Office of Inspector General

Work Plan

FISCAL YEAR 2013

U.S. Department of Health & Human Services

Office of Inspector General

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Introductory Message From the Office of Inspector General

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) *Work Plan for Fiscal Year 2013* (*Work Plan*) summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the next fiscal year (FY) and beyond.

The *Work Plan* is one of OIG's three core publications. The *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

What is our responsibility?

Our organization was created to protect the integrity of HHS programs and operations and the well-being of beneficiaries by detecting and preventing fraud, waste, 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. Our mission encompasses the more than 300 programs administered by HHS at agencies such as the Centers for Medicare & Medicaid Services (CMS), National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Administration for Children and Families (ACF).

The majority of our resources are directed toward safeguarding the integrity of the Medicare and Medicaid programs and the health and welfare of their beneficiaries. Consistent with our responsibility to oversee all HHS programs, we also focus considerable effort on HHS's other programs and management processes, including key issues such as food and drug safety, child support enforcement, conflict-of-interest and financial disclosure policies governing HHS staff, and the integrity of contracts and grants management processes and transactions. Our core organizational values are:

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

How and where do we operate?

Our staff of more than 1,700 professionals are deployed throughout the Nation in regional and field offices and in the Washington, DC, headquarters. We conduct audits, evaluations, and investigations; provide guidance to industry; and, when appropriate, impose civil monetary penalties, assessments, and administrative sanctions. We collaborate with HHS and its operating and staff divisions, the Department of Justice (DOJ) and other executive branch agencies, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds. The following are descriptions of our mission-based components.

- 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 programs and operations. These assessments help 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 CMPs.

- 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 (IO) of the Inspector General and the Office of Management and Policy (OMP).

How do we plan our work?

Work planning is a 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 proposals for the *Work Plan*, we consider a number of factors, including:

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

What do we accomplish?

For FY 2011, we reported expected recoveries of about $5.2 billion consisting of $627.8 million in audit receivables and $4.6 billion in investigative receivables (which includes $952 million in non-HHS investigative receivables resulting from our work in areas such as the States' share of Medicaid restitution). We also identified about $19.8 billion in savings estimated for FY 2011 as a result of legislative, regulatory, or administrative actions that were supported by our recommendations. Such savings generally reflect third-party estimates (such as those by the Congressional Budget Office (CBO)) of funds made available for better use through reductions in Federal spending.

We reported FY 2011 exclusions of 2,662 individuals and entities from participation in Federal health care programs; 723 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 382 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalty settlements, and administrative recoveries related to provider self-disclosure matters.

What can you learn from our Work Plan?

The OIG *Work Plan* outlines our current focus areas and states the primary objectives of each project. The word "New" after a project title indicates the project did not appear in the previous *Work Plan*. At the end of each project description, we provide the internal identification code for the review (if a number has been assigned), the year in which we expect one or more reports to be issued as a result of the review, and whether the work was in progress at the start of the fiscal year or is planned as a new start. Typically, a review designated as "work in progress" will result in reports issued in FY 2013, but a review designated as "new start," meaning it is slated to begin in FY 2013, could result in an FY 2013 or

FY 2014 report, depending upon the time when the assignments are initiated during the year and the complexity and scope of the examinations.

The body of the *Work Plan* is presented in seven major parts followed by Appendix A, which describes our reviews related to the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), and Appendix B, which describes our oversight of the funding that HHS received under the American Recovery and Reinvestment Act of 2009 (Recovery Act).

Because we make continuous adjustments to the Work Plan as appropriate, we do not provide status reports on the progress of the reviews. However, if you have other questions about this publication, please contact our Office of External Affairs at (202) 619-1343.

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FY 2013 Work Plan
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Part I
Medicare Part A and Part B

Part II
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Part I
Medicare Part A and Part B

Medicare Part A helps cover certain inpatient services in hospitals and skilled nursing facilities (SNF) and some home health services. Medicare Part B helps cover designated practitioners' services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover. Historically, the Centers for Medicare & Medicaid Services (CMS) has contracted with fiscal intermediaries (FI) and carriers to conduct Medicare's claims administration functions. Pursuant to Medicare's contracting reform initiative, FIs and carriers are being replaced by Medicare Administrative Contractors (MAC).

- Fiscal intermediaries have processed claims for Part A and Part B submitted by or on behalf of certain facility-based providers, including hospitals and skilled nursing facilities.

- Carriers have processed claims for Part B submitted by designated practitioners and other suppliers, such as physicians, laboratories, and retail pharmacies. The Centers for Medicare & Medicaid Services (CMS) also engages contractors that perform specific fee-for-service (FFS) business functions.

- MACs process both Part A and Part B claims. CMS is implementing the Medicare contracting reform initiative. The reform plan includes specialty MACs that service suppliers of durable medical equipment. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 911).

Descriptions of the Office of Inspector General's (OIG) work in progress and planned reviews of Medicare Part A and Part B payments and services for fiscal year (FY) 2013 follow.

Hospitals

Acronyms and Abbreviations for Selected Terms Used in This Section:

CAH—critical access hospital
CoP—conditions of participation (in Medicare)
DGME—direct graduate medical education (costs)
DRG—diagnosis related group
MAC—Medicare Administrative Contractor
MedPAC—Medicare Payment Advisory Commission
IPPS—inpatient prospective payment system
PPS—prospective payment system

Hospitals—Inpatient Billing for Medicare Beneficiaries (New)

We will describe how hospital billing for inpatient stays changed from FY 2008 to FY 2012. We will also describe how billing for inpatient stays in FY 2012 varied among different types of hospitals and how hospitals ensure compliance with Medicare requirements for inpatient billing. In 2010, Medicare paid hospitals $100 billion for inpatient stays. Most hospitals are paid under the inpatient prospective

payment system (IPPS), which CMS changed substantially in FY 2008. Under the IPPS, each inpatient stay is classified into one of 747 Medicare severity diagnosis related groups (MS-DRG) based on the beneficiary's diagnoses and the procedures the hospital performed, as well as other factors. Medicare pays hospitals a different amount for each MS-DRG. *(OEI; 02-10-00100; expected issue date: FY 2013; work in progress)*

Hospitals—Diagnosis Related Group Window (New)

We will analyze claims data to determine how much CMS could save if it bundled outpatient services delivered up to 14 days prior to an inpatient hospital admission into the diagnosis related group (DRG) payment. Medicare currently bundles all outpatient services delivered 3 days prior to an inpatient hospital admission. (Social Security Act, § 1886(a)(4).) Medicare does not pay separately for such preadmission services when they are delivered in a setting owned or operated by the admitting hospital. This policy is commonly known as the "DRG window." Prior OIG work identified improper payments in the DRG window. OIG work has also concluded that CMS could realize significant savings if the DRG window was expanded from 3 days to 14 days. *(OEI; 05-12-00480; expected issue date: FY 2013; work in progress)*

Hospitals—Same-Day Readmissions

We will review Medicare claims to determine trends in the number of same-day hospital readmission cases. On the basis of prior OIG work, CMS implemented an edit (a special system control) in 2004 to reject subsequent claims on behalf of beneficiaries who were readmitted to the same hospital on the same day. 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 DRG payment and should combine the original and subsequent stays into a single claim. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, § 40.2.5.) Providers are permitted to override the edit in certain situations. We will test the effectiveness of the edit. This work may also be helpful to CMS in implementing provisions of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). *(OAS; W-00-13-35439; various reviews; expected issue date: FY 2013;* new start; *Affordable Care Act.)*

