementation**

We will review the effectiveness of the Medicare Secondary Payer (MSP) recovery process. Pursuant to the Social Security Act, § 1862(b), the MSP recovery process seeks reimbursement of



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Medicare payments for which another insurer was primary to Medicare. In October 2006, CMS consolidated most recovery functions under a single MSP Recovery Contractor (MSPRC) to increase recoveries, enhance customer service, and improve the efficiency and consistency of the process. Since October 2006, the contractor has been responsible for most MSP recovery efforts when Medicare has paid a claim in error, or made a conditional payment for which another payer is ultimately deemed responsible. We will determine whether the MSPRC has increased recoveries, decreased administrative costs, and improved the efficiency of the recovery process. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Medicare Administrative Contractors: Quality Assurance Surveillance Plan Performance Evaluation**

We will review Quality Assurance Surveillance Plan (QASP) performance evaluation reports of MACs to determine whether the reports address the results of activities performed by the MACs. Section 911 of the MMA requires that the Secretary administer Medicare Part A and Part B through contracts with MACs. The section also requires the Secretary to develop specific performance requirements and standards for measuring the extent to which a MAC has met such requirements. To assist in its oversight, CMS developed the QASP review process for use in monitoring and evaluating MACs performance. Each fiscal year, CMS prepares a QASP report of contractor performance that summarizes the results of oversight activities that occurred during the year. We will also determine how CMS addressed any deficiencies identified by the QASP reports.

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

### **Zone Program Integrity Contractors' Identification of Potential Fraud and Abuse**

We will review the extent to which Zone Program Integrity Contractors (ZPIC) identified and investigated potential fraud and abuse incidents and whether these incidents were identified through proactive or external sources. Under section 911 of the MMA, CMS created ZPICs to replace program safeguard contractors (PSCs) and consolidate all program integrity functions under one type of contractor. We will determine whether ZPICs addressed potential fraud and abuse incidents, responded to requests from law enforcement, and encountered any issues or barriers in performing their contractual responsibilities.

(OEI; 03-09-00520; expected issue date: FY 2011; work in progress)

### **Conflicts of Interest in the Zone Program Integrity Contracting Process**

We will review CMS's process for overseeing contractors' organizational conflicts of interest during the ZPIC award process and throughout the period of performance. 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 ZPICs disclosed conflicts of interest and examine how they resolved the identified conflicts of interest, as well as determine how CMS addresses personal conflicts of interest among members

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of the Technical Evaluation Panel used during the awards process.  
(OEI; 03-10-00300; expected issue date: FY 2011; work in progress)

### **Vulnerabilities Identified by Medicare Benefit Integrity Contractors**

We will review how CMS addresses vulnerabilities identified by PSCs, ZPICs, and Medicare Drug Integrity Contractors (MEDIC). As outlined in CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, PSCs and ZPICs are responsible for preventing, detecting, and deterring fraud and abuse. Chapter 4, § 4.31, of the manual states that PSCs and ZPICs are required to report vulnerabilities to CMS on monthly cost reports and on quarterly vulnerability reports. Section 8.2.12 of the MEDIC Statement of Work (SOW) requires MEDICs to submit a quarterly vulnerability report. The Government Accountability Office (GAO) recently reported that CMS did not adequately address vulnerabilities found by its recovery audit contractors. We will determine the numbers and types of actions CMS took to address vulnerabilities identified by PSCs, ZPICs, and MEDICs.

(OEI; 03-10-00500; expected issue date: FY 2011; work in progress)

### **Identification and Recoupment of Improper Payments by Recovery Audit Contractors**

We will review the performance of the Recovery Audit Contractor (RAC) program. The RACs conduct postpayment reviews to identify overpayments and underpayments and attempt to recoup any overpayments they find. Following a 3-year demonstration project, the Tax Relief and Health Care Act of 2006 (TRHCA), § 302, mandated nationwide implementation of a permanent RAC program for Medicare Parts A and B. Section 6411 of the Affordable Care Act expanded the RAC program, giving it additional responsibilities to address improper payments in Medicaid, Medicare Part D (Prescription Drug Benefit), and Medicare Part C (Medicare Advantage). Previous OIG work found problems with RACs' process for identifying and reporting potential fraud during the RAC demonstration project. We will also review CMS's oversight of the RAC program.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Providers and Suppliers with Currently Not Collectible Debt**

We will review the number and dollar value of Medicare Parts A and B overpayments that CMS deemed as currently not collectible (CNC) and review CMS's actions to reduce and recover CNC debt. CMS defines a CNC debt as a Medicare overpayment that remains uncollected 210 days after the provider or supplier is notified of the debt and for which recovery attempts by CMS contractors have failed. In 2006, the amount of DMEPOS supplier debt deemed CNC was \$402 million. A recent OIG report found that overpayments referred for collection by PSCs in 2007 did not result in substantial recoveries to the Medicare program. Uncollected overpayments could represent a significant program vulnerability. We will also determine whether CNC debtors are closely associated with other businesses that continue to receive Medicare payment.

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

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## **Variation in Coverage of Services and Medicare Expenditures Due to Local Coverage Determinations**

We will review variation in Medicare spending and coverage of services due to LCDs and the evidence Medicare contractors use to develop LCDs. Pursuant to section 521 of the BIPA and the Social Security Act, § 1862(a)(1)(A), a contractor may establish an LCD to enforce its decision about whether a particular item or service is considered reasonable and necessary and is therefore covered under Medicare. These coverage decisions are not national, meaning Medicare could pay for a service for a beneficiary in one location, but deny payment for that service to a beneficiary elsewhere. Over 2,800 LCDs are in effect, but it is not possible to readily calculate the number of claims and the amount of Medicare spending associated with LCDs because claims do not indicate whether an LCD is involved. We will also assess CMS's monitoring and oversight of LCDs.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Performance of the National Supplier Clearinghouse**

We will review performance evaluation reports submitted to CMS by the National Supplier Clearinghouse (NSC) to determine whether the NSC performs all contractually required activities and to assess the results of those activities. DMEPOS suppliers are required to comply with the conditions of payment in regulations at 42 CFR pt. 424, subpart P, and 42 CFR § 424.57, which include, among other things, requirements relating to provider enrollment. CMS, through its contract with the NSC, verifies DMEPOS suppliers' initial and continuing compliance with these standards. OIG work in 2007 and 2008 found that fraudulent suppliers continue to enroll and participate in the Medicare program. We will also assess CMS's oversight of the NSC.

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

## **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. No. 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 to coordinate educational 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 2012; new start)*

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## **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-00-10-35094; W-00-11-35094; various reviews; expected issue date: FY 2011; 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-00-10-35067; W-00-11-3-35067; various reviews; expected issue date: FY 2011; 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-00-10-35148; W-00-11-35148; various reviews; expected issue date: FY 2011; 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-00-10-35067; W-00-11-35067; various reviews; expected issue date: FY 2011; 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,

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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-00-10-35095; W-00-11-35095; various reviews; expected issue date: FY 2011; work in progress)*

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# **Work Plan Part II: Medicare Part C and Part D**

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Note: Selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.



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## **Medicare Part C (Medicare Advantage)**

Beneficiaries must be enrolled in both Part A and Part B to join one of the Part C Medicare Advantage (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 the Centers for Medicare & Medicaid Services (CMS) to provide covered services. MA organizations may offer one or more 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 likely will 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 continuing and planned reviews of Medicare Part C in fiscal year (FY) 2011 follow.

### **Enhanced Payments for Certain Beneficiary Types**

We will review the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, end stage renal disease (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-00-11-35227; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Advantage Payments for Medicare Part D Drugs on Behalf of Institutionalized Beneficiaries**

We will review the extent to which Medicare Part D paid for drugs that should have been covered under Medicare Part C in 2008. Under Medicare Part C, CMS contracts with MA plans to provide managed health care coverage to Medicare enrollees, including all Part A and Part B services and some drugs that the MA plan negotiates as part of its Part C bid. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), Medicare Part D coverage does not extend to drugs covered under Part A and Part B, including drugs for beneficiaries in Part A skilled nursing facility (SNF) stays. The Code of Federal Regulations (CFR) at 42 CFR § 409.25 provides that these drugs are generally covered under Part A. We will match Part D payment data for institutionalized beneficiaries against Part C negotiated drug information between MA plans and CMS to determine whether Medicare Part D paid for drugs that should have been covered under Part C payments to the MA plans. Matches in the data will represent potential duplicate payments.

*(OAS; W-00-11-35550; various reviews; expected issue date: FY 2012; new start)*

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## **Enrollment of Medicare Beneficiaries With Chronic Conditions Into Special Needs Plans**

We will review MA-Special Needs Plans' (SNP) compliance with chronic condition enrollment requirements. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 164, instituted additional restrictions and oversight on C-SNPs by requiring them to restrict enrollment to chronic or disabling conditions. The Secretary identified 15 conditions for 2010 that meet the MIPPA's requirement of being severe or disabling and needing specialized care management. We will also assess CMS oversight of C-SNP enrollment practices.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Eligibility Requirements for Medicare Advantage Plans for Special Needs Individuals**

We will review MA-SNP processes for enrolling beneficiaries in Medicare managed care plans. SNPs exclusively enroll special needs individuals in accordance with Federal regulations at 42 CFR §§ 422.4(a)(1)(iv) and 422.52. Congress created SNPs as a new type of Medicare managed care plan focused on certain vulnerable groups of Medicare beneficiaries: those who are institutionalized, determined to be dual-eligibles, and beneficiaries who have severe or disabling chronic conditions. These beneficiaries are typically older, with multiple comorbid conditions, and thus are more challenging and costly to treat. The Medicare program typically pays more per beneficiary enrolled in a SNP than for a beneficiary enrolled in an FFS Medicare or other MA plan. The Secretary identified 15 conditions for 2010 that meet the statutory requirement of being severe or disabling and needing specialized care management. We will determine whether SNPs complied with MA eligibility requirements. We will also assess CMS oversight of MA-SNP enrollment practices.

*(OAS; W-00-11-35551; various reviews; expected issue date: FY 2011; new start.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Duplicate Fee-for-Service Billings for Beneficiaries Enrolled in Medicare Advantage**

We will determine whether Medicare Administrative Contractors (MAC) and/or fiscal intermediaries (FI) improperly reimbursed providers for inpatient hospital services provided to beneficiaries enrolled in MA plans. For beneficiaries enrolled in MA plans, Medicare makes payments directly to the plans. The managed care plans are to arrange and pay for all necessary medical services. Pursuant to Federal regulations at 42 CFR § 412.20(e)(3) inpatient hospital services should not be paid on a fee-for-service (FFS) basis on behalf of Medicare beneficiaries enrolled in an MA plan. We will determine whether the MACs and FIs complied with Federal regulations in making FFS payments to hospitals for inpatient services furnished to MA plan beneficiaries.

*(OAS; W-00-11-35552; various reviews; expected issue date: FY 2011; new start)*

## **Duplicate Medicare Payments to Cost-Based Health Maintenance Organization Plans**

We will identify duplicate Medicare capitation and FFS payments to selected cost-based Health Maintenance Organization (HMO) plans. Governing Federal regulations for costs claimed for

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Medicare payments to cost-based HMO plans are at 42 CFR pt. 417, subpart O, and CMS's *Medicare Managed Care Manual*, Pub. 100-16 ch. 17, subchapter B. Generally, under capitation agreements, health care providers are paid for services furnished to a cost plan's Medicare enrollees through monthly per capita payments from the cost plan. Accordingly, any Medicare FFS billings that the capitated providers submit for services provided to the cost plan's Medicare enrollees will result in duplicate payments to the providers.

*(OAS; W-00-11-35553; various reviews; expected issue date: FY 2011; new start)*

### **Medicare Advantage Plans and Durable Medical Equipment**

We will review MA plans' oversight of contractors that provide durable medical equipment (DME) services to enrollees. The Social Security Act, § 1834(a), and Federal regulations at 42 CFR pt. 414, subpart. D, allows Medicare coverage of medically necessary DME that is prescribed by a physician and furnished to enrollees. DME is part of the basic Medicare-covered services that MA plans provide, mostly by subcontracting with DME suppliers. We will determine the effectiveness of MA plans' controls over the selection of suppliers, assessing medical need for DME, and validating service delivery to prevent fraud, waste, and abuse for payments to DME suppliers servicing MA enrollees.

*(OAS; W-00-10-35515; W-00-11-35515; various reviews; expected issue date: FY 2011; 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 Federal regulations require MA organizations to include investment income earned on monthly capitation payments before their expenditure in developing the benefit packages or calculating the excess for the purposes of section 1854. In responding to prior Office of Inspector General (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. We will also determine the impact of investment income in computing additional benefits and Medicare payments.

*(OAS; W-00-10-35426; various reviews; expected issue date: FY 2011; 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 FFS, the costs of providing medical services to disenrollees increased by about 800 percent in the first 6 months

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after disenrollment. Following our work, CMS initiated various election periods that limit the windows of opportunity for enrollees to disenroll from MA plans. We will examine the cost of providing health services in the FFS 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 periods.

*(OAS; W-00-11-35427; various reviews; expected issue date: FY 2011; 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 represents 10 percent of the rate in 2003. Risk adjustments are processes that minimize financial incentives that 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 affect future Medicare reimbursement significantly.

*(OAS; W-00-09-35078; W-00-10-35078; W-00-11-35078; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicare Advantage Risk Adjustment Data Validation**

We will determine whether CMS adjusted payments to MA plans in accordance with Federal regulations at 42 CFR §§ 422.308(c) and 422.310(e) based on the results of their data validation reviews. Risk adjustment data validation is an annual process of verifying diagnosis codes; the process affects payments to MA plans. CMS contracts with Quality Improvement Organizations (QIO) (or QIO-equivalent contractors) to verify whether diagnosis codes are supported by medical record documentation. We will review the CMS contractors' calendar year (CY) 2007 data validation results and determine whether CMS appropriately adjusted payments.

*(OAS; W-00-11-35554; various reviews; expected issue date: FY 2012; new start)*

### **Credentialing by Medicare Advantage Plan Sponsors**

We will review the extent to which MA plan sponsors have contracted with providers that are not qualified or are ineligible to participate in the Medicare program. Regulations at 42 CFR § 422.204, requires MA plan sponsors to credential providers with whom they contract. The credentialing process should include verification of licensure, education or certification, and eligibility for payment under Medicare. We will also examine the processes that MA plan sponsors have in place to ensure that only qualified and eligible providers are allowed into their plans.

*(OEI; 00-00-00000; expected issue date: FY 2011; work in progress)*

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### **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. Pursuant to Federal regulations at 42 CFR § 422.504(i)(4), MA organizations that delegate responsibilities under their contracts with CMS to other entities must include in their contracts with those entities provisions specifying that the entities 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 2012, new start)

### **Oversight of CMS's Medicare Advantage Bid Review Process**

We will oversee work performed by CMS's Office of the Actuary and its contracted actuary reviewers to ensure that its reviews of Part C bids are in accordance with CMS policies and procedures and that issues identified during the desk reviews are sufficiently addressed before bid approval. Pursuant to Federal regulations at 42 CFR § 422.256, CMS has the authority to review the aggregate bid amounts submitted by MA plans. Our audit will include a review of compliance with the desk review methodology, as well as an assessment of the quality of that methodology. (OAS; W-00-11-35555; various reviews; expected issue date: FY 2012; new start)

### **Medicare Advantage Plans' Identification of Potential Fraud and Abuse**

We will review the extent to which potential fraud and abuse incidents were identified and addressed by MA plan sponsors in 2009. Pursuant to regulations at 42 CFR § 422.503, each MA plan sponsor is required to have a compliance plan that includes measures to detect, correct, and prevent fraud, waste, and abuse. Previous OIG work found that 28 percent of stand-alone Part D sponsors did not identify any potential fraud and abuse incidents in 2007. We will also determine whether MA plan sponsors conducted inquiries, initiated corrective actions, or referred for further investigation incidents with potential for fraud and abuse. (OEI; 03-10-00310; expected issue date: FY2011; work in progress)

### **Medicare Advantage Organizations' Reporting Requirements**

We will review Medicare Advantage Organizations' (MAOs) compliance with CMS's reporting requirements for plan year 2009. Pursuant to regulations at 42 CFR 422.516(a), CMS requires MAOs to develop, compile, evaluate, and report certain information to CMS and others. The information is necessary for CMS to assess and report on MAOs' operations, costs, availability and utilization of services. In the past, CMS has been unable to complete such assessments and reports because of lack of data. We will also review CMS's oversight of MAOs' reporting requirements and the actions CMS has taken to enforce reporting requirements. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

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# Medicare Part D (Prescription Drug Program)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established an optional 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 administration of Part D depends 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 continuing 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. Pursuant to its *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 under Part D are correct, are supported, and are 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 controls to prevent duplicate drug payments.

*(OAS; W-00-10-35307; W-00-11-35307; various reviews; expected issue date: FY 2011; work in progress)*

## **Medicare Part D Claims Duplicated in Part A and Part B**

We will review Medicare Part D claims to determine whether they were duplicated in 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

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receiving treatments as hospital inpatients. 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-00-11-35409; various reviews; expected issue date: FY 2011; new start)*

### **Part D Billing in 2009**

We will review Part D drugs billed in 2009 to identify characteristics of associated pharmacies, prescribers, and beneficiaries. Pursuant to the Social Security Act, § 1860(D)-15(f)(1), drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans, and the Department of Health & Human Services (HHS) has the right to inspect and audit the sponsors' records pertaining to the information. We will also identify the pharmacies, prescribers, and beneficiaries associated with atypically high billing and determine what, if any, characteristics they have in common.

*(OEI; 02-09-00600; expected issue date: FY 2011; work in progress)*

### **Aberrant Part D Claims**

We will review Medicare Part D claims to identify aberrant claims (those that deviate from the usual patterns) and determine how they relate to pharmacies, physicians, and/or beneficiaries. 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 plans, and HHS has the right to inspect and audit the sponsors' records pertaining to the information.

*(OAS; W-00-10-35411; W-00-11-35411; various reviews; expected issue date: FY 2011; work in progress)*

### **Excluded Category of Drugs in Part D**

We will review prescription drug event (PDE) data to determine the extent to which sponsors submitted data for drugs used for the treatment of sexual dysfunction or erectile dysfunction (ED) in Part D drug claims. Pursuant to the Social Security Act § 1860D-2(e), Part D drugs do not include those used for the treatment of sexual dysfunction or ED that are excluded from coverage under Part D. CMS's *Medicare Prescription Drug Manual*, Pub. 100-18, ch. 6, § 20.1, says that ED drugs meet the definition of a Part D drug when prescribed for medically accepted indications approved by the Food and Drug Administration (FDA) other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label. Part D claims for these drugs could indicate a lack of edits in place at sponsors that would identify this particular excluded category of drugs.

*(OAS; W-00-10-35525; W-00-11-35525; various reviews; expected issue date: FY 2011; work in progress)*

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## **Off-Formulary Drugs in Part D**

We will review PDE data to determine the extent to which selected sponsors submitted data for drugs that were not included on their approved Part D formularies. Federal regulations at 42 CFR § 423.100 define a “covered Part D drug” as one that is included in a plan’s formulary or treated as being included in a plan’s formulary as a result of a coverage determination or appeal. We will examine Part D payment data and CMS-approved Part D formularies to determine whether costs submitted by sponsors were for drugs that were not included in their approved formularies.

*(OAS; W-00-11-35560; various reviews; expected issue date: FY 2011; new start)*

## **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,” says 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-00-11-35234; various reviews; expected issue date: FY 2011; new start)*

## **Safety and Effectiveness of Part D Drugs**

We will review whether the drugs used in the Part D program were previously found to be safe and effective by FDA in accordance with statute (21 United States Code (U.S.C.) § 355). To ensure that drugs are safe and effective, FDA requires that drugs used by the public be approved and registered. As part of a safety initiative, CMS instituted a policy effective January 1, 2010, to ensure that Part D beneficiaries receive only drugs that are properly registered with FDA. We will determine whether Part D beneficiaries were dispensed drugs that FDA had deemed safe and effective.

*(OAS; W-00-11-35561; various reviews; expected issue date: FY 2011; new start)*

## **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-00-11-35506; 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



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pharmacies; 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 2008, section XI, "Overpayments," says: "Part D Sponsors will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Sponsor erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit." We will determine whether recoveries by Part D sponsors or their PBMs are properly accounted for. We will also review the extent to which pharmacy audits focus on uncovering fraud, waste, and abuse versus program noncompliance.

*(OAS; W-00-11-35235; various reviews; expected issue date: FY 2011; new start) (OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Part D Risk Adjustment Data Validation**

We will review the accuracy of data supporting diagnosis codes submitted by MA prescription drug organizations (MA-PD) that determined the final RxHCC (prescription drug model used for payment under Part D) risk scores assigned to beneficiaries. We will also review CMS risk-adjusted payments to MA-PDs as a result of the assigned risk scores. In 2006, CMS adopted the RxHCC model to calculate the risk scores of all Medicare beneficiaries eligible for Part D. As an incentive to MA-PDs to accept less healthy and higher risk beneficiaries, CMS uses a risk-adjusted payment methodology (described generally in regulations at 42 CFR § 423.329(b)) to pay a higher monthly subsidy for beneficiaries diagnosed as less healthy. The collection of medical records/diagnoses from the appropriate sources, i.e., hospital inpatient facilities, hospital outpatient facilities, and physicians, is critical in determining the appropriate diagnosis codes for accurate risk-adjusted RxHCC scores assigned to beneficiaries and determining the accurate monthly payments to MA-PDs. Federal regulations at 42 CFR §§ 422.310(b) and 423.329(b)(3)(ii) require MA organizations that offer MA-PD plans to submit to CMS the risk adjustment data that they must obtain from the providers or other practitioners that provided the service. We will determine the validity of diagnosis codes submitted by MA-PDs and the accuracy of the resultant monthly payments to MA-PDs.

*(OAS; W-00-11-35540; various reviews; expected issue date: FY 2011; new start)*

### **Medicare Part D Risk Corridors**

We will review the financial impact of risk corridors on the Part D program. The MMA requires the Federal Government to share with sponsors a portion of any unexpected Part D profits and losses. Risk corridors determine the amount of unexpected profits or losses that the Federal Government and sponsors share. Pursuant to the Social Security Act § 1860D-15, CMS has the legal authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. Previous OIG reports found that in 2007 and 2008, many Part D sponsors had profits large enough to trigger risk sharing. We will analyze risk-sharing payments between the Government and Part D sponsors for plan years 2006 to 2009. We will also determine whether

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there is potential for cost savings if the existing risk corridor thresholds are retained.  
(OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **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-00-11-35507; 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. Regulations at 42 CFR pt. 423, subpart G, calculate Part D reinsurance and risk-corridor payments on the basis of amounts actually paid by the Part D sponsors, net of direct or indirect remunerations (DIR). DIR includes 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-00-09-35508; W-00-10-35508; various reviews; expected issue date: FY 2011; work in progress)

### **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), says 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; W-00-11-35510; various reviews; expected issue date: FY 2011; work in progress)

### **Part D and Medicaid Prescription Drug Prices**

We will review prices paid by Medicare Part D plans and State Medicaid agencies for 200 high-volume prescription drugs. The Patient Protection and Affordable Care Act

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of 2010 (Affordable Care Act), § 3313, requires that OIG conduct such a review by October 1, 2011. With the creation of Part D, dual-eligible beneficiaries had their drug coverage transitioned from Medicaid to Part D. We will compare prices paid under the programs (including discounts and rebates) and assess the impact of any price discrepancies on the Federal Government and beneficiaries.

*(OEI; 03-10-00320; expected issue date: FY 2011; work in progress)*

### **340B Drug Pricing in the Medicare Part D Program**

We will review whether Part D sponsors are including in the remuneration information that they provide to CMS any savings received because their network pharmacies are part of the 340B Drug Pricing Program (340B). Federal regulations at 42 CFR § 423.265 say that a prescription drug plan (PDP) sponsor's bid must include the costs for which the plan is responsible in providing basic and supplemental benefits. Section 340B limits the cost of covered outpatient drugs to certain Federal grantees, federally qualified health center look-alikes, and qualified disproportionate share hospitals (DSH). We will determine whether any applicable savings related to the 340B program received by Part D sponsors are shared with the Federal Government.

*(OAS; W-00-11-35562; various reviews; expected issue date: FY 2011; new start)*

### **Audits of Medicare Prescription Drug Plan Sponsors**

We will review the extent to which CMS completed seven types of audits of stand-alone prescription drug plans from January 2006 through December 2009 and the types and numbers of problems identified through the audits. The seven audit types are auto-enrollment readiness, benefit integrity, bid, compliance plan, long-term-care pharmacy contract, pharmacy access, and program. CMS conducts these audits as part of its oversight of the Part D program. The Social Security Act, § 1860D-12(b)(3)(C), governs audit authority for Part D. We will also determine what actions CMS took to follow up with PDP sponsors about problems identified.

*(OEI; 03-09-00330; expected issue date: FY 2011; 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 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; work in progress)*

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### **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. Federal regulations at 42 CFR § 423.504(b)(4)(vi)(H) require Part D sponsors to have in place compliance plans that include comprehensive methods to detect, correct, and prevent fraud, waste, and abuse. CMS issued additional guidance to Part D sponsors in its *Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, that provides interpretive rules and guidelines for Part D sponsors for implementing the requirements at 42 CFR § 423.504(b)(4)(vi)(H).

*(OAS; W-00-11-35512; various reviews; expected issue date: FY 2011; new start)*

### **Medicare Prescription Drug Sponsors' Training on Fraud, Waste, and Abuse**

We will review the extent to which Part D sponsors developed and provided Part D fraud, waste, and abuse training for their network pharmacies in 2009. As a condition for contracting with CMS to offer Part D benefits, plan sponsors must have compliance plans that meet specific elements outlined in regulations at 42 CFR §423.504(b)(4). We will determine the extent to which the training's content reflected CMS guidance and the way in which sponsors and network pharmacies measure the effectiveness of the training in preventing, detecting, and responding to potential fraud, waste, and abuse.

*(OEI; 01-10-00060; expected issue date: FY 2011; work in progress)*

### **Medicare Drug Integrity Contractors' Performance Evaluation Reports**

We will review the evaluation reports that CMS produces to assess the performance of Medicare Drug Integrity Contractors (MEDIC). CMS contracts with MEDICs to support CMS's audit, oversight, and antifraud and abuse efforts associated with Part D. Regulations at 48 CFR § 42.1502(a) require that CMS conduct an annual performance evaluation of each MEDIC and use the evaluations to make decisions about task order renewal. We will describe the type and extent of information provided in performance evaluation reports and determine whether the performance evaluation reports were issued on time.

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

### **Pharmacy and Therapeutics Committee Conflicts of Interest**

We will review the number and nature of Part D Pharmacy and Therapeutics (P&T) committees' disclosed potential conflicts of interest. Pursuant to 42 CFR § 423.120(b)(1), sponsors using formularies must have P&T committees that select the drugs on sponsors' formularies and determine cost sharing, prior authorization, quantity limits, generic substitution, and other issues affecting drug access. The P&T committee must have at least one physician and one pharmacist who are free of conflicts of interest. We will also describe the extent to which CMS oversees P&T committees' conflicts of interest.

*(OEI; 05-10-00450; expected issue date: FY 2011; work in progress)*

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## **Medicare Part D Formulary Discrepancies**

We will review the extent to which Part D sponsors' formularies listed on their Web sites reflect their most current, approved formularies. Pursuant to Federal regulations at 42 CFR § 423.128, sponsors must provide to their enrollees a list of drugs included on their formularies at the time of enrollment and at least annually thereafter. The regulations also require that a sponsor's Web site be updated at least monthly to reflect the most current formularies. We will describe the nature of any formulary discrepancies.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Part D Formulary Coverage Determinations and Appeals Process**

We will review the coverage determination and appeals processes Part D sponsors established pursuant to regulations at 42 CFR pt. 423, subpart M. Section 423.566(b) permits enrollees to appeal, among other things, a determination not to cover a drug because it is not included in the formulary. We will determine whether these processes comply with Federal regulations and CMS's guidelines. In accordance with 42 CFR pt. 423 subpart M, each Part D sponsor and Part D plan that it offers must establish and maintain procedures for standard and expedited coverage determinations and appeals. We will also determine the number of beneficiaries requesting and appealing coverage determinations.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **Dual Eligibles' Access to Drugs Under Medicare Part D**

We will review the extent to which Part D drug formularies developed by sponsors in accordance with 42 CFR § 423.120, include drugs commonly used by dual-eligible beneficiaries. These beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as they meet certain limitations outlined in 42 CFR § 423.120, plans have the discretion to include different Part D drugs and drug utilization tools in their formularies. Section 3313 of the Affordable Care Act requires OIG to conduct this review annually. We will also compare the availability of drugs commonly used by dual-eligible beneficiaries enrolled in plans that have premiums above the national average monthly bid amount to the availability under those plans that have premiums below that amount.

*(OEI; 05-10-00390; expected issue date: FY 2011; work in progress)*

## **Medicare 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 systems and data.

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## **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-00-11-41010; expected issue date: FY 2011; 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 FY 2007 and 2008. The purpose of this review will be 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 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-00-11-41011; various reviews; expected issue date: FY 2011; 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 that are 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-00-11-41012; expected issue date: FY 2011; new start)*

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## **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-00-11-41013; various reviews; expected issue date: FY 2011; 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. Office of Management and Budget (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 for electronic health information protections, access, storage, and transport.

*(OAS; W-00-11-41014; various reviews; expected issue date: FY 2011; new start)*

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# **Work Plan Part III: Medicaid Reviews**



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Note: Selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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# Medicaid Reviews

The Federal and State Governments jointly fund Medicaid, a program that provides medical assistance to certain low-income individuals. The Federal share of a State's expenditures is called the Federal medical assistance percentage (FMAP). 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 continuing and new reviews of Medicaid in Fiscal Year (FY) 2011 address payments related to hospitals, long-term and community care, prescription drugs, other services, Medicaid administration, and information systems controls.

## Medicaid Hospitals

### 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 Office of Inspector General (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. The review is a followup to work involving Medicaid outlier payments.

*(OAS; W-00-10-31069; W-00-11-31069; various reviews; expected issue date: FY 2011; work in progress)*

### Provider Eligibility for Medicaid Reimbursement

We will review whether States appropriately determined provider eligibility for Medicaid reimbursement. The Code of Federal Regulations (CFR) at 42 CFR § 440.10 requires hospital providers to meet Medicare program participation requirements to receive Medicaid funding. Various State regulations may extend the Federal requirement to cover other provider types, such as medical equipment and supplies or home health. We have previously found significant unallowable Medicaid payments to hospitals that did not meet Medicare program eligibility requirements as part of the disproportionate share hospital (DSH) program.

*(OAS; W-00-10-31301; W-00-11-31301; various reviews; expected issue date: FY 2011; work in progress)*

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## **Supplemental Payments to Private Hospitals**

We will review Medicaid supplemental payments by States to private hospitals. States are permitted to make payments under their approved plans to hospitals up to the applicable aggregate upper payment limit (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 the limits. The regulation at 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 found errors. We will determine whether errors exist involving supplemental payments to private facilities.

*(OAS; W-00-10-31126; W-00-11-31126; various reviews; expected issue date: FY 2011; 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. Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Att. A, § C.1.a, says that to be allowable, costs must be necessary and reasonable for the proper and efficient performance and administration of Federal awards. Section C.1.c of the circular says that costs must be authorized, or not prohibited, under State or local laws or regulations. The Social Security Act, § 1903(d)(2)(A), and regulations at 42 CFR pt. 433, subpart E, provide for the Centers for Medicare & Medicaid Services (CMS) to adjust quarterly payments to States to account for overpayments and underpayments by States to providers. Prior OIG work involving Medicare inpatient and outpatient claims found that many excessive payments to the hospitals were attributable to billing errors on the submitted claims, such as inaccuracies in 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; W-00-11-31127; various reviews; expected issue date: FY 2011; work in progress)*

## **Medicaid Home, Community, and Nursing Home Care**

### **Community Residence Rehabilitation Services**

We will review Medicaid payments for beneficiaries who reside in community residences for people who have mental illnesses to determine whether States improperly claimed Federal financial participation (FFP). OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal*

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*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; W-00-11-31087; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Payments to Continuing Day Treatment Providers**

We will review Medicaid payments to continuing day treatment (CDT) providers in one State. CDT providers render an array of services to those who have mental illnesses on a relatively long-term basis. A CDT provider bills Medicaid on the basis of 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., provides 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 to CDT providers in that State are adequately supported.