Hospitals—Non-Hospital-Owned Physician Practices Using Provider-Based Status (New)

We will determine the impact of non-hospital-owned physician practices billing Medicare as provider-based physician practices. We will also determine the extent to which practices using the provider-based status met CMS billing requirements. Provider-based status allows a subordinate facility to bill as part of the main provider. Provider-based status can result in additional Medicare payments for services furnished at provider-based facilities and may also increase beneficiaries' coinsurance liabilities. In 2011, the Medicare Payment Advisory Commission (MedPAC) expressed concerns about the financial incentives presented by provider-based status and stated that Medicare should seek to pay similar amounts for similar services. *(OEI; 04-12-00380; 04-12-00381; expected issue date: FY 2013; work in progress)*

Hospitals—Compliance With Medicare's Transfer Policy (New)

We will review Medicare payments made to hospitals for beneficiary discharges that should have been coded as transfers. We will determine whether such claims were appropriately processed and paid. We will also review the effectiveness of the MAC's claims processing edits used to identify claims subject to the transfer policy. Pursuant to Federal regulations, a hospital discharging a beneficiary is paid the full DRG amount. (42 CFR § 412.4 (e).) In contrast, a hospital that transfers a beneficiary to another facility is paid a graduated per diem rate, not to exceed the full DRG payment that would have been made if the beneficiary had been discharged without being transferred. (42 CFR§ 412.4(f).) *(OAS; W-00-12-35102; various reviews; expected issue date: FY 2013; work in progress)*

Hospitals—Payments for Discharges to Swing Beds in Other Hospitals (New)

We will review Medicare payments made to hospitals for beneficiary discharges that were coded as discharges to a swing bed in another hospital. Swing beds are inpatient beds that can be used interchangeably for either acute care or skilled nursing services. Pursuant to Federal regulations, a hospital discharging a beneficiary is paid the full DRG amount. (42 CFR § 412.4 (e).) In contrast, Medicare pays hospitals a reduced payment for shorter lengths of stay when beneficiaries are transferred to another prospective payment system (PPS) hospital (42 CFR § 412.4(f).) This is based on the assumption that acute care hospitals should not receive full DRG payments for beneficiaries discharged "early" and then admitted to additional care in other clinical settings. However, Medicare does not pay the reduced graduated per diem rate if that patient was discharged to a swing bed in another hospital. If appropriate, we will recommend that CMS evaluate its policy related to payment for hospital discharges to swing beds in other hospitals. *(OAS; W-00-13-35700; various reviews; expected issue date: FY 2013; new start)*

Hospitals—Acute-Care Inpatient Transfers to Inpatient Hospice Care

We will determine the extent to which acute care hospitals discharge beneficiaries after a short stay to hospice facilities. Analysis of Medicare claims data demonstrates significant occurrences of a discharge from an acute care hospital after a short stay that is immediately followed by hospice care. Medicare pays a full PPS rate to hospitals that discharge beneficiaries for hospice care (42 CFR § 412.4(e). In contrast, Medicare pays hospitals a reduced payment for shorter lengths of stay when beneficiaries are transferred to another PPS hospital or, for certain DRGs, to postacute care settings, such as a skilled nursing facility. (42 CFR § 412.4(f).) This is based on the assumption that acute care hospitals should not receive full DRG payments for beneficiaries discharged "early" and then admitted for additional care in other clinical settings. If appropriate, we will recommend that CMS evaluate its policy related to payment for hospital discharges to hospice facilities. *(OAS; W-00-12-35602; various reviews; expected issue date: FY 2013; work in progress)*

Hospitals—Payments for Canceled Surgical Procedures (New)

We will determine costs incurred by Medicare related to inpatient hospital claims for canceled surgical procedures. Our preliminary analysis of Medicare claims data for inpatient stays demonstrated significant occurrences of an initial PPS payment to hospitals for a canceled surgical procedure followed

by a second, higher PPS payment to the same hospitals for the rescheduled surgical procedure. For these claims, the canceled surgical procedure was the principal reason for the initial hospital admission. For these short-stay claims, few, if any, inpatient services (i.e., laboratory or diagnostic tests) were provided by the hospitals because the surgical procedure was canceled. Medicare makes two payments to hospitals that generate two bills unless the patient is readmitted to the hospital on the same day, in which case a single payment is made. Our analysis also identified inpatient claims with canceled surgical procedures for stays of less than 2 days that were not followed by subsequent inpatient admissions to the same hospitals for the rescheduled surgical procedures. Current Medicare policy does not preclude payment for these claims. *(OAS; W-00-13-35626; various reviews; expected issue date: FY 2013; new start)*

Hospitals—Payments for Mechanical Ventilation (New)

We will review Medicare payments for mechanical ventilation to determine whether the DRG assignments and resultant payments were appropriate. We will review selected Medicare payments to determine whether patients received fewer than 96 hours of mechanical ventilation. Mechanical ventilation is the use of a ventilator or respirator to take over active breathing for a patient. CMS requires that claims be completed accurately to be processed correctly and promptly. (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, § 80.3.2.2.) For certain DRG payments to qualify for Medicare coverage, a patient must receive 96 or more hours of mechanical ventilation. *(OAS; W-00-12-35575; various reviews; expected issue date: FY 2013; work in progress)*

Hospitals—Admissions With Conditions Coded Present on Admission

We will review Medicare claims to determine whether specific acute care hospitals are frequently transferring patients with certain diagnoses that were coded as being present when patients were admitted (referred to as "present on admission" (POA)) to another acute care hospital. Medicare requires acute care hospitals to report on their claims which diagnoses were present when patients were admitted. (Social Security Act, § 1886(d)(4)(D), and CMS's *Change Request 5679*, Pub. 100-20, One-Time Notification, Transmittal 289.) *(OAS; W-00-12-35500; various reviews; expected issue date: FY 2013; work in progress)*

Hospitals—Inpatient and Outpatient Payments to Acute Care Hospitals

We will review Medicare payments to hospitals to determine compliance with selected billing requirements. We will use the results of these reviews to recommend recovery of overpayments and identify providers that routinely submit improper claims. Prior OIG audits, investigations, and inspections have identified areas at risk for noncompliance with Medicare billing requirements. Using computer matching and data mining techniques, we will select hospitals for focused reviews of claims that may be at risk for overpayments. Using the same techniques, we will identify hospitals that broadly rank as least risky across compliance areas and those that broadly rank as most risky. We will then review the hospitals' policies and procedures to compare the compliance practices of these two groups of hospitals. We will also survey or interview hospitals' leadership and compliance officers to provide

contextual information related to hospitals' compliance programs. *(OAS; W-00-11-35538; W-00-12-35538; various reviews; expected issue date: FY 2013; work in progress)*

Hospitals—Inpatient Outlier Payments: Trends and Hospital Characteristics

We will review hospital inpatient outlier payments, examine trends of outlier payments nationally, and identify characteristics of hospitals with high or increasing rates of outlier payments. Medicare typically reimburses hospitals for inpatient services based on a predetermined per-discharge amount, regardless of the actual costs incurred. Medicare pays hospitals supplemental payments, called outlier payments, for patients incurring extraordinarily high costs. (Social Security Act, § 1886(d)(5)(A)(ii).) 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. *(OEI; 06-10-00520; expected issue date: FY 2013; work in progress)*

Hospitals—Reconciliations of Outlier Payments

We will review Medicare outlier payments to determine whether CMS performed the necessary reconciliations in a timely manner so that Medicare contractors could perform final settlement of the associated cost reports submitted by providers. We will also examine whether MACs referred all providers that meet the criteria for reconciliations to CMS. Outliers are additional payments made for beneficiaries who incur unusually high costs. Outlier payment reconciliations must be based on the most recent cost-to-charge ratio from the cost report to properly determine outlier payments. (42 CFR § 412.84(i)(4).) Outlier payments also may be adjusted to reflect the time value of money for overpayments and underpayments. *(OAS; W-00-11-35451; W-00-12-35451; W-00-13-35451; various reviews; expected issue date: FY 2013; work in progress and new start)*

Hospitals—Quality Improvement Organizations' Work With Hospitals (New)

We will determine the extent to which Quality Improvement Organizations (QIO) worked with hospitals either to conduct quality improvement projects or to provide technical assistance. We will also assess the barriers QIOs experience when engaging hospitals. CMS is required to enter into contracts with QIOs, formerly called utilization and quality control peer review organizations. (Social Security Act § 1862 (g).) The purpose of the QIOs is to improve the efficiency, effectiveness, economy, and quality of services delivered to Medicare beneficiaries. Medicare spends about $1.1 billion for each 3-year QIO contract period, and each contract calls for QIOs to provide technical assistance to providers and specifies clinical areas for the quality improvement projects. *(OEI; 01-12-00650; expected issue date: FY 2014; work in progress)*

Hospitals—Duplicate Graduate Medical Education Payments

We will review provider data from CMS's Intern and Resident Information System (IRIS) to determine whether duplicate or excessive graduate medical education (GME) payments have been claimed. We will also assess the effectiveness of IRIS in preventing providers from receiving payments for duplicate GME costs. Medicare pays teaching hospitals for direct graduate medical education

(DGME) and indirect medical education (IME) costs. In the calculation of payments for DGME and IME costs, no intern or resident may be counted by Medicare as more than one full-time-equivalent (FTE) employee. (42 CFR §§ 413.78(b) and 412.105(f)(1)(iii).) The primary purpose of IRIS 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. *(OAS; W-00-13-35432; various reviews; expected issue date: FY 2013; new start)*

Hospitals—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 and the effect on Medicare of inaccurate reporting of occupational-mix data. Hospitals must accurately report data every 3 years on the occupational mix of their employees. (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 PPS for hospitals. *(OAS; W-00-13-35452; various reviews; expected issue date: FY 2013; new start)*

Hospitals—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. Medicare does not cover items or services for which neither the beneficiary nor anyone on his or her behalf has an obligation to pay. (Social Security Act, §1862(a)(2).) 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. Medicare requires hospitals 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-00-13-35516; various reviews; expected issue date: FY 2013; new start)*

Hospitals—Outpatient Dental Claims

We will review Medicare hospital outpatient payments for dental services to determine whether such payments were made in accordance with Medicare requirements. Dental services are generally excluded from Medicare coverage, with a few exceptions. (Social Security Act, § 1862(a)(12).) For example, Medicare reimbursement is allowed for the extraction of teeth to prepare the jaw for radiation treatment (CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 150). As indicated by current OIG audits, providers received Medicare reimbursement for noncovered dental services, which resulted in significant overpayments. *(OAS; W-00-13-35603; various reviews; expected issue date: FY 2013; new start)*

Hospitals—Outpatient Observation Services During Outpatient Visits

We will describe the use of observation services from 2008 to 2011 and the characteristics of beneficiaries receiving observation services in 2011. We will also determine how much Medicare and

beneficiaries paid for observation and related services in 2011 and the extent to which hospitals inform beneficiaries about observation services. Part B coverage of hospital outpatient services and reimbursement for such services under the hospital outpatient PPS are provided by the Social Security Act, §§ 1832(a) and 1833(t).) Observation services are short-term treatments and assessments that hospitals use to determine whether a beneficiary should be admitted as an inpatient or discharged. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 4, § 290.) Improper use of observation services may subject beneficiaries to high cost sharing. *(OEI; 02-12-00040; expected issue date: FY 2013; work in progress)*

Hospitals—Acquisitions of Ambulatory Surgical Centers: Impact on Medicare Spending (New)

We will determine the extent to which hospitals acquire ASCs and convert them to hospital outpatient departments. We will also determine the effect of such acquisitions on Medicare payments and beneficiary cost sharing. Medicare reimburses outpatient surgical services performed in hospital outpatient departments at a higher rate than similar services performed in ASCs. Hospitals may be acquiring ASCs and providing outpatient surgical services in that setting. *(OEI; 06-12-00590; expected issue date: FY 2014; work in progress)*

Critical Access Hospitals— Variations in Size, Services, and Distance From Other Hospitals

We will review CAHs to profile variations in size, services, and distance from other hospitals. We will also examine the numbers and types of patients that critical access hospitals (CAH) treat. To be designated as CAHs, hospitals must meet several criteria, such as being located in a rural area, furnishing 24-hour emergency care, providing no more than 25 inpatient beds; and having an average annual length of stay of 96 hours or less. (Social Security Act, § 1820(c)(2)(B).) CAHs are a separate provider type with their own Medicare CoP and payment method. There are approximately 1,350 CAHs, but information about their structure and services is limited. *(OEI; 05-12-00080; expected issue date: FY 2013; work in progress)*

Critical Access Hospitals—Payments for Swing-Bed Services (New)

We will compare reimbursement for swing-bed services at CAHs to the same level of care obtained at traditional skilled nursing facilities (SNF) to determine whether Medicare could achieve cost savings through a more cost effective payment methodology. Swing beds are inpatient beds that can be used interchangeably for either acute care or skilled nursing services. The Balanced Budget Act of 1997 (BBA) created the CAH Program to ensure access to health care services in rural areas. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed CAHs to receive Medicare reimbursement equal to 101 percent of reasonable cost and have up to 25 inpatient beds that could be used for acute care or swing-bed services, with CMS approval. (Social Security Act, § 1814(l).) Neither the BBA nor the MMA established any length-of-stay limits for swing-bed utilization. Unlike CAHs, traditional SNFs are reimbursed under a PPS through case-mix, adjusted per-diem prospective payment rates for all SNFs. The payment rates represent payment in full for all costs associated with

furnishing covered SNF services to Medicare beneficiaries. *(OAS; W-00-12-35101; various reviews; expected issue date: FY 2013; work in progress)*

Inpatient Rehabilitation Facilities—Transmission of Patient Assessment Instruments

We will determine whether IRFs 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 provide that they be reduced if patient assessments are not encoded and transmitted within defined time limits. (42 CFR § 412.614(d)(2).) 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-00-11-35522; various reviews; expected issue date: FY 2013; work in progress)*

Inpatient Rehabilitation Facilities—Appropriateness of Admissions and Level of Therapy

We will examine the appropriateness of admissions to IRFs. We will also examine the level of therapy provided in IRFs and how much concurrent and group therapy IRFs provide. IRFs provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and a multidisciplinary, coordinated team approach to improve patients' ability to function. Patients must undergo preadmission screening and evaluation to ensure that they are appropriate candidates for IRF care. (42 CFR §§ 412.622(a)(3)-(5).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Long -Term-Care Hospitals—Payments for Interrupted Stays (New)