*(OAS; W-00-09-31128; W-00-11-31128; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Home Health Agency Claims**

We will review home health agency (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 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; W-00-11-31304; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Payments for Personal Care Services**

We will review Medicaid payments for personal care services (PCS) to determine whether States have appropriately claimed the FFP. Pursuant to the Social Security Act, § 1905(a)(24), Medicaid covers PCS only for those who are not inpatients or residents of hospitals, nursing facilities, institutions for mental diseases (IMD), or intermediate care facilities for those with mental retardation. PCS must be authorized by a physician or (at the option of the State)

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otherwise authorized in accordance with a plan of treatment, must be provided by someone who is qualified to render such services and who is not a member of the individual's family, and must be furnished in a home or other location. The Deficit Reduction Act of 2005 (DRA), § 6087, further allowed States, beginning January 1, 2007, to pay individuals for self-directed personal assistance services for the elderly and disabled, including PCS that could be provided by a family member.

*(OAS; W-00-09-31035; W-00-10-31035; W-00-11-31035; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Hospice Services**

We will review Medicaid payments for hospice services to determine whether the services were provided in accordance with Federal reimbursement requirements. Pursuant to the Social Security Act, § 1905(o)(1)(A), Medicaid may cover hospice services for terminally ill recipients. Hospice care provides relief of pain and other symptoms and supportive services to terminally ill persons and assistance to their families in adjusting to the patient's illness and death. CMS's *State Medicaid Manual*, Pub. 45, § 4305, says the individual, having been certified as terminally ill, must elect hospice coverage and waive all rights to certain otherwise covered Medicaid services. In FY 2009, Medicaid payments for hospice services totaled more than \$2.2 billion. We will also conduct a medical review of claims for a sample of Medicaid recipients receiving hospice care to determine that services were reasonable and necessary.

*(OAS; W-00-11-31385; various reviews; expected issue date: FY 2011; new start. OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicaid Adult Day Care Services for Elderly Individuals Who Have Chronic Functional Disabilities**

We will review Medicaid payments to providers for adult day care services. The Social Security Act, § 1929(a)(7), allows Medicaid payments for adult day care services through home and community care for elderly individuals who have chronic functional disabilities. We will determine whether Medicaid payments to providers for adult day care health services were in compliance with Federal and State regulations.

*(OAS; W-00-11-31386; various reviews; expected issue date: FY 2011; new start)*

### **Medicaid Adult Day Health Service**

We will review adult day health services reimbursed by Medicaid programs in select States. The Social Security Act, § 1915(c)(4)(B), allows Medicaid payments for adult health services through home- and community-based waiver programs. Previous Federal and State reviews of Medicaid adult day health services found problems with reimbursement systems and questionable billings. Additionally, CMS and State Medicaid programs do not receive information about the individual services provided to beneficiaries because reimbursement is based on bundled payment rates. We will describe the services provided, review the qualifications of providers, and assess the appropriateness of documentation.

*(OEI; 09-07-00500; expected issue date: FY 2011; work in progress)*

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

We will review the States' eligibility evaluation process for Medicaid home- and community-based services (HCBS) waiver recipients. Medicaid HCBS waiver programs allow States to provide alternative HCBS services for individuals who would otherwise need nursing home care. The enrollment of Medicaid beneficiaries in HCBS waivers increased dramatically in recent years, rising more than 60 percent between 1999 and 2006. Regulations at 42 CFR § 441.302(c) and 42 CFR § 441.352(c), require States to assess whether each potential waiver recipient meets criteria for the level of care provided by a nursing home. We will determine the extent to which States are following Federal regulations for assessing the level of care of HCBS recipients and whether level-of-care assessments are appropriate.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

## **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 those who otherwise would require care in nursing homes. In accordance with 42 CFR § 441.302, States must provide assurances that necessary safeguards have been taken to protect the health and welfare of recipients. However, a 2003 Government Accountability Office (GAO) review found that CMS and States did not provide adequate oversight of HCBS waivers. We will determine the extent to which States monitor the quality of care given to participants in HCBS waiver programs for the aged and disabled. We will also determine the extent to which CMS oversees States' efforts to ensure the quality of care provided under such waiver programs.

*(OEI; 02-08-00170; expected issue date: FY 2011; work in progress)*

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

We will review the extent to which assisted living facilities (ALFs) provide HCBS to their Medicaid-eligible residents. ALFs may receive Medicaid funding through the HCBS waiver program under the Social Security Act, § 1915(c). Regulations at 42 CFR § 441.302 require States to provide CMS with assurances that necessary safeguards have been taken to protect the health and welfare of HCBS recipients. 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 2011; work in progress)*

## **CMS Oversight of Accuracy of Nursing Home Minimum 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 an instrument that includes the MDS. Regulations at 42 CFR § 483.20 specify the requirements of



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the assessment instrument. MDS data include the residents' physical and cognitive functioning, health status and diagnoses, preferences, and life care wishes. CMS implemented a skilled nursing facility prospective payment system (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. About half of the States base their Medicaid payment systems on MDS data. We will also review CMS's processes for ensuring that nursing homes submit accurate and complete MDS data.

*(OEI; 00-00-00000; expected issue date: FY 2012; 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 difficult because of the ownership structure. 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 investor-owned entities are benefiting from Medicaid reimbursement and study the effects of ownership changes on the care received by beneficiaries.

*(OAS; W-00-11-31130; various reviews; expected issue date: FY 2011; new start)*

### **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 CMP funds they collect to ensure the safety of residents of penalized nursing homes. We will identify 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 2012; new start)*

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

We will review Medicaid incentive payments by States 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 incentive payments were in accordance with program requirements.

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*(OAS; W-00-10-31331; W-00-11-31331; various reviews; expected issue date: FY 2011; work in progress)*

### **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 help 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 in amounts exceeding 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; W-00-11-31332; various reviews; expected issue date: FY 2011; work in progress)*

### **Health Screenings of Medicaid Home Health Care Workers**

We will review health-screening records of Medicaid home health care workers to determine whether the workers were screened in accordance with Federal and State requirements. Home health agencies provide home health care services to Medicaid beneficiaries on a visiting basis in beneficiaries’ homes. Pursuant to the Social Security Act, §1891(a)(5), a home health care agency must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations and with accepted standards that apply to personnel providing services within such an agency. The Federal requirements for home health services are found at 42 CFR § 440.70, 441.15, and 441.16 and at 42 CFR pt 484. Other applicable requirements are found in State and local regulations.

*(OAS; W-00-11-31387; various reviews; expected issue date: FY 2011; new start)*

## **Medicaid Prescription Drugs**

### **Calculation of Average Manufacturer Prices**

We will review selected drug manufacturers to evaluate methodologies they use to calculate the average manufacturer price (AMP) and the best price for Medicaid drug rebate program and Medicaid drug reimbursement purposes. We will determine whether the methodologies are consistent with applicable statutes, regulations, and 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 reimbursement for multiple-source drugs. The changes involve revisions in the calculation of the AMP and the best price that will affect amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program

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and will 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-00-11-31202; various reviews; expected issue date: FY 2011; new start)*

### **Recalculation of Base Date Average Manufacturer Prices**

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

*(OEI; 00-00-00000; expected issue date: FY 2012; 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 that CMS provides to States includes all covered drugs and indicates drugs' termination dates, if applicable. We will also determine whether reimbursements to States are correct and are supported for the drugs claimed.

*(OAS; W-00-10-31203; various reviews; expected issue date: FY 2011; 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 Federal Upper Limits (FUL) on reimbursements. The Social Security Act, § 1927(e)(4), establishes FULs for all multiple-source drugs. As a result of whistleblowers' actions, several pharmacies have admitted changing dosage forms for some commonly prescribed Medicaid drugs, thereby inflating reimbursements by avoiding FULs established on other dosage forms. We will determine whether there has been manipulation of FULs.

*(OAS; W-00-11-31333; various reviews; expected issue date: FY 2011; new start)*

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## **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; W-00-10-31318; W-00-11-31318; various reviews; expected issue date: FY 2011; work in progress)*

## **Medicaid Pharmacy Reimbursement**

We will review drug acquisition costs for pharmacies participating in the Medicaid program. Federal regulations at 42 CFR § 447.512 provide that drugs for which no upper limits have been established are reimbursed at the lower of usual and customary charges or estimated acquisition costs (EAC) plus a dispensing fee. States have historically based EACs on a discount average wholesale price (AWP). In previous work, we have reported that reimbursements for prescription drugs significantly exceeded EACs. As of October 2011, the AWP will not be available for States to use in setting reimbursement. We will compare actual pharmacy acquisition costs to other potential benchmark prices, such as the wholesale acquisition cost (WAC) and the AMP to determine what effects the lack of AWP data will have on State Medicaid programs.

*(OAS; W-00-11-31388; various reviews; expected issue date: FY 2011; new start)*

## **Medicaid Payments for Drugs Not Approved for Use by Children**

We will review Medicaid paid claims to determine whether payments were for drugs not approved for children by the Food and Drug Administration (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 section 1927(g)(1). We will examine drug services paid for children under age 18 in 2007 by reviewing States' Medicaid and Children's Health Insurance Program (CHIP) paid claims files.

*(OAS; W-00-11-31131; 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." 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.

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*(OAS; W-00-10-31134; W-00-11-31134; various reviews; expected issue date: FY 2011; 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 the 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's 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-00-10-31317; various reviews; expected issue date: FY 2011; 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 by regulations at 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. Rebates to States from manufacturers pursuant to 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. The change in definition 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 the DRA provisions.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **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. Section 6002 of the DRA, requires States to collect utilization and coding information for single-source drugs and 20 multiple-source drugs that have the highest dollar volume of physician-administered

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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. We will also estimate the savings that could result if all States were to collect the rebates.

*(OEI; 03-09-00410; expected issue date: FY 2011; 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. The 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 2011; new start)*

### **Review of Medicaid Policies and Oversight Activities Related to 340B Entities**

We will review States' policies and oversight activities for reimbursements related to the 340B Drug Discount program (340B). The 340B Program provides for sales of drugs at or below established ceiling prices to 340B covered entities that provide health care to certain disadvantaged individuals. The Veterans Health Care Act of 1992 established the 340B Drug Program in section 340B of the Public Health Service Act (PHS Act). We will also examine States' activities to identify claims for 340B-purchased drugs.

*(OEI; 05-09-00321; expected issue date: FY 2011; 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 the centralized approach produced significant savings.

*(OAS; W-00-10-31334; W-00-11-31334; various reviews; expected issue date: FY 2011; work in progress)*

### **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

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nongovernmental payers for each drug. The State's Medicaid program then reimburses pharmacies at the lower of those rates or 11 percent below the AWP for the drug. We will determine whether the State's use of the 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-00-11-31336; various reviews; expected issue date: FY 2011; 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 URAs for drugs included in the Medicaid drug rebate program and provides the amounts to State Medicaid agencies. 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 when CMS is unable to calculate URAs. This occurs if and when manufacturers have not reported the necessary data for the calculations. The URAs for such products are listed as \$0, i.e., zero-dollar URAs. However, States are still required to work with manufacturers to determine the appropriate rebates for the drugs. We will determine the financial impact of zero-dollar URAs and examine possible causes for States not receiving required rebates from manufacturers.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

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

We will review State Maximum Allowable Cost programs to determine how maximum allowable cost lists are developed, how maximum allowable cost prices are set, and how maximum allowable cost prices compare to the FUL amounts. To take advantage of lower market prices for certain generic products, States use the FUL list and/or State maximum allowable cost programs in determining reimbursement amounts. State maximum allowable cost programs are designed to ensure Medicaid programs pay appropriate prices for generic drugs. In 2004, a CMS-contracted study looked at maximum allowable cost programs in five States and found considerable variation between these programs and the FUL program. The study concluded that expansion of existing maximum allowable cost programs and implementation of new ones could contribute to cost containment efforts nationwide. This study will compare State maximum allowable cost programs to determine which State maximum allowable cost programs are most successful in reducing Medicaid expenditures.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **States' Efforts and Experiences With Resolving Medicaid Rebate Disputes**

We will review the causes of and resolutions to Medicaid rebate disputes. The Social Security Act, § 1927(a), requires a drug manufacturer to enter into a drug rebate agreement as a prerequisite to coverage of its drugs under Medicaid State plans. In 2008, the Medicaid program spent approximately \$24 billion on prescription drugs and received approximately \$8 billion in rebates. Previous OIG reports have found large amounts of money in uncollected

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rebates. This study will follow up on previous work done by OIG and will describe both the causes of rebate disputes, as well as methods States use to address rebate disputes.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Changes in Prices for Medicaid Brand-Name Drugs**

We will review annual price increases for brand-name prescription drugs used by Medicaid beneficiaries. According to a recent report released by AARP, the rate of increase in published prices for brand-name drugs has been substantially higher than the overall rate of inflation, which has raised concerns among members of Congress. Because most States base their Medicaid reimbursement amounts on published prices, disproportionate price increases could create fraud vulnerabilities and lead to excessive Medicaid spending. The study will determine how price increases for brand-name drugs affect Medicaid payment amounts.

*(OEI; 03-10-00260; expected issue date: FY 2011; work in progress)*

## **Other Medicaid Services**

### **Medicaid Dental Services**

We will review Medicaid payments for dental services to determine whether States have properly claimed the FFP. Pursuant to the Social Security Act, §§ 1905(a)(4)(B) and 1905(r), dental services are required for most Medicaid-eligible individuals under age 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 teeth and the 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-00-10-31135; W-00-11-31135; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Payments for Physical, Occupational, and Speech Therapy Services**

We will review the extent to which payments for Medicaid physical, occupational, and speech therapy services comply with State standards and limits on coverage. Pursuant to the Social Security Act, § 1905(a), and regulations at 42 CFR § 440.110, States may provide physical, occupational, and speech therapy services to Medicaid beneficiaries. Previous OIG studies found that some therapy services provided under Medicare were billed incorrectly. Through a review of selected States, we will determine whether Medicaid has similar program integrity issues.

*(OEI; 07-10-00370; expected issue date: FY 2011; work in progress)*



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## **Rehabilitative Services**

We will review claims for rehabilitative services to determine whether the services were provided in accordance with State and Federal guidelines. The Social Security Act, § 1905(a)(13), and regulations at 42 CFR § 440.130 define “rehabilitative services” and require that they 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-00-11-31389; various reviews; expected issue date: FY 2011; new start)*

## **Medicaid Medical Equipment**

We will review Medicaid payments for medical supplies and equipment to determine whether the equipment and/or supplies billed were properly authorized by physicians, the products were received by the beneficiaries, and the amounts paid were within Medicaid payment guidelines. Federal regulations at 42 CFR pt. 440 and various provisions of CMS’s *State Medicaid Manual* provide rules and guidance about necessary medical supplies and equipment for home health services; physical therapy services; occupational therapy services; services for individuals with speech, hearing, and language disorders; and home- or community-based services.

*(OAS; W-00-11-31390; various reviews; expected issue date: FY 2011; new start)*

## **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 found improper claims for enhanced funds for family planning services.

*(OAS; W-00-09-31078; W-00-10-31078; W-00-11-31078; various reviews; expected issue date: FY 2011; work in progress)*

## **Medicaid School-Based Services**

We will review Medicaid services provided in schools to determine whether payments for school-based health services complied with laws and regulations. The Social Security Act, § 1903(c), permits Medicaid payment for medical services provided to children under the Individuals with Disabilities Education Act of 2004 (IDEA) through a child’s plan or family plan. States are permitted to use their Medicaid programs to help pay for certain health care services, such as physical and speech therapy, delivered to children in schools. Schools also may receive Medicaid reimbursement for the costs of administrative activities, such as Medicaid outreach, application assistance, and coordination and monitoring of health services. OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, permits in certain circumstances the use of substitute systems for allocation of salaries and wages to Federal

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awards to be used in place of activity reports when employees work on multiple activities or cost objectives. Prior OIG reviews of school-based services found significant unallowable payments.

*(OAS; W-00-11-31391; various reviews; expected issue date: FY 2011; new start)*

### **Medicaid Payments for Transportation Services**

We will review payments 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-00-09-31121; W-00-10-31121; W-00-11-31121; various reviews; expected issue date: FY 2011; 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 the effective program termination date or during periods of exclusion.

*(OAS; W-00-10-31337; W-00-11-31337; various reviews; expected issue date: FY 2011; work in progress)*

### **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 unique physician identifier numbers (UPIN), including claims for services alleged to have been provided after the dates of the referring physicians' deaths. In a prior OIG review, we found instances in which Medicare had paid durable medical equipment (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-00-11-31338; various reviews; expected issue date: FY 2011; new start)*

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## **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 the 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. OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, precludes the claiming of the costs of such contingency fee arrangements 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-00-11-31045; various reviews; expected issue date: FY 2011; work in progress)*

### **Early Results From Medicaid Integrity Contractors**

We will review the progress of CMS's Medicaid Integrity Contractors (MICs) in completing program integrity tasks outlined in their contracts. Section 6034 of the DRA established the Medicaid Integrity Program (MIP) in the Social Security Act, § 1936. An integral part of MIP is the program integrity work that will be performed by MICs. MICs are tasked with preventing and detecting Medicaid fraud, waste, and abuse through the review of the actions of individuals or entities furnishing items or services under the Medicaid program. CMS began awarding contracts in April 2008 and subsequently awarded contracts covering CMS's 10 regions. We will also examine the results of the MICs' work.

*(OEI; 05-10-00200, 05-10-00210; expected issue date: FY 2011; work in progress)*

### **State Oversight of Provider Credentialing by Medicaid Managed Care Plans**

We will review how States ensure that Medicaid managed care plans follow a structured process for credentialing and recredentialing of providers. Regulations at 42 CFR 438.214, require States to ensure that managed care plans serving the Medicaid population implement written policies and procedures for selection and retention of providers. Each managed care plan must also document its process for credentialing and recredentialing providers that have signed contracts or participation agreements. Plans may not employ or contract with providers excluded from participation in Federal health care programs. We will also examine how CMS ensures that States comply with requirements for provider credentialing by Medicaid managed care plans.

*(OEI; 09-10-00270; expected issue date: FY 2011; work in progress)*

### **Medicaid Managed Care Entities' Marketing Practices**

We will review State Medicaid agencies' oversight policies, procedures, and activities to determine the extent to which States monitor Medicaid managed care entities' (MCEs) marketing practices and compliance with Federal and State contractual marketing

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requirements. The Social Security Act, § 1932(d)(2), provides that no marketing materials may be distributed by Medicaid MCEs without first obtaining States' approval. The regulations at 42 CFR § 438.104, permit States to impose additional requirements in contracts with MCEs about marketing activities. We will also determine the extent to which CMS ensures States' compliance with Federal requirements involving Medicaid MCE marketing practices.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Excluded Providers in Medicaid Managed Care Entities**

We will review the extent to which OIG excluded individuals and entities contracted with selected MCEs to provide services and the extent to which OIG-excluded individuals were employed by entities that provide services through MCEs' provider networks in 2009.

Pursuant to the Social Security Act, §§ 1128, 1156, and 1892, HHS and OIG have authority to exclude individuals and entities from all Federal health care programs. The Social Security Act, § 1862(e)(1), and regulations at 42 CFR § 1001.1901(b), preclude Medicare or any other Federal health care program from paying for any items or services furnished, ordered, or prescribed by an excluded individual or entity, except under specific limited circumstances (e.g., the individual or entity provides an emergency item or service or the items or services are furnished, ordered, or prescribed pursuant to a waiver obtained from OIG). The payment prohibition applies to the excluded individual or entity, anyone who employs or contracts with the excluded individual or entity, and any hospital or other provider through which the excluded individual or entity provides services. Recent State Medicaid program integrity reviews by CMS's Medicaid Integrity Group have identified provider enrollment, including the employment of excluded providers, as one of the most common vulnerabilities. We will also determine the extent to which safeguards are in place to prevent excluded individuals and entities from participating in Medicaid managed care provider networks.

*(OEI; 07-09-00630; expected issue date: FY 2011; work in progress)*

### **Medicaid Managed Care Fraud and Abuse Safeguards**

We will review Medicaid managed care organizations' (MCO) fraud and abuse safeguards. Regulations at 42 CFR § 438.608 require Medicaid MCOs to have administrative and management arrangements or procedures, including mandatory compliance plans, that are designed to guard against fraud and abuse. We will also 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. Finally, we will review CMS's plans and procedures for overseeing States' compliance with these requirements.

*(OEI; 01-09-00550; expected issue date: FY 2011; work in progress)*

### **Use of Prepayment Review To Detect and Deter Fraud and Abuse in Medicaid Managed Care**

We will review the extent to which Medicaid MCOs use prepayment reviews to detect and deter fraud and abuse. Regulations at 42 CFR § 438.608 require Medicaid MCOs to have administrative and management arrangements or procedures that are designed to guard

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against fraud and abuse and that include mandatory compliance plans and provisions for internal monitoring and auditing. Prepayment reviews can serve as effective fraud and abuse safeguards because they occur during the claims-processing phase prior to claim payment. We will also examine the results of prepayment reviews, challenges the MCOs addressed in developing and implementing such programs, and lessons learned by MCOs about them. *(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **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 with the State's administrative costs. We will determine whether administrative costs in additional States 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-00-10-31123; W-00-11-31123; various reviews; expected issue date: FY 2011; work in progress)*

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

We will determine whether States are complying with Federal regulations for claiming certified public expenditures (CPE). CPEs are normally generated by local governments as part of their contribution to the coverage of Medicaid services. States may claim CPEs to provide the State's share in claiming Federal reimbursement as long as the CPEs comply with Federal regulations at 42 CFR § 433.51 and 45 CFR 95.13 and the CPEs are being used for the required purposes. *(OAS; W-00-11-31110; various reviews; expected issue date: FY 2011; new start)*

### **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 regulations at 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 Medicaid Managed Information System (MMIS) costs have not been performed by OIG in recent years. *(OAS; W-00-10-31312; W-00-11-31312; various reviews; expected issue date: FY 2011; 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 regulations at 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

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Medicare Part B. 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-00-10-31220; W-00-11-31220; various reviews; expected issue date: FY 2011; work in progress)*

### **State Agency Oversight of Medical Loss Ratio Experience Adjustment**

We will review the accuracy of experience adjustment reports provided by managed care plans to State agencies under Title XIX and Title XXI. Medical contracts between State agencies and managed care plans may contain a provision requiring a minimum percentage of total costs to be expended on medical expenditures (medical loss ratio). The experience adjustment reports provide the costs that a managed care plan has incurred throughout the year and calculate whether the medical loss ratio threshold has been met. If the medical loss ratio threshold is not met, the managed care plan is to refund the State agency a percentage of the premiums paid. OMB Circular A-87 requires State Agencies to properly report expenditures and to apply any applicable credits. We will review State Agencies' oversight and validation of experience adjustment reports and assess whether managed care plans accurately reported medical costs and properly adjusted when the medical loss ratio thresholds were not met. Prior OIG work found deficiencies because the wrong capitation amount was used when calculating the experience adjustment.

*(OAS; W-00-11-31372; various reviews; 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 the 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 that State Medicaid agencies had in identifying and collecting third-party payments. We will examine changes 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 2012; new start)*

### **States Reporting of Program Income From Third-Party Reimbursements**

We will review States' compliance with the requirement that they accurately report all program income from third-party reimbursements. Federal regulations at 42 CFR §433.140(c) require that if a State receives FFP for Medicaid payments for which it receives third-party reimbursement, the State is to pay the Federal Government a portion of the reimbursement, determined in accordance with the FMAP for that State. One third-party recovery vendor noted on its Web site that it recovered over \$1 billion in 1 year for various health care programs and

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disbursed the recoveries to State clients. Prior OIG reviews indicated that States are using such third-party collection contractors and receiving reimbursements for claims that had previously been paid partially with Federal funds.

*(OAS; W-00-10-31376; W-00-11-31376; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Credit Balances**

We will review providers to determine whether there are Medicaid overpayments in patient accounts with credit balances. The Social Security Act, § 1902(a)(25); Federal regulations at 42 CFR pt. 433, subpart D; various State laws; and CMS's *State Medicaid Manual*, Pub. No. 45, pt. 3, § 3900.1, require that Medicaid be the payer of last resort and that providers identify and refund overpayments received. Prior OIG work has found Medicaid overpayments in patients' accounts with credit balances.

*(OAS; W-00-10-31311; W-00-11-31311; various reviews; expected issue date: FY 2011; work in progress)*

### **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 & Families (ACF). Using States' eligibility data, PARIS identifies those who concurrently receive benefits from Medicaid and other means-tested programs, such as food stamps, in more than one State. The Qualifying Individual Program Supplemental Funding Act of 2008 (QI) amended the Social Security Act, § 1903, to require that States' Medicaid eligibility determination systems provide data matching through PARIS. 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 2012; new start)*

### **Duplicate Medicaid Payments for Beneficiaries With Multiple Medicaid Identification Numbers**

We will review duplicate payments on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and procedures for preventing such payments. A preliminary data match has identified a significant number of individuals who were assigned more than one Medicaid identification number and for whom multiple Medicaid payments were made for the same period. The Improper Payments Information Act of 2002 (IPIA) states that a duplicate payment is an improper payment. We will determine whether duplicate Medicaid payments were made by State agencies on behalf of beneficiaries who were assigned more than one Medicaid identification number.

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(OAS; W-00-10-31374; W-00-11-31374; various reviews; expected issue date: FY 2011; work in progress)

### **Medicaid Managed Care Payments for Deceased Beneficiaries**

We will review capitation payments that States make to MCOs for deceased beneficiaries. Pursuant to the Social Security Act, § 1915(b), CMS grants waivers to States allowing them to contract with MCOs. Under the waiver authority, the MCOs receive capitated payments to provide services to certain target groups of Medicaid-eligible beneficiaries. Prior reviews of the Medicare Advantage (MA) program have found improper capitation payments for deceased beneficiaries. We will review States' and CMS's oversight of capitated payments to determine the accuracy of payments subsequent to enrollees' deaths.

(OAS; W-00-11-31392; various reviews; expected issue date: FY 2011; 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 persons with intellectual disabilities, or other medical institutions. 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. The Social Security Act, § 1917(b)(4), requires States at a minimum to 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; W-00-11-31113; various reviews; expected issue date: FY 2011; work in progress)

### **Medicaid Services to Incarcerated Juveniles**

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



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*(OAS; W-00-07-31222; W-00-11-31222; various reviews; expected issue date: FY 2011; work in progress)*

### **Medicaid Citizenship Documentation Requirements**

We will review the eligibility status of Medicaid beneficiaries to ensure that States are meeting the new citizenship documentation requirements. As of July 1, 2006, all U.S. citizens 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 claiming U.S. citizenship who have not provided documentation to prove 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. The Children's Health Insurance Program Reauthorization Act of 2009, § 211, also provides a new optional State process for verifying citizenship. We will determine whether States implemented the citizenship documentation requirement and document the amount of payments on behalf of individuals not meeting the new citizenship documentation requirements.

*(OAS; W-00-10-31224; W-00-11-31224; various reviews; expected issue date: FY 2011; work in progress)*

### **Payment Error Rate Measurement: Fiscal Year 2008 Error Rate**

We will review certain aspects of CMS's Medicaid Payment Error Rate Measurement (PERM) process for determining the FY 2008 Medicaid FFS payment error rate. The IPIA and the OMB implementation of that Act in memorandum M-06-23 require Federal agencies to annually develop a statistically valid estimate of improper payments under programs with a significant risk of erroneous payments. CMS contracted with an independent medical review organization to perform a random independent review of its PERM contractor's payment determinations for 250 Medicaid FFS claims. We will evaluate this CMS initiative, which was designed to ensure the accuracy of the 2008 reported error rate. We will determine whether the independent medical review organization met its contractual obligations to CMS and will analyze the organization's review. We will also evaluate the methodology and medical review determinations underlying the error rate testing conducted by the PERM contractor.

*(OAS; W-00-10-40045; W-00-11-40045; expected issue date: FY 2011; work in progress)*

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

We will review CMS's PERM process to determine whether the PERM has produced valid and reliable error rate estimates for Medicaid and Children's Health Insurance Program (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 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

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developed the PERM. The PERM process includes conducting FFS, managed care, and eligibility reviews pursuant to Federal regulations at 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 (PII). We will also review CMS's corrective actions in response to recommendations in OIG's March 2010 report on the California Department of Health Care Services' FY 2007 PERM universes. We will verify actions taken by CMS to implement our recommendations.

*(OAS; W-00-11-40046; various reviews; expected issue date: FY 2011; 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 and OMB's implementation of that act in memorandum M-06-23 require Federal agencies annually to develop statistically valid estimates of improper payments under programs with significant risk of erroneous payments. To comply with the IPIA, CMS developed the PERM program. The PERM process includes conducting FFS, managed care, and eligibility reviews pursuant to regulations at 42 CFR pt. 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 (CFO Act) 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 2011; 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 2011; 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.

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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 2011; work in progress)*

### **State Compliance With CHIP Eligibility and Enrollment Notification and Review Requirements**

We will review State compliance with the CHIP eligibility and enrollment notification and review requirements. Regulations at 42 CFR pt. 457, subpart K, contains requirements relating to applicant and enrollee protections. It requires, among other things, that eligibility determinations be timely and be in writing and that the State ensure that an applicant or enrollee has an opportunity for an impartial review of eligibility denials and that the results of such reviews be timely and be in writing. We will also review whether beneficiaries remain enrolled during reviews of suspension or termination in enrollment.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Medicaid Program Integrity Best Practices**

We will review State Medicaid agencies' program integrity activities. We will examine State Medicaid program integrity policies and procedures required by Federal regulations at 42 CFR pt. 455 to identify best practices and verify which procedures are operating as intended. Ensuring Medicaid program integrity includes identifying payment risks, implementing actions to minimize the risks, and identifying and collecting overpayments and improper payments.

*(OAS; W-00-11-31396; various reviews; expected issue date: FY 2011; new start)*

### **Medicare and Medicaid Data Matching Project**

We will review CMS's oversight and monitoring of the Medicare and Medicaid Data Matching Project (Medi-Medi) contractors to determine whether they are meeting contractual requirements outlined in the Medi-Medi task orders. Pursuant to the Social Security Act, § 1893, CMS began the Medi-Medi project in 2001 in partnership with the State of California to improve coordination of Medicare and Medicaid program integrity efforts. The objective of the project is to match Medicare and Medicaid data to proactively identify program vulnerabilities and potential fraud and abuse that may have gone undetected by reviewing Medicare and Medicaid program data individually. As of 2007, there were 10 active Medi-Medi Task Orders in the States of California, Texas, Washington, Pennsylvania, North Carolina, New Jersey, New York, Florida, Ohio, and Illinois. Federal regulations at 48 CFR §§ 42.1500 to 42.1503 provide policies and establish responsibilities for agencies to record and maintain contractor performance information. We will also determine the extent to which Medi-Medi contractors

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identified potential fraud, waste, and abuse through the Medi-Medi project.  
(OEI; 09-08-00370; expected issue date: FY 2011; work in progress)

### **Collection and Verification of Provider Ownership Information by State Medicaid Agencies**

We will review State practices for collection and verification of Medicaid provider ownership information. The regulation at 42 CFR § 455.104 requires Medicaid providers to disclose the name and address of each person with an ownership or control interest in the provider. State Medicaid agencies cannot approve a provider participation agreement or contract with any entity that has not disclosed the required information, and payments to providers that have not disclosed the required information are not eligible for FFP. We will also assess the accuracy of the provider ownership information on file for a sample of providers to determine the effectiveness of State practices for Medicaid provider ownership information collection and verification.