We will determine the extent to which Medicare made improper payments for interrupted stays in long-term -care hospitals (LTCH) in 2011. We will also identify readmission patterns and determine the extent to which LTCHs readmit patients directly following the interrupted stay periods. LTCHs are generally defined as inpatient acute care hospitals with an average length of stay greater than 25 days. An interrupted stay occurs when a patient is discharged from an LTCH for treatment and services that are not available at the LTCH and is readmitted after a specific number of days. Interrupted stays in LTCHs cause an adjustment in Medicare payments. (42 CFR § 412.531.) Prior OIG work has identified vulnerabilities in CMS's ability to detect readmissions and appropriately pay for interrupted stays. *(OEI; 04-12-00490; expected issue date: FY 2014; work in progress)*

Nursing Homes

Acronyms and Abbreviations for Selected Terms Used in This Section:

IRF—inpatient rehabilitation facility
RAI—Resident Assessment Instrument
SNF—skilled nursing facility

Nursing Homes—Adverse Events in Post-Acute Care for Medicare Beneficiaries

We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving postacute care in SNFs and inpatient rehabilitation facilities (IRF). We will also identify contributing factors to these events, determine the extent to which the events were preventable, and estimate the associated costs to Medicare. Medicare Part A pays for up to 100 days of care in SNFs and IRFs following a hospital stay of at least 3 days and in cases when a medical professional verifies the need for nursing care and rehabilitation related to the hospitalization. SNFs are the primary providers of postacute care, admitting 85 percent of Medicare beneficiaries receiving facility care following a hospitalization. Medicare expenditures for SNF care have more than doubled in the last decade; Medicare paid $12 billion for SNF care in 2000 and $28 billion in 2011. IRFs provide a far smaller percentage of postacute facility care (11 percent) but like SNFs have experienced rapid growth over the last decade and accounted for $7 billion in Medicare expenditures in 2011. *(OEI; 06-11-00370; expected issue date: FY 2014; work in progress)*

Nursing Homes—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 use the Residential Assessment Instruments (RAI) to develop care plans to provide services to beneficiaries in accordance with the plans of care and to plan for beneficiaries' discharges. We will also describe any instances of poor quality of care . Prior OIG reports revealed that about a quarter of residents' needs for care, as identified through RAIs, were not reflected in care plans and that nursing home residents did not receive all the psychosocial services identified in care plans. Federal laws require nursing homes participating in Medicare or Medicaid to use RAIs to assess each nursing home resident's strengths and needs. (Social Security Act, §§ 1819(b)(3) and 1919(b)(3).) *(OEI; 02-09-00201; expected issue date: FY 2013; work in progress)*

Nursing Homes—State Agency Verification of Deficiency Corrections (New)

We will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. Federal regulations require nursing homes to submit correction plans to the State survey agency or CMS for deficiencies identified during surveys. (42 CFR § 488.402(d).) CMS requires State survey agencies to verify the correction of identified deficiencies through onsite reviews or by obtaining other evidence of correction. (*State Operations Manual*, Pub. No. 100-07, § 7300.3.) A prior OIG review found that one State survey agency did not always verify that nursing homes corrected deficiencies identified during surveys in accordance with Federal requirements. *(OAS; W-00-13-35701; various reviews; expected issue date: FY 2013; new start)*

Nursing Homes—Oversight of Poorly Performing Facilities

We will identify poorly performing nursing homes and determine the extent to which CMS and States use enforcement measures to improve nursing home performance. We will also identify CMS and States' followup actions to ensure that poorly performing nursing homes implement corrective actions. Federal requirements include a survey-and-certification process, with associated enforcement measures, to ensure that nursing homes meet Federal standards for participation in Medicare and

Medicaid. (Social Security Act, §§ 1819(g) and 1864.) We will examine enforcement decisions by CMS and States resulting from surveys and complaint allegations. *(OEI; 06-12-00120; expected issue date: FY 2014; work in progress)*

Nursing Homes—Use of Atypical Antipsychotic Drugs (New)

We will assess nursing homes' administration of atypical antipsychotic drugs, including the percentage of residents receiving these drugs and the types of drugs most commonly received. We will also describe the characteristics associated with nursing homes that frequently administer atypical antipsychotic drugs. According to 42 CFR § 488.3, nursing homes must comply with Federal quality and safety standards, including requiring the monitoring of the prescription drugs prescribed to its residents. Federal requirements, 42 CFR § 483.25(l)(1), also require that nursing home residents' drug regimens be free from unnecessary drugs. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Nursing Homes—Hospitalizations of Nursing Home Residents

We will determine the extent to which Medicare beneficiaries residing in nursing homes have been hospitalized. We will also determine the extent to which hospitalizations were a result of manageable or preventable conditions. Hospitalizations of nursing home residents are costly to Medicare and may indicate quality-of-care problems at nursing homes. A 2007 OIG review found that 35 percent of hospitalizations during a SNF stay were caused by poor quality of care or unnecessary fragmentation of services. *(OEI; 06-11-00040; expected issue date: FY 2013; work in progress)*

Nursing Homes—Questionable Billing Patterns for Part B Services During Nursing Home Stays

We will identify questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to nursing home residents. Part B services provided during a nursing home stay must be billed directly by suppliers and other providers. (CMS's *Medicare Benefits Policy Manual*, Pub. 100-02, ch. 8, § 70.) Congress directed OIG to monitor these services for abuse. (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 313.) A series of studies will examine podiatry, ambulance, laboratory, and imaging services. *(OEI; 06-11-00280; various reviews; expected issue dates: FY 2013; work in progress)*

Nursing Homes—Oversight of the Minimum Data Set Submitted by Long-Term-Care Facilities (New)

We will determine whether and the extent to which CMS and the States oversee the accuracy and completeness of Minimum Data Set (MDS) data submitted by nursing facilities. Certified nursing facilities are required to complete the MDS for all residents at specified intervals and submit data electronically to the State. States then submit data to CMS, which uses it for a number of programs, including payment, quality monitoring, and consumer information. *(OEI; 06-12-00440; expected issue dates: FY 2014; work in progress)*

Hospices

Acronyms and Abbreviations for Selected Terms Used in This Section:

MedPAC—Medicare Payment Advisory Commission
CoPs—(Medicare) conditions of participation

Hospices—Marketing Practices and Financial Relationships with Nursing Facilities

We will review hospices' marketing materials and practices and their financial relationships with nursing facilities. Medicare covers hospice services for eligible beneficiaries under Medicare Part A. (Social Security Act, § 1812(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, an independent congressional agency that advises Congress on issues affecting Medicare, has noted that hospices and nursing facilities may be involved in inappropriate enrollment and compensation. MedPAC has also highlighted instances in which hospices aggressively marketed services to nursing facility residents. We will focus our review on hospices that have a high percentage of their beneficiaries in nursing facilities. *(OEI; 02-10-00071; 02-10-00072; expected issue date: FY 2013; work in progress)*

Hospices—General Inpatient Care

We will review the use of hospice general inpatient care in 2011. We will also assess the appropriateness of hospices' general inpatient care claims. Federal regulations address Medicare CoPs for hospice at 42 CFR Part 418. We will review hospice medical records to address concerns that this level of hospice care is being misused. *(OEI; 02-10-00490; expected issue date: FY 2013; work in progress)*

Home Health Services

Acronyms and Abbreviations for Selected Terms Used in This Section:

CoP—(Medicare) conditions of participation
HHA—home health agency
OASIS—Outcome and Assessment Information Set
PPS—prospective payment system

HHAs—Home Health Face-to-Face Requirement (New)

We will determine the extent to which home health agencies (HHA) are complying with a statutory requirement that physicians (or certain practitioners working with physicians) who certify beneficiaries as eligible for Medicare home health services have face-to-face encounters with the beneficiaries. (Patient Protection and Affordable Care Act (Affordable Care Act), § 6407.) The encounters must occur within 120 days: either within the 90 days before beneficiaries start home health care or up to 30 days after care begins. (42 CFR § 424.22.) OIG work conducted before the Affordable Care Act mandate went into effect found that only 30 percent of beneficiaries had at least one face-to-face visit with the

physicians who ordered their home health care. *(OEI; 01-12-00390; expected issue date: FY 2013; work in progress. Affordable Care Act.)*

HHAs—Employment of Home Health Aides With Criminal Convictions (New)

We will determine the extent to which HHAs are complying with State requirements that criminal background checks be conducted with respect to HHA applicants and employees. Federal law requires that HHAs comply with all applicable State and local laws and regulations. (Social Security Act, §1891(a)(5), implemented at 42 CFR § 484.12(a).) A previous OIG review found that 92 percent of nursing homes employed at least one individual with at least one criminal conviction; however, this review could not determine whether the nursing home employees were disqualified from working in nursing homes because OIG did not have access to detailed information on the nature of the employees' crimes. Nearly all States have laws prohibiting certain care-related entities from employing individuals with prohibited criminal convictions. *(OEI; 12-12-00630; expected issued date: FY 2013; work in progress)*

HHAs—States' Survey and Certification: Timeliness, Outcomes, Followup, and Medicare Oversight

We will review the timeliness of HHA recertification and complaint surveys conducted by State Survey Agencies and Accreditation Organizations, the outcomes of those surveys, and the followup of complaints against HHAs. We will also look at CMS oversight designed to monitor HHA surveys. CMS relies on the survey and certification process to ensure HHA compliance with Medicare CoPs. HHAs must be surveyed at least every 36 months. (Social Security Act, § 1891(c)(2).) Regulations on surveys to validate the accreditation process are at 42 CFR § 488.8, and instructions on surveys to monitor State Survey Agencies' performance are in CMS's *State Operations Manual*, §§ 4157 and 4158. *(OEI; 06-11-00400; expected issue date: FY 2013; work in progress)*

HHAs—Missing or Incorrect Patient Outcome and Assessment Data

We will review home health agencies Outcome and Assessment Information Set (OASIS) data to identify payments for episodes for which OASIS data were not submitted or for which the billing codes on the claims are inconsistent with OASIS data. OASIS data are electronically submitted to CMS, independently of the home health agency's claim for episode payment. Federal regulations require that HHAs submit OASIS data as a condition for payment. (42 CFR § 484.210(e).) HHAs receive prospective payments on the basis of 60-day episodes of care. The OASIS is a standard set of data items used to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services and includes the billing code for the episode of care. *(OAS; W-00-13-35600; various reviews; expected issue date: FY 2013; new start)*

HHAs—Medicare Administrative Contractors' Oversight of Claims

We will review the activities that CMS and its contractors performed to identify and prevent improper home health payments from January to October 2011. We will also determine the extent to which CMS and its contractors performed activities to identify and address potential fraud among HHAs. In 2010, Medicare paid approximately $19.5 billion to 11,203 HHAs for services provided to 3.4 million

beneficiaries. Previous OIG and the Department of Justice (DOJ) investigations indicate that the home health benefit may be susceptible to fraud. *(OEI; 04-11-00220; expected issue date: FY 2013; work in progress)*

HHAs—Home Health Prospective Payment System Requirements

We will review compliance with various aspects of the home health PPS, including the documentation required in support of the claims paid by Medicare. Some beneficiaries who are confined to their homes are eligible to receive home health services. (Social Security Act, §§ 1835(a)(2)(A) and 1861(m).) Such services include part-time or intermittent skilled nursing care, as well as other skilled care services, such as physical, occupational, and speech therapy; medical social work; and home health aide services. *(OAS; W-00-12-35501; W-00-13-35501; various reviews; expected issue date: FY 2013 ;work in progress and new start)*

HHAs—Trends in Revenues and Expenses

We will review cost report data to analyze HHA revenue and expense trends under the home health PPS to determine whether the payment methodology should be adjusted. We will examine various Medicare and overall revenue and expense trends for freestanding and hospital-based HHAs. Since the home health PPS was implemented in October 2000, HHA expenditures have significantly increased. Home health services are paid under a PPS pursuant to the Social Security Act, § 1895, added by the Balanced Budget Act of 1997 (BBA), § 4603. *(OAS; W-00-10-35428; various reviews; expected issue date: FY 2013; work in progress)*

Medical Equipment and Supplies

Acronyms and Abbreviations for Selected Terms Used in This Section:

CBA—Competitive Bidding Areas
CPAP—continuous positivie airway pressure (machine)
LCD—local coverage determination
PMD—power mobility device

Quality Standards—Accreditation of Medical Equipment Suppliers (New)

This review will examine accreditation organizations' (AO) requirements and processes for granting accreditation to ensure that medical equipment suppliers meet each of Medicare's quality standards. Failure to meet quality standards could pose a threat to beneficiary safety and quality of care as well as place Medicare resources at risk. Medical equipment suppliers must become accredited by a CMS-approved AO and must comply with quality standards to maintain their billing privileges. CMS oversees AOs through validation surveys. This review will also evaluate CMS's procedures for conducting validation surveys. Such surveys help CMS determine whether an AO's accreditation procedures are adequately ensuring that suppliers are complying with Medicare's quality standards. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Program Integrity—Reliability of Service Code Modifiers on Medical Equipment Claims

We will determine the appropriateness of Part B payments that Medicare made on the basis of specific service code modifiers that suppliers entered on the claims. Such modifiers indicate that suppliers have required supporting documentation on file. Suppliers must provide, upon request, the documentation to support the claims for payment. Payments to service providers are precluded unless the provider maintains and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, § 1833(e).) Reviews of suppliers conducted by Medicare claims processing contractors found that suppliers had little or no documentation to support their claims, suggesting that many of the claims submitted may have been improper and should not have been paid by Medicare. *(OAS; W-00-11-35305; W-00-12-35305; various reviews; expected issue date: FY 2013; work in progress)*

Program Integrity—Use of Surety Bonds To Recover Medical Equipment Supplier Overpayments

We will review CMS's use of surety bonds to recover overpayments made to medical equipment suppliers. We will determine the extent to which CMS maintains complete and accurate surety bond information for medical equipment suppliers. We will also determine the number of medical equipment suppliers with overpayment debt, the extent to which these suppliers had surety bond coverage, and the amount of overpayment debt that could have been recovered through surety bonds since October 2009. Certain medical equipment suppliers must provide and maintain a surety bond of no less than $50,000. (Balanced Budget Act of 1997 (BBA), § 4312(a)(16).) By requiring medical equipment surety bonds, CMS aims to limit fraud risk to Medicare by ensuring only legitimate suppliers are enrolled and to recoup overpayments resulting from fraudulent or abusive billing practices. *(OEI; 03-11-00350; expected issue date: FY 2013; work in progress)*