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

### **Oversight of State Data Reporting**

We will examine CMS's oversight of State quarterly expenditure reporting on Form CMS-64. CMS-64 is a detailed accounting of expenditures that the Federal Government uses to reimburse States under Title XIX of the Social Security Act. Regulations at 42 CFR §430.30(c) require each State to submit the CMS-64 as a report of actual quarterly expenditures. Previous OIG and GAO studies have shown significant inaccuracies in the reporting of State expenditures, which affects the Federal reimbursement match. We will also identify opportunities to improve the accuracy of State expenditure reporting.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **States' Readiness to Comply With ACA Eligibility and Enrollment Requirements**

We will review States' readiness to comply with new eligibility and enrollment requirements for the Health Insurance Exchange, Medicaid, CHIP, and health subsidy programs. Section 1413 of the Affordable Care Act requires the Secretary to establish a system for State residents to apply for enrollment and receive eligibility determinations for applicable programs. The States' eligibility systems must ensure that applicants who are eligible for Medicaid or CHIP are enrolled in these programs. We will also identify challenges and barriers that States report regarding the implementation of eligibility and enrollment systems. Finally, we will review the extent to which the Office of the National Coordinator for Health Information Technology (ONC) and CMS have provided guidance, technical assistance, and financial incentives to States to develop model eligibility and enrollment systems.

(OEI; 07-10-00530; expected issue date: FY 2012; work in progress)

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## **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.

### **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 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 Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rules at 45 CFR pt. 164, subpart C, which establish minimum requirements for contracts with business associates to protect the security of electronic-protected 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-00-11-41015; various reviews; expected issue date: FY 2011; 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 regulations at 45 CFR § 160.103, which also define "health plan" to include Medicaid programs. Thus Medicaid programs must comply with the security standards set forth at 45 CFR pt. 164, subpart C, which is known as the HIPAA Security Rule. Using an application security assessment tool, we will determine whether States' Web-based applications contain any vulnerabilities that could affect the confidentiality, integrity, and availability of the Medicaid claims' protected health information.

*(OAS; W-00-11-41016; various reviews; expected issue date: FY 2011; new start)*

### **Medicaid Security Controls at the Mainframe Data Centers That Process States' Claims Data**

We will review security controls at States' mainframe data centers that process Medicaid claims data. 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 States' mainframe computers, such as access controls over the mainframe operating system and security software. We will also review some limited

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general controls, such as disaster recovery plans and physical security.  
(OAS; W-00-10-40019; W-00-11-40019; *expected issue date: FY 2011; work in progress, new start*)

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**Work Plan Part IV:  
Legal and Investigative Activities  
Related to Medicare and Medicaid**

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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.



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# Legal and Investigative Activities Related to Medicare and Medicaid

## Legal Activities

OIG's resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalties (CMP) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIA) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the anti-kickback statute, and issues compliance program guidance (CPG). OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements and provides them a self-disclosure protocol and guidance.

## Exclusions From Program Participation

Pursuant to the Social Security Act, § 1128, § 1156, and other statutes, OIG may exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs for many reasons, some of which include program-related convictions, patient abuse or neglect convictions, licensing board disciplinary actions, or other actions that pose a risk to beneficiaries or programs. Exclusions are generally based on referrals from Federal and State agencies. We work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. In fiscal year (FY) 2009, OIG excluded 2,556 individuals and entities from participation in Federal health care programs. The total for FY 2010 will be published in OIG's Fall FY 2010 *Semiannual Report to Congress*. Searchable exclusion lists are available on OIG's Web site at: <http://exclusions.oig.hhs.gov/>.

## Civil Monetary Penalties

OIG pursues 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 the Emergency Medical Treatment and Labor Act of 1986 (EMTALA); items and services furnished to patients of a quality that fails to meet professionally recognized standards of health care; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

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

When adequate evidence of violations exists, OIG staff members 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

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from the False Claims Amendments Act of 1986 and the Fraud Enforcement and Recovery Act of 2009. We assist DOJ prosecutors in litigation and settlement negotiations arising from these cases. We also consider whether to invoke our exclusion authority based on the defendants' conduct. When appropriate and necessary, we require defendants to implement CIAs aimed at ensuring compliance with Federal health care program requirements.

### **Providers' Compliance With Corporate Integrity Agreements**

OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Subsequently, OIG assesses providers' compliance with the terms of the integrity agreements. For example, we conduct site visits to entities that are subject to integrity agreements to verify compliance efforts, to confirm information submitted to us by the entities, and to assess the providers' compliance programs. We review a variety of information submitted by providers to determine whether their compliance mechanisms are appropriate and identify problems and establish a basis for corrective action. When warranted, we impose sanctions, in the form of stipulated penalties or exclusions, on providers that breach integrity agreement obligations. Active CIAs, Certification of Compliance Agreements, and settlement agreements with integrity provisions are listed on OIG's Web site at: [http://www.oig.hhs.gov/fraud/cia/cia\\_list.asp](http://www.oig.hhs.gov/fraud/cia/cia_list.asp).

### **Advisory Opinions and Other Industry Guidance**

To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the anti-kickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful advice on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and CPG for specific areas. For example, in FY 2008, we issued a revised supplemental CPG for nursing facilities, updating the original CPG that was published in 2000 to reflect OIG's focus on quality-of-care issues, including staffing, care plan development, and patient neglect and abuse. Examples are available on OIG's Web site at:

- Advisory Opinions: <http://www.oig.hhs.gov/fraud/advisoryopinions.asp>
- Fraud Alerts: <http://www.oig.hhs.gov/fraud/fraudalerts.asp>
- Compliance Guidance: <http://www.oig.hhs.gov/fraud/complianceguidance.asp>
- Open Letters: <http://www.oig.hhs.gov/fraud/openletters.asp>

### **Provider Self-Disclosure**

OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements. In October 1998, OIG announced a self-disclosure protocol for all health care providers. The protocol offers steps, including a detailed audit methodology, that providers may use if they choose to work openly and cooperatively with us. Many

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providers, including hospitals, laboratories, and physicians, make disclosures using the protocol.

In a 2006 Open Letter, OIG encouraged health care providers to disclose improper arrangements under the anti-kickback statute and the physician self-referral law 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. On April 15, 2008, OIG issued another Open Letter that discussed certain refinements and clarifications of our policies to increase the efficiency of the self-disclosure protocol and benefit providers that self-disclose. The 2008 Open Letter stated that OIG would generally not require compliance obligations in exchange for a release of exclusion authorities. A March 2009 Open Letter further refined the protocol by stating that OIG would no longer accept self-disclosures solely alleging violations of the physician self-referral law.

The self-disclosure protocol is designed only for providers who believe a potential violation of the law has occurred. Matters exclusively involving overpayments or errors that do not indicate violations of the law are brought directly to the attention of the entity responsible for claim processing and payment. Self-disclosure information is available on OIG's Web site at: <http://www.oig.hhs.gov/fraud/selfdisclosure.asp>.

## **Investigative Activities**

To safeguard programs, protect beneficiaries, and ensure that personnel and contractors uphold the highest level of integrity, the Office of Inspector General (OIG) reviews and investigates allegations of fraud and misconduct. Investigations lead to 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 OIG's attention for review, investigation, and resolution. The nature and volume of complaints and priority of issues vary from year to year. We describe some of the more significant investigative outcomes in OIG's *Semiannual Report(s) to Congress*, which are available on our Web site at: <http://www.oig.hhs.gov/publications.asp>.

### **Health Care Fraud**

OIG devotes significant resources to investigating Medicare and Medicaid fraud. We conduct investigations in conjunction with other law enforcement entities, such as the Federal Bureau of Investigation (FBI), the United States Postal Inspection Service (USPS), the Internal Revenue Service (IRS), and State Medicaid Fraud Control Units (MFCU).

OIG investigates individuals, facilities, or entities that, for example, bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes to inflate reimbursement amounts, and false claims submitted to obtain program funds.

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We also investigate business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians.

OIG examines quality-of-care issues such as in nursing facilities, institutions, community-based settings, and other care settings and instances in which the programs may have been billed for medically unnecessary services, for services either not rendered or not rendered as prescribed, or for substandard care that is so deficient that it constitutes “worthless services.”

Other areas of investigative activity include Medicare and Medicaid drug benefit issues and assisting the Centers for Medicare & Medicaid Services (CMS) in identifying program vulnerabilities and schemes such as prescription shorting (a pharmacy dispensing fewer doses of a drug than prescribed, charging the full amount, and then instructing the customer to return to pick up the remainder). Working with law enforcement partners at the Federal, State, and local levels, we 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, deter the illegal use of prescription drugs, and to curb the danger associated with street distribution of highly addictive medications.

OIG applies lessons learned through our Strike Force work related to fraudulent durable medical equipment (DME). The Strike Force model brings together a multiorganizational and multidisciplinary team 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 Force teams operate in South Florida, Detroit, Houston, Los Angeles, Brooklyn, Tampa, and Baton Rouge.

We assist State MFCUs to investigate allegations of false claims submitted to Medicaid and will continue to strengthen coordination between OIG and organizations such as the National Association of Medicaid Fraud Control Units and National Association for Medicaid Program Integrity.

Highlights of recent enforcement actions to which OIG has contributed are posted to OIG’s Web site at: <http://www.oig.hhs.gov/fraud/enforcement/criminal/>.

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# **Work Plan Part V: Public Health Reviews**

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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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# Public Health Reviews

## Public Health Agencies

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Public health agencies within the Department of Health & Human Services (HHS) include the following:

- Agency for Healthcare Research and Quality (AHRQ). AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access.
- 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 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 who have or are at risk for mental and substance abuse disorders.

Issues related to public health are also addressed by several offices within the Office of the Secretary. 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.

Descriptions of work in progress and work planned for fiscal year (FY) 2011 follow.



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## Agency for Healthcare Research and Quality

### **Bioterrorism Epidemic Outbreak Response Model**

We will survey and review 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 of 2006 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 Model, and at the request of the Office of Public Health Emergency Preparedness (OPHEP), BERM model 2.0 was released in 2005. OPHEP was ASPR’s predecessor and funded the planning guide in 2004. We will also determine 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 2012; 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 the program is to upgrade and integrate State and local public health jurisdictions’ preparedness for and response to terrorism and other public health emergencies. The Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, App. B, § h(3) and the Code of Federal Regulations (CFR) at 2 CFR pt. 225, require State grantees of the PHEP program to provide time and effort certifications for employees who are expected to work solely on that Federal award. Regulations at 45 CFR § 92.40, require grantees to also manage and monitor day-to-day operations of 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-00-11-58140; expected issue date: FY 2011; 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 the Public Health Service Act (PHS Act), § 319C-1 (42 U.S.C. §§ 247d-3a), CDC funds PHEP Cooperative Agreements that include critical

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tasks that States must accomplish to improve the timeliness and accuracy of communications about 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). The 24/7 systems enable health care providers to report to or consult with State or local health department staff at any time about 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 the systems.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Radiological and Nuclear Preparedness: Assessing Selected State and Local Public Health Emergency Response Plans**

We will review the extent to which selected States and/or localities have developed and exercised radiological and nuclear (RN) public health emergency response plans. According to CDC and Department of Homeland Security (DHS) guidance documents, States and localities will be the first to respond to an RN incident. To respond to such incidents, CDC provides guidance to States and localities on how to develop RN preparedness plans. We will also determine the extent to which selected States and/or localities are prepared to respond to the public health needs of the population in the event of an RN incident.

*(OEI; 04-10-00250; expected issue date: FY 2011; work in progress)*

### **Shelf Life Extension Program**

We will determine whether CDC is utilizing the Shelf Life Extension Program (SLEP), managed by FDA, to extend the expiration dates on Strategic National Stockpile (SNS) drugs in lieu of destroying expired drugs and replacing them. In 2002, the CDC entered into a memorandum of agreement for SLEP to reduce the cost of replacing SNS inventory. The SNS maintains significant amounts of pre-positioned drugs to prepare for emergencies. While all drugs have an expiration date set by the manufacturer, the actual shelf life of certain drugs, if stored properly, can be much longer. We will verify the data SNS used to report the dollars saved through SLEP and will examine inventory records and SLEP records to verify the extent to which CDC is submitting drugs for SLEP.

*(OAS; W-00-11-52320; expected issue date: FY 2011; new start)*

### **Vaccines For Children Program: Storage and Management of Vaccines**

We will review the extent to which Vaccines for Children (VFC) providers are storing and managing vaccines according to CDC's VFC Operations Guide. The VFC program was created by the Omnibus Budget Reconciliation Act of 1993 (BBRA) as an entitlement program to be a required part of each State's Medicaid plan. The VFC program is funded by CMS and implemented by CDC. The VFC Operations Guide contains requirements and procedures for all States and immunization grantees that receive VFC-funded vaccines, as well as minimum requirements that providers must meet, including requirements relating to storage of vaccines, to participate in the VFC program. The VFC program cost \$3.4 billion in 2009. In examining

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VFC providers' qualifications pursuant to the VFC Operations Guide, we will also determine whether vaccines were stored within temperature ranges required by FDA.  
(OEI; 04-10-00430; expected issue date: FY 2011; work in progress)

## **Food and Drug Administration**

### **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. 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*, ch. 8, § 8.2. We will also review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries.  
(OAS; W-00-11-51010; expected issue date: FY 2011; new start)

### **Oversight of Food Safety Operations**

We will review FDA's oversight and operations related to imported pet food and feed products, including the extent of FDA's enforcement authorities, its procedures to implement those authorities, how 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 that apply 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, we will determine why.  
(OAS; W-00-11-51002; expected issue date: FY 2011; new start)

### **Oversight of State Food Facility Inspections**

We will review FDA's oversight of food facility inspections conducted by States under contract with FDA. FDA created the Contract Inspection Audit Program in 2006, in response to an OIG report recommending that FDA take steps to address shortcomings in its system of oversight. Under this program, 7 percent of each State's inspectors are audited by FDA or the State each year to ensure that the State's contract inspections are adequate and that the State is complying with contract requirements. When audits identify deficiencies in the State inspector's performance or systemic deficiencies in the State's inspection program, FDA and the State take action to ensure deficiencies are corrected. We will determine the extent to which FDA is meeting its program guidelines, and the extent to which deficiencies are identified and corrected.  
(OEI; 02-09-00430; expected issue date: FY 2011; work in progress)

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### **FDA Reportable Food Registry**

We will determine the extent to which food facilities comply with key requirements of the FDA's Reportable Food Registry. Pursuant to the Food and Drug Administration Amendments Act of 2007, § 1005, FDA created the reportable food registry to provide a reliable mechanism to track outbreaks of foodborne illness. Beginning in September 2009, FDA began requiring food facilities to report all instances in which there is a reasonable probability that the use of, or exposure to, an article of food will cause severe health problems or death. FDA refers to such foods as "reportable foods." When a food facility discovers that it is in possession of a reportable food, the facility must (1) report the adulteration in FDA's reportable food registry within 24 hours and submit supplemental information as required by FDA, (2) investigate the cause of the adulteration if the adulteration originated with the facility, and (3) work with FDA authorities to follow up as needed. We will also determine whether there are any known instances of reportable foods that facilities did not report to FDA as required.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **FDA's Oversight of Investigational New Drug Applications**

We will review FDA's process for evaluating investigational new drug (IND) applications. The Food, Drug, and Cosmetic Act of 1938 (FDCA), § 505(i), 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 2011; new start)*

### **FDA's Policies and Procedures for Resolving Scientific Disputes**

We will review the FDA Center for Devices and Radiological Health's (CDRH) policies and procedures for resolving scientific disputes about approval of devices. Such disputes may arise between FDA and industry or within the FDA (e.g., reviewer and management). Federal regulations at 21 CFR § 10.70 require FDA reviewers to maintain an administrative file documenting their product recommendations and decisions, including significant controversies or differences of opinion and the resolution. The regulation at 21 CFR § 10.75(a) provides for supervisory review of a decision if requested by the FDA reviewer or an outside stakeholder, or initiated by the supervisor, using information in the administrative file. We will review a sample of administrative files for disputed device decisions and assess the extent to which regulations, policies, and procedures were followed during the dispute resolution process. We will also assess whether CDRH managers and staff are aware of and trained on policies and procedures for resolving scientific disputes.