Lower Limb Prostheses—Supplier Compliance With Payment Requirements (New)

We will review Medicare Part B payments for claims submitted by medical equipment suppliers for lower limb prosthetics to determine whether the requirements of CMS's *Benefits Policy Manual*, Pub. 100-02, ch. 15, § 120, were met. Payments to service providers are precluded unless the provider has and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, §1833(e).) Medicare does not pay for items or services that are "not reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) OIG conducted a national review of suppliers of lower limb prosthetics and identified 267 suppliers that had questionable billings. Prior OIG work found that suppliers frequently submitted claims that did not meet certain Medicare requirements; were for beneficiaries with no claims from their referring physicians; and had other questionable billing characteristics (e.g., billing lower limb prostheses for a high percentage of beneficiaries with no history of an amputation or missing limb). Such claims are improper and should not be paid by Medicare. *(OAS; W-00-13-35702; various reviews; expected issue date: FY 2013; new start)*

Power Mobility Devices—Supplier Compliance With Payment Requirements (New)

We will conduct a series of reviews related to power mobility devices (PMD). The reviews will focus on whether Medicare payments for PMD claims submitted by medical equipment suppliers were made in

accordance with requirements at 42 CFR § 410.38(c)(2). Medicare does not pay for items or services that are "not reasonable and necessary." We will also determine whether savings can be achieved by Medicare for PMDs that are not affected by the Affordable Care Act, § 3136, which eliminated the option of a lump-sum purchase for certain PMDs. Prior to the enactment of the Affordable Care Act, a beneficiary was given the option to make a "lump sum" purchase of a power-driven wheelchair at the time it was furnished instead of renting it. *(OAS; W-00-13-35703; various reviews; expected issue date: FY 2013; new start. Affordable Care Act.)*

Vacuum Erection Systems—Reasonableness of Medicare's Fee Schedule Amounts Compared to Amounts Paid by Other Payers (New)

Our review will determine the reasonableness of the Medicare fee schedule amount for Vacuum Erection Systems (VES). We will compare Medicare payments made for VES to the amounts paid by non-Medicare payers, such as private insurance companies and the Department of Veterans Affairs (VA), to identify potentially wasteful spending. We will estimate the financial impact on the Medicare program and on beneficiaries of aligning the fee schedule payments for VESs with those of non-Medicare payers. *(OAS; W-00-13-35705; various reviews; expected issue date: FY 2013; new start)*

Back Orthoses—Reasonableness of Medicare Payments Compared to Supplier Acquisition Costs

We will compare Medicare reimbursement amounts for the back orthosis procedure code L0631 to supplier acquisition costs to evaluate the reasonableness of Medicare's spending. Back orthoses, which are covered by Social Security Act, § 1832(a)(2), are supplied by Medicare medical equipment suppliers who purchase them from wholesalers or directly from orthotics manufacturers. For 2011, the median Medicare reimbursement amount for an L0631 back brace was $929. OIG has encountered suppliers who can purchase these back orthoses for prices significantly lower than Medicare reimbursement rates. Internet retail prices for back orthoses are also significantly lower than Medicare pays. *(OEI; 03-11-00600; expected issue date: FY 2013; work in progress)*

Parenteral Nutrition—Reasonableness of Medicare Payments Compared to Payments by Other Payers

We will compare Medicare's fee schedule for parenteral nutrition with fees paid by other sources of reimbursement to evaluate the reasonableness of Medicare's spending. We will identify reimbursement amounts paid by public and private payers for parenteral nutrition services. Parenteral nutrition is the practice of feeding a person intravenously to replace the function of a permanently inoperative or malfunctioning internal 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 (HMO), and 11 times higher than some manufacturers' contract prices. *(OEI; 04-12-00640; expected issue date: FY 2014; work in progress)*

Frequently Replaced Supplies—Supplier Compliance With Medical Necessity, Frequency, and Other Requirements

We will review claims for frequently replaced medical equipment supplies to determine whether medical necessity, frequency, and other Medicare requirements are met. For supplies and accessories used periodically, orders or certificates 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 Program Integrity Manual*, Pub. 100-08, ch. 5, §§ 2.3 and 5.9.) Beneficiaries or their caregivers must specifically request refills of repetitive services and/or supplies before suppliers dispense them. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 20, § 200.) Suppliers may not initiate refills of orders, and suppliers must not automatically dispense a quantity of supplies on a predetermined regular basis. Medicare does not pay for items or services that are "not reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Prior OIG work found that suppliers automatically shipped continuous positive airway pressure system and respiratory-assist device supplies when no physician orders for refills were in effect. Such claims are improper and should not be submitted to Medicare for payment.
(OAS; W-00-13-35240; various reviews; expected issue date: FY 2013; new start)

Continuous Positive Airway Pressure Supplies—Reasonableness of Medicare's Replacement of Supplies Compared to That of Other Federal Programs (New)

We will determine the extent to which Medicare's supply replacement schedules for supplies related to continuous positive airway pressure (CPAP) machines (equipment used to treat obstructive sleep apnea) vary from those of Medicaid, VA, and Federal Employees Health Benefits programs. We will also identify savings that might be achieved by adopting alternative schedules to avoid wasteful spending. Medicare Part B covers medical equipment and the services and supplies that are essential to its effective use . Separate charges for replacement supplies, such as masks, tubing, and filters, are covered if a beneficiary either rents or owns a CPAP machine. There are no national coverage determinations for the frequency of replacement of CPAP supplies; rather, this is at the discretion of designated Medicare payment contractors. The contractors have established identical CPAP supply replacement schedules.
(OEI; 07-12-00250; expected issue date: FY 2013; work in progress)

Diabetes Testing Supplies—Supplier Compliance With Payment Requirements for Blood Glucose Test Strips and Lancets

We will review Medicare Part B payments for home blood glucose test strips and lancet supplies to determine their appropriateness. The local coverage determinations (LCD) issued by the four Medicare contactors that process medical equipment and supply claims 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 code to identify when a patient is treated with insulin or not treated with insulin. The amount of supplies allowable for Medicare reimbursement differs depending on the applicable service code modifier. Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).)
(OAS; W-00-11-35407; W-00-12-35407; various reviews; expected issue date: FY 2013; work in progress)

Diabetes Testing Supplies —Effectiveness of System Edits To Prevent Inappropriate Payments for Blood-Glucose Test Strips and Lancets to Multiple Suppliers

We will review Medicare's claims processing edits (special system controls) designed to prevent payments to multiple suppliers of home blood-glucose test strips and lancets and determine whether they are effective in preventing inappropriate payments. The LCDs issued by the pertinent claims processing contractors state that medical equipment suppliers may not dispense test strips and lancets until beneficiaries have nearly exhausted the previously dispensed supplies. The LCDs also require that beneficiaries or their caregivers must specifically request the refills before the suppliers dispense them. Prior OIG work found that inappropriate payments were made to multiple medical equipment suppliers for test strips and lancets dispensed to the same beneficiary with overlapping service dates. Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) *(OAS; W-00-13-35604; various reviews; expected issue date: FY 2013; new start)*

Diabetes Testing Supplies—Potential Questionable Billing for Test Strips in 2011

We will review Medicare claims data from 2011 to identify suppliers with inappropriate payments and/or questionable billing for diabetes test strips. We will also analyze the geographic location of suppliers that had questionable billing and the extent to which the suppliers were associated with claims for beneficiaries residing in competitive bidding areas in 2011. Recent investigations and prior Office of Inspector General studies have found that diabetes test strips are vulnerable to improper claims, fraud, waste, and abuse. *(OEI; 04-11-00330; expected issue date: FY 2013; work in progress)*

Diabetes Testing Supplies—Improper Supplier Billing for Test Strips in Competitive Bidding Areas (New)

We will determine the extent to which suppliers improperly billed Medicare non-mail-order diabetes test strips in Competitive Bidding Areas (CBA) in 2011. We will also describe billing trends for test strips in CBAs between 2010 and 2011 and the extent to which suppliers conducted activities that we determined to be inappropriate (i.e., waiving copayments, contacting beneficiaries, sending unsolicited test strips in 2010 or 2011. There is concern that suppliers may be undermining the Competitive Bidding Program by billing for non-mail order test strips that are actually provided via mail order to receive a higher reimbursement amount and/or may be providing incentives to beneficiaries to receive test strips via non-mail order rather than via mail order, such as by waiving Medicare Part B copayments for beneficiaries. In 2011, the Competitive Bidding Program started in nine CBAs, resulting in lower reimbursement rates for mail-order test strips than for non-mail-order test strips. *(OEI; 04-11-00760; expected issue date: FY 2013; work in progress)*

Diabetes Testing Supplies—Supplier Compliance With Requirements for Non-Mail-Order Claims (New)

We will determine whether Part B payments for non-mail-order diabetes testing supplies (e.g., supplies purchased from suppliers that have physical locations) were made in accordance with Medicare requirements. Federal law required a 9.5-percent reduction in fee schedule payments for certain items included in Round 1 of the Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies

Competitive Bidding Program, including diabetic testing supplies delivered by mail. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(2).) The reduction applied to items provided on or after January 1, 2009, in any geographical area. Suppliers are required to use the service code "KL" modifier on claims for such supplies delivered to Medicare beneficiaries by mail (e.g., common carrier). Claims with the KL modifier are paid at the lower rate. We will review claims billed without KL modifiers to confirm whether the resulting higher payments were proper. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 36, § 20.5.4.1.) *(OAS; W-00-13-35704; various reviews; expected issue date: FY 2013; new start)*

Competitive Bidding—Mandatory Review

We will review the process CMS used to conduct competitive bidding and to make subsequent pricing determinations for certain medical equipment items and services in selected competitive bidding areas under rounds 1 and 2 of the competitive bidding program. Federal law requires OIG to conduct postaward audits to assess this process. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(1)(E).) *(OAS; W-00-12-35241; W-00-13-35241; various reviews; expected issued date: FY 2013; work in progress and new start)*

Other Providers and Suppliers

Acronyms and Abbreviations for Selected Terms Used in This Section:

ASC—ambulatory surgical center
CERT—Comprehensive Error Rate Testing (program)
E/M—evaluation and management (services)
ESRD—end stage renal disease
HOPD—hospital outpatient department
PHP—partial hospitalization program
POD—physician-owned distributor
PPS—prospective payment system
RHC—rural health clinic

Program Integrity—Onsite Visits for Medicare Provider and Supplier Enrollment and Reenrollment (New)

We will determine how often onsite visits occur as part of the Medicare enrollment or reenrollment process. CMS reserves the right, when deemed necessary, to perform onsite inspections of a provider or supplier to verify enrollment information submitted to CMS. (42 CFR § 424.510(d)(8).) Moreover, CMS is authorized to expand the role of unannounced preenrollment site visits. (Affordable Care Act, § 6401(a)(3).) CMS implemented the Affordable Care Act provider and enrollment provisions by requiring onsite visits for provider and supplier types identified by CMS as moderate risk or high risk. (76 Fed. Reg. 5862 (February 2, 2011).) A prior OIG review found that 33 percent of medical equipment suppliers in South Florida did not maintain physical facilities, a vulnerability that might be reduced by confirming legitimacy of location with onsite visits conducted during the enrollment process. *(OEI; 00-00-00000; expected issue date: FY 2014; new start. Affordable Care Act.)*

Program Integrity—Medical Review of Part A and Part B Claims Submitted by Top Error-Prone Providers

We will review Medicare Part A and Part B claims submitted by error-prone providers to determine their validity, project our results to each provider's population of claims, and recommend that CMS request refunds on projected overpayments. 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 over a 4-year period. In this review, we will select the top error-prone providers on the basis of expected dollar error amounts and match the 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. Providers must submit accurate claims for services provided to Medicare beneficiaries. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04.) *(OAS; W-00-13-35565; various reviews; expected issue date: FY 2013; new start)*

Program Integrity—Improper Use of Commercial Mailboxes (New)

We will determine the extent to which Medicare Part B providers and suppliers had practice locations that matched commercial mailbox addresses in 2011. Medicare providers and suppliers are required to establish physical business facilities of adequate size and with permanent, visible signs and must provide CMS with specific street addresses (not mailboxes) recognized by the U. S. Postal Service. Recent evidence suggests that individuals attempting to defraud Medicare may be using mailbox rental services to evade enforcement of this requirement, as commercial mailbox services provide a recognized street address without a mailbox number. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Program Integrity—Payments to Providers Subject to Debt Collection (New)

We will review providers and suppliers that received Medicare payments after CMS referred them to the Department of the Treasury (Treasury) for failure to refund overpayments. We will determine the extent to which they ceased billing under one Medicare provider number but billed Medicare under a different number after being referred to Treasury. CMS may deny a provider's or supplier's enrollment in the Medicare program if the current owner, physician, or nonphysician practitioner has an existing overpayment at the time of filing an enrollment application. Federal law requires CMS to seek the recovery of all identified overpayments. The Debt Collection Improvement Act of 1996 (DCIA) requires Federal agencies to refer eligible delinquent debt to Treasury for appropriate action. (42 CFR § 424.530(a)(6).) (*OAS; W-00-12-35622; various reviews; expected issue date: FY 2013; work in progress*)

Program Integrity—High Cumulative Part B Payments

We will review payment systems controls that identify high cumulative Medicare Part B payments to physicians and suppliers. We will determine whether payment system controls are in place to identify such payments and assess the effectiveness of those controls. Medicare Part B services must be reasonable and necessary (Social Security Act, § 1862(a)(1)(A)), be adequately documented (§ 1833(e)), and be provided consistent with Federal regulations (42 CFR, § 410). A high cumulative payment is an unusually high payment made to an individual physician or supplier, or on behalf of an individual

beneficiary, over a specified period. Prior OIG work found that unusually high Medicare payments may indicate incorrect billing or fraud and abuse. *(OAS; W-00-13-35605; various reviews; expected issue date: FY 2013; new start)*

Independent Therapists—High Utilization of Outpatient Physical Therapy Services

We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable, medically necessary, or properly documented. Our focus is on independent therapists who have a high utilization rate for outpatient physical therapy services. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Documentation requirements for therapy services are in CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 220.3. *(OAS; W-00-11-35220;W-00-12-35220; W-00-13-35220; various reviews; expected issue date: FY 2013; work in progress and new start)*