*(OEI; 01-10-00470; expected issue date: FY 2011; work in progress)*

### **510(k) Process for Device Approval**

We will review FDA's internal controls and quality review procedures for the 510(k) device approval process. Pursuant to sections 510(k) and 513(f) of the FDCA (implemented

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by regulations at 21 CFR 807.92), certain devices may be approved under a simplified “510(k) process,” in which an entity must demonstrate that the device is as safe and effective as a device already approved (“substantial equivalence”). This is a faster process, and there are concerns that manufacturers may stretch the evidence to claim that the device is substantially equivalent to an already-approved device. We will also examine the extent to which manufacturers submit data on long-term safety under the 510(k) process and FDA’s post-marketing surveillance of such medical devices.

*(OEI; 04-10-00480; expected issue date: FY 2011; work in progress)*

### **FDA’s Oversight of Postmarketing Surveillance Studies of Medical Devices**

We will review FDA’s oversight of medical device postmarketing surveillance studies. Under section 522 of the FDCA, FDA may require manufacturers of medical devices to complete postmarketing surveillance for any moderate- to high-risk medical device (Class II or III) that, if it failed, has a reasonable likelihood of serious adverse health outcomes. A 2006 OIG study of FDA’s oversight of postmarketing study commitments for drugs found that FDA could not readily determine whether or how expeditiously such postmarketing study commitments were progressing toward completion, in part because some information submitted by drug applicants was incomplete and because information was missing from some applications. We will examine the extent to which FDA has required postmarketing studies of medical devices, the level of compliance among sponsors that have been required to perform such studies, and FDA’s oversight of sponsors’ study commitments. We will also identify trends and challenges associated with postmarketing surveillance studies.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **Submission of Electronic Drug Labels**

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

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

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## **Health Resources and Services Administration**

### **Ryan White CARE Act Payer of Last Resort Provision**

We will review States' compliance with the payer of last resort requirement in their administration of the AIDS Drugs Assistance Program (ADAP) funds. Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) stipulates that grant funds not be used to make payments for items or services 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 2011; work in progress)*

### **Human Immunodeficiency Virus (HIV) Testing in Health Centers**

We will describe HIV testing practices of Health Resources and Services Administration (HRSA) funded health centers, and the factors that health centers staff report influence their decisions regarding HIV testing practices. The Centers for Disease Control and Prevention (CDC) estimates that 56,300 new HIV infections occurred in the United States in 2006. In an effort to reduce this number, CDC issued new recommendations to make HIV testing a routine part of medical care. Health centers are critical to this effort because they provide health services to populations that are disproportionately affected by HIV. However, HRSA estimates that only 3.5 percent of health center patients were tested in 2007 and little information exists regarding health center HIV testing practices. We will describe the extent to which health centers do or do not provide HIV testing. For health centers that provide HIV testing, we will describe their practices and the factors that influence them.

*(OEI; 06-10-00290; expected issue date: FY 2011; work in progress)*

## **Indian Health Service**

### **Accounting for Medication Inventory**

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

*(OAS; W-00-08-55060; various reviews; expected issue date: FY 2011; work in progress)*

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## **IHS Medicaid Reimbursements**

We will review IHS's expenditure of Medicaid reimbursements. The Social Security Act, § 1911, allows IHS and tribal facilities to bill State Medicaid programs for services provided to Indian beneficiaries also enrolled in Medicaid. The facilities bill for services using OMB encounter rates, which are set payment amounts for inpatient and outpatient services (visitations). Unlike the Medicaid program whereby the States provide some of the funds for Medicaid services, the Social Security Act, § 1905(b), permits the Federal Government to reimburse 100 percent of the services provided to Indian beneficiaries also enrolled in Medicaid. Accordingly, States may lack incentive to require accountability for expenditures of Medicaid reimbursements that, according to law, must be used exclusively for the purpose of making improvements to IHS and tribal health care facilities.

*(OAS; W-00-11-55065; expected issue date: FY 2011; new start)*

## **Background Investigations To Protect Indian Children**

We will review the handling of background investigations required by the Indian Child Protection and Family Violence Prevention Act. This law requires that all IHS employees and contractors who have regular contact with, or control over, Indian children be investigated for any history of certain criminal acts. Previous OIG work found inconsistent practices in staff background investigations. We will determine whether IHS and tribal organizations have completed required background investigations.

*(OAS; W-00-11-50020; various reviews; expected issue date: FY 2011; new start)*

## **Mental Health and Dialysis Services at Indian Health Service and Tribal Facilities**

We will review the availability of mental health and dialysis services at Indian Health Service and tribal facilities. Funding for such services is provided under the Indian Health Care Improvement Act that was reauthorized in the Health Care and Education Reconciliation Act of 2010. Mortality resulting from alcoholism, diabetes, and suicide is significantly higher among American Indians and Alaska Natives (AI/AN) than among other Americans. Dialysis and mental health services pose particular challenges because of limited access to specialized equipment and/or staff. We will evaluate barriers to access.

*(OEI; 09-08-00580 and 09-08-00581; expected issue date: FY 2011; work in progress)*

## **National Institutes of Health**

### **Superfund Financial Activities for Fiscal Year 2009**

We will review the payments, obligations, reimbursements, and other uses of Superfund amounts 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.

*(OAS; W-00-11-56030; expected issue date: FY 2011; new start)*

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### **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-00-11-50036; expected issue date: FY 2011; 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 Financial Resources (ASFR) and the Assistant Secretary for Administration (ASA).

*(OAS; W-00-11-50037; various reviews; expected issue date: FY 2011; new start)*

### **Review of Extra Service Compensation Payments Made By Education Institutions**

We will review payments for extra compensation charged to Federally sponsored grants, contracts, and cooperative agreements by education institutions to determine whether the payments were in accordance with Federal regulations. Pursuant to OMB Circular A-21, *Cost Principles for Education Institutions*, Att., § J.8.d(1), charges for work performed on sponsored agreements by faculty members will be based on the individual faculty member's regular compensation. Any charges for work representing "extra compensation" above the faculty member's base salary are allowable provided that arrangements are specifically provided for in the agreement or are approved in writing by the sponsoring agency. We will determine whether extra compensation payments were properly calculated and approved by the sponsoring agency. Recent OIG work has indicated problems with extra compensation payments charged to Federally sponsored agreements at several colleges and universities.

*(OAS; W-00-11-50040; expected issue date: FY 2011; new start)*

### **Recharge Centers at Colleges and Universities**

We will determine whether recharge centers at colleges and universities have a reasonable and consistent rate schedule and comply with the standards set forth in OMB Circular A-21, *Cost Principles for Educational Institutions*, Att., § J.44 for specialized service facilities.

Specialized service funds (recharge centers) at universities operate as in-house enterprises and are used to finance, account for, and report on the provision of goods and services to other university operating units. Recent OIG work identified problems in this area. We will review the rate schedules of various recharge centers at colleges and universities to ensure that the amounts charged are reasonable and consistent. We will also review the recharge centers' expenses to determine reasonableness and necessity.

*(OAS; W-00-11-50041; expected issue date: FY 2011; new start)*



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## **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 who have 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 2012; new start)*

## **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 primary responsibility for research and development of such medical countermeasures. From FY 2005 to FY 2010, NIAID awarded approximately \$100 million in grants for Project BioShield-related medical countermeasure research and development. NIAID is required to follow HHS rules for 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 2012; 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 in regulations at 45 CFR pt. 74. Congress awarded

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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 NCR's monitoring of programmatic involvement with CTAs, particularly awardee-generated goals and milestones.

*(OEI; 07-09-00300; expected issue date: FY 2011; work in progress)*

## **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 regulations at 45 CFR § 96.134.

*(OAS; W-00-09-57205; A-04-09-03526; expected issue date: FY 2011; work in progress)*

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

We will review SAMHSA's progress in identifying performance goals for the Substance Abuse Treatment Block Grant program. The goal of the block grant program is to improve access, reduce barriers, and promote effective treatment and recovery services for people who have 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 2012; new start)*

### **SAMHSA Oversight of High-Risk Grantees**

We will review the extent to which SAMHSA monitors high-risk grantees in accordance with Federal regulations at 45 CFR pt. 74 and pt. 92, departmental directives, and agency policies. As part of grant applications, States must outline a plan for sustaining the program and services after Federal funds expire. We will determine the extent to which SAMHSA is reviewing sustainability plans and whether SAMHSA project officers and financial managers are communicating with high-risk grantees to identify opportunities for improvement.

*(OEI; 07-10-00220; expected issue date: FY 2011; work in progress)*

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## **Cross-Cutting Public Health Activities**

### **Conflict of Interest Waivers at the Department of Health & Human Services**

We will review the extent to which waivers for HHS employees who had conflicts of interest were documented in accordance with Office of Government Ethics (OGE) requirements. Federal statutes, including 18 U.S.C. § 208, and OGE regulations, including at 5 CFR § 2635, address conflicts of interest. Conflict of interest waivers must be adequately documented pursuant to requirements set forth in regulations at 5 CFR §§ 2640.301 and 302. The Secretary issued a memorandum that provided further instructions for issuing adequately documented waivers to HHS employees in accordance with Federal statutes and OGE regulations. Prior OIG work found vulnerabilities in waivers for special Government employees on Federal advisory committees at CDC. We will also determine whether employees signed waivers in accordance with Federal ethics requirements.

*(OEI; 04-10-00010; expected issue date: FY 2011; work in progress)*

### **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-00-11-57228; various reviews; expected issue date: FY 2011; 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 supplies of pre-pandemic vaccines, post-pandemic vaccines, and antivirals; and vaccine and antiviral distribution. We will also determine the extent to which States are reporting and meeting performance goals. This will include an assessment of how the SNS provides countermeasures to the States in light of the 2009-H1N1 pandemic, during which 11 million doses of anti-virals were released. Many of these remained unused because they were released without regard to the sufficiency of existing State stockpiles.

*(OAS; W-00-11-57229; expected issue date: FY 2011; new start)*

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## **Public Health Investigations**

### **Violations of Select Agent Requirements**

On March 18, 2005, HHS issued a final regulation at 42 CFR pt. 73 on possession, use, and transfer of select (biological) 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 2010, OIG had settled 14 cases involving violations of the select-agent regulations and had collected nearly \$2 million in CMPs. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation (FBI), and the Department of Agriculture (USDA) to investigate violations of the statute governing the registration, storage, and transfer of select agents and toxins.

### **Public Health Legal Activities**

OIG assists the Department of Justice (DOJ) in the resolution of civil and administrative fraud cases and promotes compliance of recipients of HHS grant funding. In the public health area, OIG assists DOJ to develop and pursue Federal False Claims Act (FCA) cases against institutions that receive grants from NIH and other public health service agencies. We assist DOJ prosecutors in litigation and in settlement negotiations.

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# **Work Plan Part VI: Human Services Reviews**

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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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# Human Services Programs

Several Department of Health & Human Services (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 & 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.

OIG's work in progress and planned new start for fiscal year (FY) 2011 follow.

## Administration on Aging

### Performance Data for the Senior Medicare Patrol Projects

We will review 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 the projects. Beginning in 1997, pursuant to congressional recommendations in a report accompanying the Omnibus Consolidated Appropriations Act of 1997 (OCAA), 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 providers.

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

## Administration for Children and Families

### 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 risks minimized. The Code of Federal Regulations (CFR) at 45 CFR § 95.621 requires 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

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planning, design, development, and installation of a statewide child welfare information system. We will determine whether the costs claimed by States for the systems are allowable. (OAS; W-00-11-25040; *expected issue date: FY 2011; 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 Office of Inspector General (OIG) review of one State's adoption assistance subsidies found payments to families that did not meet eligibility requirements.

(OAS; W-00-09-24009; W-00-10-24009; W-00-11-24009; *expected issued date: FY 2011; work in progress and new start*)

### **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-00-08-24002; W-00-11-24100; *various reviews; expected issue date: FY 2011; work in progress and new start*)

### **Administrative Costs Charged to the Foster Care Program by One County Probation Department**

We will review one State's county probation department's claims for Title IV-E administrative costs charged to the Foster Care program. Federal regulations at 45 CFR § 1356.60(c)(2) list the costs that are necessary for the administration of the Foster Care program, and therefore allowable. A prior OIG review disclosed instances in which a county probation department charged administrative costs to the Foster Care program for activities that were not listed in the Federal regulation or closely related to those listed in Federal regulations.

(OAS; W-00-11-24120; *expected issue date: FY 2011; new start*)

### **Training Costs Charged to the Foster Care Program by one County Probation Department**

We will review one State's county probation department's claims for Title IV-E training costs charged to the Foster Care Program. Federal regulations at 45 CFR § 1356.60(b)(1) provide that



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Federal financial participation is available at the enhanced rate of 75 percent for the costs of (1) training personnel employed or preparing for employment by the State or local agency administering the State's foster care training plan and (2) providing short-term training to current or prospective foster or adoptive parents, as well as personnel of childcare institutions. (OAS; W-00-11-24121; expected issue date: FY 2011; new start)

### **Foster Care Per Diem Rates**

We will review foster care maintenance payments claimed under Title IV-E of the Social Security Act. 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-00-11-24101; expected issue date: FY 2011; 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. The Social Security Act, § 475(4)(A), provides foster care maintenance payments that 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, the 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 2011; 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 FFP 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 requires 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-00-11-24111; expected issue date: FY 2011; new start)

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### **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-00-08-25023; W-00-11-25023; various reviews; expected issue date: FY 2011; 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. In accordance with regulations at 45 CFR § 1356.60(c)(2), administrative costs cover staff members' 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-00-11-24112; expected issue date: FY 2011; 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 they are 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-00-11-24113; various reviews; expected issue date: FY 2011; 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

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

*(OAS; W-00-11-25041; expected issue date: FY 2011; new start)*

### **Monitoring the Health and Safety of Foster Children**

We will review foster children's case files in a State to determine whether county social workers are monitoring foster care placements to ensure the health and safety of children. Pursuant to the Social Security Act, § 471(a)(16), a State must have a plan approved by the Secretary that provides for the development of a case plan for each child receiving foster care maintenance payments and provides for a case review system. The Social Security Act, § 475(5)(B), defines "case review system" as a procedure for assuring that the status of each child is reviewed periodically, but no less frequently than one every 6 months either by a court or by an administrative review.

*(OAS; W-00-11-24122; expected issue date: FY 2011; 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 pt. 1304 and pt. 1306 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 regulations 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. We will also assess ACF oversight of States' licensing, health, and safety requirements for CCDF-funded child care facilities.

*(OAS; W-00-11-22005; various reviews; expected issue date: FY 2011; new start.*

*OEI; 07-10-00230; expected issue date: FY 2011; work in progress)*

### **Interest Earned on Child Support Enforcement Funds**

We will review interest earned by local government entities that receive CSE funds. Regulations at 45 CFR § 92.21(i) provide that 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

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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-00-11-20031; expected issue date: FY 2011; 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-00-11-20032; expected issue date: FY 2011; new start)*

### **Investigations Under the Child Support Enforcement Task Force Model**

Project Save Our Children seeks to identify, investigate, and prosecute individuals who fail to meet their court-ordered support obligations. The project brings together OIG, the U.S. Marshals Service, Departments of Justice (DOJ), State (DOS) and local law enforcement, local prosecutors, State child-support agencies, and others to enforce Federal and State criminal child-support statutes. In FY 2011, we plan to continue to encourage and coordinate enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases.

### **Head Start Grantees' Progress Toward Meeting New Teacher Credentialing Requirements**

We will review the progress that Head Start grantees have made toward meeting new teacher credentialing requirements. The Improving Head Start for School Readiness Act of 2007 (Head Start Act) established new requirements for Head Start teaching credentials that take effect in 2010, 2011, and 2013. Some requirements pertain to grantees while others pertain to the program as a whole. We will also describe Head Start's strategies for hiring and retaining qualified classroom teachers, and assess ACF's actions to ensure that grantees meet the teacher credentialing requirements.

*(OEI; 05-10-00240; expected issue date: FY 2011; work in progress)*

### **TANF Recipient Social Security Numbers**

We will determine whether a State agency's TANF records contain valid social security numbers (SSN), and whether the State agency verified the SSNs with the Social Security Administration. The Federal regulation at 45 CFR § 205.52 requires that applicants and recipients of certain programs, including TANF, provide their SSNs to State agencies as a condition of eligibility for the program, and that State agencies submit the SSNs to the Social

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Security Administration for verification.

*(OAS; W-00-11-25050; expected issue date: FY 2011; new start)*

### **Use of Smart Card Technology to Reduce TANF Payment Errors**

We will determine whether States have adopted or are contemplating adoption of Smart Card technology in their TANF programs. Smart cards can validate the identity of TANF recipients and ensure that payments are allowed only for authorized items. This technology could greatly reduce fraud and abuse in the TANF program. We will survey a number of States to quantify the impact of using the technology.

*(OAS; W-00-11-25051; expected issue date: FY 2011; new start)*

### **ACF Oversight of TANF Work Participation and Verification Requirements**

We will review ACF oversight of States' compliance with TANF program work participation verification requirements. TANF provides assistance and work opportunities to needy families by granting States Federal funds and wide flexibility to develop and implement their own welfare programs. Regulations implementing the TANF program are at 45 CFR pts. 261-265. The regulations include, among other things, the requirement that States ensure that 50 percent of all families and 90 percent of two-parent families are working and that States report and verify work activities. We will also describe the types of procedures States have established in Work Verification Plans.

*(OEI; 00-00-00000; expected issue date: FY 2012; 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 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 such grants and contracts.

*(OAS; W-00-11-25042; expected issue date: FY 2011; new start)*

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# **Part VII: Departmentwide Issues**

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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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## Departmentwide Issues

Certain financial, performance, and investigative issues cut across Department of Health & Human Services (HHS) programs. The Office of Inspector General's (OIG) work in progress and planned work address departmentwide matters, such as financial statement audits; financial accounting; information systems management; and other departmental issues, including discounted airfares and protections for people who have disabilities in residential settings.

Although we have discretion in allocating most of our non-Medicare and non-Medicaid resources, a portion is used for mandatory reviews, including 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 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 the Centers for Medicare & Medicaid Services (CMS).

Descriptions of OIG's reviews of departmentwide matters in fiscal year (FY) 2011 follow.

### Financial Statement Audits

#### Audits of Fiscal Years 2010 and 2011 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 2010 financial statements are due to the Office of Management and Budget (OMB) by November 15, 2010; for FY 2011, they are due by November 15, 2011.

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

- Consolidated HHS – This audit incorporates all operating divisions, including CMS, which will receive a separate audit report (listed below).  
(OAS; W-00-10-40009; A-17-10-00001)



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- CMS – (OAS; W-00-10-40008; A-17-10-02010)

The following FY 2011 financial statement audits will be completed and reports will be issued during FY 2012:

- Consolidated HHS – This audit will incorporate all operating divisions, including those that will receive separate audit reports (listed below). (OAS; W-00-11-40009)
- CMS – (OAS; W-00-11-40008)

### **Fiscal Year 2011 Statement on Auditing Standards Examinations**

We will review an independent auditor's workpapers to determine whether examinations of HHS's service organizations were conducted in accordance with applicable laws and regulations. Such 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 2011 financial statement audits and will be issued during FY 2011:

- Center for Information Technology (NIH Computer Center)  
(OAS; W-00-11-40012; A-17-11-00010)
- Payment Management System  
(OAS; W-00-11-40012; A-17-11-00009)

### **Fiscal Years 2010 and 2011 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*, §§ 6.11 and 13.

The FY 2010 financial-related reviews that will be issued during 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)

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

- Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the Department of Defense (DOD)

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OIG in performing the OMB Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, Section 11, Agreed-Upon Procedures.  
(OAS; W-00-11-40009; A-17-11-00008)

- Department of State Agreed Upon Procedures. These procedures focus on reviewing certain financial information for allocation transfers from the Department of State (DOS) to HHS under the President's Emergency Plan for AIDS Relief (PEPFAR) program. OMB Bulletin 07-04 paragraph 6.05 requires auditors to work together to ensure that allocation transfers receive audit coverage that in the transferring agency auditor's professional judgment is required as part of the annual financial statement audit. The procedures are performed in accordance with the American Institute of Certified Public Accountants' attestation standards.  
(OAS; W-00-11-40009; A-17-11-0001)

The FY 2011 financial-related reviews that will be issued during FY 2012 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-00-11-40009; A-17-11-00006)

## 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 PEPFAR program. HHS received PEPFAR funds from both the annual HHS appropriation and the Foreign Operations appropriation. PEPFAR funds support international programs for acquired immunodeficiency syndrome (AIDS) prevention, treatment, and care.  
(OAS; W-00-10-52300; W-00-11-52300; *expected issue date: FY 2011; work in progress and 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 unsupported and that the State has been required to revise it. The Code of Federal Regulations (CFR) 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-00-11-52310; *expected issue date: FY 2011; new start*)

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### **Annual Accounting of Drug Control Funds**

We will review HHS agencies' compliance with the requirement at 21 United States Code (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 2010 annual accounting.

*(OAS; W-00-11-52312; expected issue date: FY 2011; new start)*

### **Use of Appropriated Funds in Program Support Center Contracting**

We will review the appropriateness of the Program Support Center's obligation of appropriated funds for services it obtains through contracts to ensure that appropriated funds were used only during the period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and, pursuant to 31 U.S.C. § 1502, 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 as required by 31 U.S.C. § 1341(a)(1). We will review contracts and contract modifications issued by the Program Support Center to determine whether appropriated funds were used in accordance with the Anti-Deficiency Act.

*(OAS; W-00-11-52313; expected issue date: FY 2011; new start)*

### **Reasonableness of Prime Contractor Fees**

We will review fees negotiated for prime contracts that involve significant subcontractor efforts. Federal acquisition laws and regulations, i.e., 10 U.S.C. 2306(d), 41 U.S.C. 254(b), and Federal Acquisition Regulation (FAR) 15.404-4(b)(4)(i)), impose limits on the amount of fee that can be negotiated with a contractor. Subcontractor fees are typically considered "costs" to the prime contractor and may not be considered during the Government's negotiations with the prime contractor. This "fee on fee" situation may result in fees that exceed the limits established in Federal laws and regulations. We will determine whether the Government negotiated reasonable fees for such prime contracts taking into consideration any fees the prime contractor expected to pay subcontractors.

*(OAS; W-00-11-52320; expected issue date: FY 2011; 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 HHS Acquisition Regulation (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-00-11-52314; various reviews; expected issue date: FY 2011; new start)*

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## **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 funds that they receive. Our reviews ensure that the audits and reports meet applicable standards, identify any followup 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 in compliance with provisions of the American Recovery and Reinvestment Act of 2009 (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. We analyze and record electronically the audit findings that are reported by non-Federal auditors for use by HHS managers. Our reviews provide HHS managers 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, it designates which Federal agency has primary 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. (*OAS; W-00-11-50012; various reviews; expected issue date: FY 2011; new start*)

## **Requested Audit Services**

Throughout the year, Congress, HHS, and other Federal organizations request that we perform a variety of audit services. Such 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.

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We evaluate 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.

### **Compliance with Executive Order 13520: Reducing Improper Payments**

We will review certain aspects of CMS's compliance with Executive Order 13520 on reducing improper payments. The Executive Order requires Federal agencies to reduce improper payments by intensifying efforts to eliminate payment errors, waste, fraud, and abuse in major programs administered while continuing to ensure that Federal programs serve and provide access to the intended beneficiaries. Pursuant to the Executive Order, CMS is required to provide to OIG each high priority program's improper payment measurement methodology, plans to meet reductions targets, and plans for ensuring that the initiatives undertaken pursuant to this order do not hinder program access for eligible beneficiaries. We will assess the level of risk associated with the applicable programs, determine the extent of oversight warranted, and provide CMS any recommendations for modifying its methodology, improper payment reduction plans, or program access and participation plans.

*(OAS; W-00-10-40047; W-00-11-40047; various reviews; expected issue date: FY 2011; work in progress)*

## **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 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; W-00-10-42020; W-00-11-42000; expected issue date: FY 2011; work in progress and 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. 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; W-00-11-42001; various reviews; expected issue date: FY 2011; work in progress and new start)*

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## **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; W-00-11-42002; various reviews; expected issue date: FY 2011; work in progress and 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. The Federal Travel Regulation (FTR), 41 CFR § 301-10.106, 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-00-11-58125; expected issue date: FY 2011; new start)*

### **State Protections for People Who have Disabilities in Residential Settings**

We will review actions taken by CMS, the Administration for Children & Families (ACF), the Substance Abuse and Mental Health Administration (SAMHSA), and the Food and Drug Administration (FDA) on OIG recommendations to work cooperatively to provide information and technical assistance to States for strengthening State protections for people who have disabilities in residential settings. Several HHS operating divisions fund programs or services that play a role in protecting people who have 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-00-11-58126; expected issue date: FY 2011; 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

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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-00-11-58127; expected issue date: FY 2012; new start)*

### **Pre-Existing Condition Insurance Plans**

We will review the controls the Office of Consumer Information and Insurance Oversight (OCIIO) and States have in place to prevent and identify fraudulent health care claims for individuals covered by Pre-Existing Condition Insurance Plans (PCIP). PCIPs are temporary high-risk health insurance pool programs that provide health insurance coverage to uninsured individuals who have pre-existing conditions. The program was mandated by the Patient Protection and Affordable Care Act (Affordable Care Act). § 1101. Funding for PCIPs became available on July 1, 2010 and interim final regulations governing PCIPs went into effect July 1. The program will continue until Health Insurance Exchanges begin operating in 2014. Federal regulations at 45 CFR §152.27(a) require each PCIP to develop, implement, and execute operating procedures to prevent, detect, recover payments (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse. OCIIO will partner with other Federal agencies and non-profit entities to maintain a network of health care providers and adjudicate claims. We will also examine the effectiveness of Federal agencies in working together to administer the PCIP program.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

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# **Work Plan Appendix A: Recovery Act Reviews**



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Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

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# Recovery Act Reviews: Medicare and Medicaid

## Medicare Part A and Part B

The Office of Inspector General's (OIG) work in progress and new starts planned for fiscal year (FY) 2011 follow.

### Medicare Incentive Payments for Electronic Health Records

We will review Medicare incentive payments to eligible health care professionals and hospitals for adopting electronic health records (EHR) and the Centers for Medicare & Medicaid Services' (CMS) safeguards to prevent erroneous incentive payments. An EHR is an electronic record of health-related information for an individual that is generated by health care providers. It may include a patient's health history, along with other items. The American Recovery and Reinvestment Act of 2009 (Recovery Act), §§ 4101 and 4102, authorize Medicare incentive payments over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology. Incentive 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. According to Congressional Budget Office (CBO) estimates, CMS's net spending for incentives will total about \$20 billion. We will review Medicare incentive payment data from 2011 to identify payments to providers that should not have received incentive payments (e.g., those not meeting meaningful use criteria). We will also assess CMS's plans to oversee incentive payments for the duration of the program and actions taken to remedy erroneous incentive payments.

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

## Medicaid Hospitals

### Medicaid Disproportionate Share Hospital Payments

We will review disproportionate share hospital (DSH) payments to determine whether the expenditures claimed met Medicaid requirements. Section 5002 of the Recovery Act provides fiscal relief to States by increasing most States' FY 2009 and 2010 Medicaid DSH allotments by 2.5 percent. Such 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 about \$11.33 billion.

*(OAS; W-00-11-31350; various reviews; expected issue date: FY 2011; new start, Recovery Act)*

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## **Medicaid Administration**

### **State Medicaid Agencies' Progress in Implementing Medicaid Recovery Act Incentives for Electronic Health Records**

We will review State Medicaid agencies' progress in implementing Medicaid incentive payments for EHRs. Sections 4101 and 4201 of the Recovery Act created incentives for eligible health care providers and hospitals to adopt certified EHR technology in the Medicare and Medicaid programs. According to CBO estimates, CMS's net spending for incentive payments will total about \$20 billion. We will determine the progress of State Medicaid agencies in getting CMS's approval to make incentive payments. We will also determine when State Medicaid agencies plan to make incentives available to health care providers and hospitals. *(OEI; 05-10-00080; expected issue date: FY 2011; work in progress; Recovery Act)*

### **Medicaid Incentive Payments for Electronic Health Records**

We will review Medicaid incentive payments to providers and hospitals for adopting EHRs and CMS's safeguards to prevent erroneous incentive payments. 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. Section 4201 also provides a 90-percent Federal match for State administrative expenses for the adoption of certified EHR technology by Medicaid providers. According to CBO estimates, Medicaid spending for incentives will total about \$12 billion between 2011 and 2019. We will determine whether incentive payments to Medicaid providers to purchase, implement, and operate EHR technology were claimed in accordance with Medicaid requirements. We will also assess CMS's actions to remedy erroneously made incentive payments and its plans for securing the payments for the duration of the incentive program, as well as review payments to States for administrative expenses. *(OAS; W-00-11-31351; various reviews; expected issue date: FY 2011; 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 Federal medical assistance percentage (FMAP) if any amount attributable (directly or indirectly) to such an increase is deposited or credited into any State reserve or rainy-day fund. We will determine how selected States expended increased FMAP funding and whether they used the increased funding to supplement reserve or rainy-day funds. *(OAS; W-00-10-31358; W-00-11-31358; various reviews; expected issue date: FY 2011; 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

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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 about expenditures claimed on Form CMS-64.

*(OAS; W-00-10-31359; W-00-11-31359; various reviews; expected issue date: FY 2011; work in progress, 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 claims 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-00-10-31360; W-00-11-31360; various reviews; expected issue date: FY 2011; work in progress, Recovery Act)*

## **Medicare and Medicaid Information Systems and Data Security**

### **Health Information Technology System Enhancements**

We will review health information technology (health IT) enhancements to CMS systems to ensure that they include standards adopted by the Department of Health & Human Services (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 the new requirements.

*(OAS; W-00-10-27109; various reviews; expected issue date: FY 2011; work in progress; Recovery Act)*

### **Contractor System Enhancements**

We will review health IT 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 health IT initiatives. CMS contractor systems require modification to comply with the new requirements.

*(OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)*

### **Breaches and Medical Identity Theft Involving Medicare Identification Numbers**

We will review CMS's policies and procedures on breaches and medical identity theft. Section 13400 of the Recovery Act defines a "breach" as an "unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of the protected health information." The Recovery Act requires covered entities, including health plans such as Medicare, to notify individuals whose unsecured protected health information

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has been or is reasonably believed to have been accessed, acquired, or disclosed as a result of a breach. Breaches of protected health information increase Medicare beneficiaries' and providers' vulnerability to medical identity theft. We will review CMS's breach policies, determine the number of known breaches and instances of medical identity theft involving beneficiary and provider Medicare identification numbers, and assess the actions that CMS has taken in response to them.

*(OEI; 02-10-00040; expected issue date: FY 2011; work in progress; Recovery Act)*

### **Medicare and Medicaid Health Information Data Privacy**

We will review Medicare and Medicaid program providers' implementation of the Privacy Rule standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The standards address use and disclosure of individuals' Protected Health Information (PHI) by covered entities, which include Medicare and Medicaid providers. The Health Information Technology for Economic and Clinical Health Act (HITECH), part of the Recovery Act, strengthened and expanded Privacy Rule protections. The Office for Civil Rights (OCR) is responsible for overseeing compliance with and enforcement of the Privacy Rule. Sections 13409 and 13410 of the Recovery Act established increased civil penalties for noncompliance, as well as new enforcement responsibilities for OCR. We will also review the adequacy of OCR's oversight of the HIPAA Privacy Rule.

*(OEI; 09-10-00510; expected issue date: FY 2012; work in progress; Recovery Act)*

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## **Recovery Act Reviews: Public Health Programs**

### **Centers for Disease Control and Prevention**

#### **Recipient Compliance With Cooperative Agreement Requirements**

We will review compliance with the Recovery Act and applicable Federal regulations by recipients of the Centers for Disease Control and Prevention's (CDC) cooperative agreements. The Recovery Act provides \$1 billion, primarily through cooperative agreements, for prevention and wellness strategies. The 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 in the Recovery Act and applicable Federal regulations.

*(OAS; W-11-09-27102; expected issue date: FY 2011; new start, Recovery Act)*

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## Health Resources and Services Administration

### HRSA Health Information Technology Grants

We will review health center controlled networks' (HCCN) progress in implementing EHR and other health IT initiatives funded through Health Resources and Services Administration (HRSA) grants. During 2007 and 2008, HRSA awarded 74 grants totaling \$50 million to HCCNs and large multisite health centers to implement EHRs and other health IT innovations to improve the safety and quality of health care delivery and eliminate waste and duplication of care. The Recovery Act provided HRSA another \$120 million for HCCNs to support EHR and health IT implementation and EHR quality improvement. HRSA's Bureau of Primary Health Care (BPHC) is charged with promoting the adoption and effective use of health IT through grants and technical assistance. We will examine BPHC's efforts to promote and oversee grantees' implementation of EHRs and other health IT innovations.

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

### Limited-Scope Audits of Grantees' Capacities

We will determine whether 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 \$156 million in Recovery Act funds for new service delivery sites are new grantees. In light of the Office of Inspector General's (OIG) oversight role in preventing fraud, waste, and abuse and given the increased number of grants and the expanded revenue base of grantees, we will also conduct limited-scope audits of grants for Increased Demand for Services (\$342 million), the Capital Improvement Program (\$853 million), and the Facility Investment Program (\$520 million). The objective of the audits will be to assess grantees' capacities to manage and account for Federal funds and to operate community health service delivery sites in accordance with Federal regulations.

*(OAS; W-00-10-27105; W-00-11-27105; various reviews; expected issue date: FY 2011; work in progress and new start, Recovery Act)*

### Recovery Act Funding for Community Health Centers Infrastructure Development

We will review community health centers and other facilities in two States to determine whether Recovery Act funds were spent in accordance with Federal regulations. The Recovery Act provided \$2 billion to be invested in community health centers. Of that amount, \$1.5 billion funds infrastructure development for community health centers, which includes acquisition of equipment, construction, and renovation. Another \$500 million has been provided to fund operations of health centers. Community health centers are locally directed and operated providers of preventive and primary care. Ten community health centers in Florida were awarded about \$30 million in Recovery Act funding. In Alabama, one community health center received about \$15 million, half of the entire State's allotment. Based on the results, audits may be performed in other States.

*(OAS; W-00-11-27105; expected issue date: FY 2011; new start; Recovery Act)*

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## **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 \$120 million in Recovery Act funding available for health IT systems and network grants to support EHR for health centers. The review will focus on the controls in place to safeguard health IT 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-00-11-27109; various reviews; expected issue date: FY 2011; 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 health IT grants to ensure that adequate health IT security controls are in place to protect sensitive EHR and personal information. HRSA will expend \$120 million of \$1.5 billion in Recovery Act funding for health IT systems and network grants to support EHR for community health centers. Almost 300 community health centers are expected to benefit from the funding.

*(OAS; W-00-11-27109; various reviews; expected issue date: FY 2011; 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-00-11-27103; 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



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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 equipment monitoring. 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 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 health IT environment and to improve service to its constituents. Activities to be funded with the 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) health IT infrastructure security improvements to ensure safety of health data, as well as network upgrades to provide enhanced health services to IHS constituents.

*(OAS; W-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)*

## **National Institutes of Health**

### **Implementation of Internal Controls for Grantee Reporting**

We will review the National Institutes of Health's (NIH) 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-00-11-27101; expected issue date: FY 2011; 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 in Recovery Act funds for renovations, repairs, and improvements, or construction of core research facilities. The shared instrumentation spending plan proposes \$300 million in

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Recovery Act funds to purchase 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; W-00-11-27101 expected issue date: FY 2011; work in progress and 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 we will determine the reasonableness and allowability of proposed costs; we will also evaluate bid estimation procedures. The Recovery Act provides \$500 million for 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-00-11-27101; expected issue date: FY 2011; 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 for 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 future construction projects.

*(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 found problems in this area. 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 the costs may be appropriate when the nature of the work performed under a specific project requires extensive administrative or clerical support.

*(OAS; W-00-09-27101; expected issue date: FY 2012; new start, Recovery Act)*

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## **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 controls are in place. We will assess whether NIH has processes in place or in 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 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, government 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-00-11-27109; various reviews; expected issue date: FY 2011; 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 in OMB guidance. The recipients and uses of Recovery Act funds must be transparent to the public, and the public benefits of the funds must be reported clearly, accurately, and in a timely manner. We will review recipients' reports for compliance with the reporting requirements, including accuracy and completeness. *(OAS; W-00-11-27101; W-00-11-27103; W-00-11-27105; various reviews; expected issue date: FY 2011; 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 pursuant 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 security controls.

*(OAS; W-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)*

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# Recovery Act Reviews: Human Services Programs

## Administration for Children and Families

### Community Service Block Grants

We will review Administration for Children & Families' (ACF) controls over the grant award and oversight process for Community Services Block Grant (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 found many internal control weaknesses in ACF's oversight of the States' use of CSBG funds. As part of our oversight role under the Recovery Act, we will conduct a followup 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-00-11-27100; expected issue date: FY 2011; 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 Improving Head Start for School Readiness Act of 2007 (Head Start Act). Head Start performance standards in the Code of Federal Regulations (CFR) 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 in the regulation 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-00-10-27100; W-00-11-27100; various reviews; expected issue date: FY 2011; work in progress and 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, 92.24, and 1301.20 establish which costs

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a grantee may consider to satisfy the required match. We will identify any challenges facing grantees in meeting the matching requirement.

*(OAS; W-00-11-27100; 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 the funds are used for authorized purposes as required by 45 CFR §§ 74.21(b)(3) and 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-00-11-27100; 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 45 CFR §§ 74.21(b)(3) and 92.20(b)(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-00-10-27100; W-00-11-27100; expected issue date: FY 2011; work in progress and 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 the funds are used for authorized purposes as required by 45 CFR §§ 74.21(b)(3) and 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-00-11-27100; 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 grant

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programs and process grant applications from receipt through award. ACF received \$10 billion for grants supporting Head Start, Early Head Start, Temporary Assistance for Needy Families (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-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)*

### **Administration for Children & Families Health Information Technology Grants**

We will review general IT security controls for systems funded by ACF health IT grants to determine whether adequate security controls are in place to protect sensitive EHR and personal information. ACF will award health IT grants to State agencies, local governments, nonprofit organizations, and school systems administering Head Start, Early Head Start, TANF, Child Care and Community Development Block Grant (CCDBG) and CSBG programs. We will also assess whether ACF grantees receiving health IT 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-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)*

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## **Recovery Act Reviews: Departmentwide Issues**

### **Cross-Cutting Investigative Activities**

#### **Integrity of Recovery Act Expenditures**

We will review and evaluate credible allegations of improper expenditures of Recovery Act funds to identify cases in which criminal investigations will be opened and enforcement actions pursued. Recovery Act funding will result in a significant increase in the number of grants and contracts awarded by HHS. Accordingly, we expect 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 of reprisals 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

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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)*

### **Pre-award Screening of Potential Grant Recipients**

We will develop a process by which HHS granting agencies will be able to quickly consult with OIG to determine whether there are any OIG or other criminal investigations in progress before making awards. This will reinforce HHS's efforts to ensure integrity in the awarding of Recovery Act funds.

*(OI; expected implementation date: FY 2009; work in progress; Recovery Act)*

## **Information Systems Reviews**

### **Health Information Technology Standards**

We will review the process used by ONC to develop and recommend health IT standards to the HHS Secretary. Section 3003 of the PHS Act, as added by section 13101 of the Recovery Act, established the health IT 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 the 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-00-11-27109; various reviews; expected issue date: FY 2011; work in progress; Recovery Act)*

### **Departmentwide Network Improvements**

We will review the acquisition of staff, hardware, and software intended to improve IT security at HHS and, when 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-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)*

### **Security Controls for Grants Web Site**

We will review general and application IT security controls for the [Grants.gov](http://Grants.gov) Web site to ensure that adequate 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

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applications filed using Grants.gov have risen to an unprecedented level, reaching almost 11,500 per week, about three times the weekly average number of submissions during FY 2008. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2011; new start; Recovery Act)



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# **Work Plan Appendix B: Acronyms and Abbreviations**

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## Terms and Titles

The Work Plan refers to the following selected acronyms and abbreviations for terms and titles. Organization and Public Law acronyms and abbreviations are listed in separate sections that follow this table.

340B	section 340B drug pricing program
ADAP	AIDS Drug Assistance Program
AI/AN	American Indians and Alaska Natives
AIDS	acquired immunodeficiency syndrome
ALF	assisted living facility
ALJ	administrative law judge
AMD	age-related macular degeneration
AMP	average manufacturer price
ASC	ambulatory surgical center
ASP	average sales price
AWP	average wholesale price
BERM	Bioterrorism Epidemic Outbreak Response Model
CAH	critical access hospital
CAS	cost accounting standards
CATT	Comparison of age-related macular degeneration treatments trials
CCDBG	Child Care and Development Block Grant
CCDF	Child Care and Development Fund
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
CNC	currently not collectible
CoP	Conditions of Participation
CORF	Comprehensive Outpatient Rehabilitation Facility
CPE	certified public expenditures
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
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies

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DRG	diagnosis-related group
DSH	disproportionate share hospital
DSMB	Data and Safety Monitoring Board
DSMT	diabetes self-management training
EAC	estimated acquisition cost
ED	erectile dysfunction
E&M	evaluation and management (services)
EHR	electronic health records
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
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
HAC	hospital-acquired condition
HCBS	home- and community-based services
HCCN	health center controlled networks
HCPCS	Healthcare Common Procedure Coding System
HHA	home health agency
HHRG	home health resource group
HHSAR	HHS Acquisition Regulation (CFR, Title 48)
HIT	health information technology
HIV	human immunodeficiency virus
HMO	health maintenance organization
HPMP	Hospital Payment Monitoring Program
IDTF	independent diagnostic testing facility
IGRT	image-guided radiation therapy
IMD	institution for mental diseases
IME	indirect medical education
IMPAC	Information for Management, Planning, Analysis, and Coordination (system)
IMRT	intensity modulated radiation therapy
IND	investigational new drug
IPPS	inpatient prospective payment system
IRF	inpatient rehabilitation facility
IRIS	Intern and Resident Information System
IT	information technology
LCD	local coverage determination
LIHEAP	Low-Income Home Energy Assistance Program
LTCH	long term care hospital
MA	Medicare Advantage

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MAC	Medicare Administrative Contractor
MAO	Medicare Advantage organization
MA-PD	Medicare Advantage prescription drug organization
MCE	Medicaid managed care entities
MCO	managed care organization
MDS	Minimum Data Set
MEDIC	Medicare drug integrity contractor
MIC	Medicaid Integrity Contractors
MIP	Medicaid Integrity Program
MMIS	Medicaid Management Information System
MPFS	Medicare physician fee schedule
MSN	Medicare Summary Notice
MSP	Medicare Secondary Payer
MSPRC	Medicare Secondary Payer Recovery Contractor
NCD	national coverage determination
NPI	national provider identifier
NSC	National Supplier Clearinghouse
OASIS	Outcome and Assessment Information Set
OPPS	outpatient prospective payment system
PARIS	Public Assistance Reporting Information System
PBM	pharmacy benefit manager
P&T	pharmacy and therapeutics (committee)
PCA	progressive correction action
PCIP	Pre-Existing Condition Insurance Plan
PCS	personal care services
PDE	prescription drug event
PDP	prescription drug plan
PECOS	Provider Enrollment Chain and Ownership System
PEPFAR	President's Emergency Plan for AIDS Relief
PERM	Payment Error Rate Measurement (program)
PHEP	Public Health Emergency Preparedness (program)
PHI	protected health information
PHP	partial hospitalization program
PII	personally identifiable information
POA	present on admission
PPS	prospective payment system
PSC	Program Safeguard Contractor
QASP	Quality Assurance Surveillance Plan
QI	Qualifying Individual program
QIO	Quality Improvement Organization
RAC	Recovery Audit Contractor
RAI	Resident Assessment Instrument
RN	radiological and nuclear
RUG	resource utilization group
Rx-HCC	prescription drug model used for payment under Part D
SACWIS	Statewide Automated Child Welfare Information System

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SAPTBG	SAMHSA-Funded Prevention and Treatment Block Grants
S&C	survey and certification
SAS	Statement on Auditing Standards
SLEP	Shelf-Life Extension Program
SNF	skilled nursing facility
SNP	special needs plan
SNS	Strategic Nuclear Stockpile
SOW	Statement of Work
SSN	Social Security number
TANF	Temporary Assistance for Needy Families (program)
TrOOP	true out-of-pocket costs for Part D
UPIN	unique physician identifier number
URA	unit rebate amount
UPIN	Unique Physician Identifier Number
UPL	upper payment limit
U.S.C.	United States Code
VFC	Vaccines for Children (grants)
WAC	wholesale acquisition cost
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 & Families
AHRQ	Agency for Healthcare Research and Quality
AoA	Administration on Aging
ASA	Office of the Assistant Secretary for Administration
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASFR	Office of the Assistant Secretary for Financial Resources and Technology
BLS	Bureau of Labor Statistics
BPHC	Bureau of Primary Health Care
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
DHS	Department of Homeland Security
DOD	Department of Defense
DOJ	Department of Justice
DOS	Department of State
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration

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GAO	Government Accountability Office
GSA	General Services Administration
HHS	Department of Health & Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IRS	Internal Revenue Service
MFCU	State Medicaid Fraud Control Units
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
OCIO	Office of Consumer Information and Insurance Oversight
OHIT	Office of Health Information Technology
OCR	Office for Civil Rights
OCSE	Office of Child Support Enforcement
OEI	Office of Evaluation and Inspections
OGE	Office of Government Ethics
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
ONDCP	Office of National Drug Control Policy
PSC	Program Support Center
SAMHSA	Substance Abuse and Mental Health Services Administration
USDA	Department of Agriculture
VA	Department of Veterans Affairs

## Public Laws

The Work Plan refers to the following acronyms and abbreviations for Public Laws (P.L.).

Affordable Care Act	Patient Protection and Affordable Care Act of 2010, P.L. No. 111-148
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. 11-3

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DRA	Deficit Reduction Act of 2005, P.L. No. 109-171
EMTALA	Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272
FCA	False Claims Act, updated in August 2010 as an incorporating passage of P.L. No. 111-203
FCCA	Federal Claims Collection Act of 1966, P. L. No. 89-508
FDAAA	Food and Drug Administration Amendments Act of 2007, P.L. No. 110-85
FDAMA	Food and Drug Administration Modernization Act of 1997, P.L. No. 105-115
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
GPRA	Government Performance and Results Act of 1993, P.L. No. 103-62
Head Start Act	Improving Head Start for School Readiness Act of 2007, P.L. No. 110-134
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191
HITECH	Health Information Technology for Economic and Clinical Health Act, enacted as part of the Recovery Act
IDEA	Individuals with Disabilities Education Act of 2004, P.L. No. 108-446
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
OCAA	Omnibus Consolidated Appropriations Act of 1997, P.L. 104-368
PHS Act	Public Health Service Act of 1944
QI	Qualifying Individual Program Supplemental Funding Act of 2008, P.L. No. 110-380
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. 109-432

## Laws Cited Without Abbreviation

- Alaska Native and American Indian Direct Reimbursement Act of 2000, P.L. No. 106-417
- Breast and Cervical Cancer Mortality Prevention Act of 1990, P.L. No. 101-354
- Child Care and Development Block Grant Act of 1990, P.L. No. 101-508
- Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, P.L. No. 110-329
- False Claims Amendments Act of 1986, P.L. No. 99-562
- Food and Drug Administration Amendments Act of 1968, P.L. No. 110-85
- Fraud Enforcement and Recovery Act of 2009, P.L. No. 111-21
- Health Care and Education Reconciliation Act of 2010, P.L. No. 111-52
- Indian Child Protection and Family Violence Prevention Act, P.L. No. 101-630
- Intergovernmental Cooperation Act of 1968, P.L. No. 90-577
- Pandemic and All-Hazards Preparedness Act of 2006, P.L. No. 109-417
- Refugee Act of 1980, P.L. No. 96-212
- Social Security Act of 1935, P.L. No. 74-271
- Veterans Health Care Act of 1992, P.L. No. 102-585