Sleep Testing—Appropriateness of Medicare Payments for Polysomnography

We will identify questionable billing patterns for Medicare sleep study services provided in 2009 and 2010. Medicare payments for polysomnography increased from $62 million in 2001 to $235 million in 2009, and coverage was also recently expanded. Sleep studies are reimbursable for patients who have symptoms such as sleep apnea, narcolepsy, or parasomnia in accordance with the CMS's *Medicare Benefit Policy Manual*, Pub. 102, ch. 15, § 70. *(OEI; 05-12-00340; expected issue date: FY 2013; work in progress)*

Sleep Disorder Clinics—High Utilization of Sleep Testing Procedures

We will review the appropriateness of Medicare payments for high utilization sleep testing procedures to determine whether they were in accordance with Medicare requirements. Our analysis of CY 2010 Medicare payments for Current Procedural Terminology (CPT) codes 95810 and 95811, which totaled approximately $415 million, showed high utilization associated with these sleep test procedures. We will examine Medicare payments to physicians, hospital outpatient departments, and independent diagnostic testing facilities for sleep testing procedures. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under 1862(a)(1)(A) of the Act. Requirements for coverage of sleep tests under Part B are in CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 70. *(OAS; W-00-10-35521; W-00-12-35521; various reviews; expected issue date: FY 2013; work in progress)*

Physician-Owned Distributors— High Utilization of Orthopedic Implant Devices Used in Spinal Fusion Procedures

We will determine the extent to which physician-owned distributors (POD) provide spinal implants purchased by hospitals and are associated with high utilization of such implants. PODs are business

arrangements involving physician ownership of medical device companies and distributorships. PODs distribute orthopedic implants, such as devices used in spinal fusion procedures. However, PODs appear to be quickly growing into other areas, such as cardiac implants. Congress has expressed concern that PODs could create conflicts of interest and safety concerns for patients. *(OEI; 01-11-00660; expected issue date: FY 2013; work in progress)*

Ambulances—Compliance With Medical Necessity and Level-of-Transport Requirements

We will examine Medicare claims data to identify questionable billing for ambulance services such as transports that were potentially not medically reasonable and necessary and potentially unnecessary billing for Advanced Life Support Services and specialty care transport. We will also examine relationships between ambulance companies and other providers. Medicare pays for emergency and nonemergency ambulance services when a beneficiary's medical condition at the time of transport is such that other means of transportation are contraindicated (i.e., would endanger the beneficiary). (Social Security Act, § 1861(s)(7).) Medicare pays for different levels of ambulance service, including Basic Life Support and Advanced Life Support as well as specialty care transport. (42 CFR § 410.40(b).) *(OEI; 09-12-00351; expected issue date: FY 2012; new start; and OAS; W-00-11-35574; W-00-12-35574; various reviews; expected issue date: FY 2013; work in progress)*

Anesthesia Services —Payments for Personally Performed Services (New)

We will review Medicare Part B claims for personally performed anesthesia services to determine whether they were supported in accordance with Medicare requirements. We will also determine whether Medicare payments for anesthesiologist services reported on a claim with the "AA" service code modifier met Medicare requirements. Physicians report the appropriate anesthesia modifier to denote whether the service was personally performed or medically directed. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch.12, § 50) The service code "AA" modifier is used for anesthesia services personally performed by an anesthesiologist, and the "QK" modifier is used for medical direction of two, three, or four concurrent anesthesia procedures by an anesthesiologist. The QK modifier limits payment at 50 percent of the Medicare-allowed amount for personally performed services claimed with the AA modifier. Payments to any service provider are precluded unless the provider has furnished the information necessary to determine the amounts due. (Social Security Act, §1833(e).) *(OAS; W-00-13-35706; various reviews; expected issue date: FY 2013; new start)*

Ophthalmological Services—Questionable Billing (New)

We will review Medicare claims data to identify questionable billing for ophthalmological services during 2011. We will also review the geographic locations of providers exhibiting questionable billing for ophthalmological services in 2011. Medicare payments for Part B for physician services, which include ophthalmologists, are authorized by the Social Security Act, § 1832(a)(1), and 42 CFR § 410.20. In 2010, Medicare allowed over $6.8 billion for services provided by ophthalmologists. *(OEI; 04-12-00280; expected issue date: FY 2014; work in progress)*

Ambulatory Surgical Centers—Payment System

We will review the appropriateness of Medicare's methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. In addition, we will determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. Federal law required the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs beginning January 1, 2008. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 626.) (See also 42 CFR § 416.171). *(OAS; W-00-10-35423; W-00-11-35423; W-00-12-35423; various reviews; expected issue date: FY 2013; work in progress)*

Ambulatory Surgical Centers and Hospital Outpatient Departments—Safety and Quality of Surgery and Procedures

We will review the safety and quality of care for Medicare beneficiaries having surgeries and procedures in ASCs and hospital outpatient departments (HOPD). We will assess care in preparation for and provided during surgeries and procedures in both settings. We will identify adverse events in both settings. CMS and stakeholders have expressed interest in the comparative safety and quality of care provided by ASCs and HOPDs. When Medicare beneficiaries require certain surgeries or procedures that do not require hospitalization, physicians generally have the option of performing such surgeries or procedures in an ASC; an HOPD; or other health care setting, such as a physician's office. Site determinations are typically made on the basis of the type of surgery or procedure, as well as the patient's health status and comorbidities. Surgeries and procedures performed in ASCs have risen substantially over the past decade. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Partial Hospitalization Programs—Services in Hospital Outpatient Departments and Community Mental Health Centers

We will review the appropriateness of Medicare payments for partial hospitalization program (PHP) psychiatric services in hospital outpatient departments and freestanding community mental health centers. We will determine whether the payments met Medicare requirements. A PHP is an intensive outpatient program of psychiatric services that hospitals may provide to individuals in lieu of inpatient psychiatric care. The program provides individuals who have mental health conditions with an individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. This review focuses on whether payments met Medicare requirements on the basis of documentation supporting the services, including patient plans of care and physician supervision and certification requirements. Medicare coverage of PHP services is provided by the Social Security Act, § 1832(a)(2)(J), and conditions for payment are in CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 4, § 260, and at 42 CFR §§ 410.43 and 424.24(e). *(OAS; W-00-13-35453; various reviews; expected issue date: FY 2032; new start)*

Rural Health Clinics—Compliance With Location Requirements (New)

We will determine the extent to which Rural Health Clinics (RHC) do not meet basic location requirements. The Balanced Budget Act of 1997 permitted the Centers for Medicare & Medicaid

Services (CMS) to remove clinics that do not meet location requirements from the RHC program. In 2005, OIG recommended that CMS promulgate regulations implementing the Balanced Budget Act of 1997. CMS has yet to promulgate the final regulations allowing for the removal of RHCs. As a result, RHCs that no longer meet eligibility requirements continue to receive enhanced Medicare reimbursement. We will determine the extent to which such reimbursements are occurring. *(OEI; 00-00-00000; expected issue date: FY 2014)*

Electrodiagnostic Testing—Questionable Billing (New)

We will review Medicare claims data to identify questionable billing for electrodiagnostic testing. We will also determine the extent to which Medicare utilization rates differ by provider specialty, diagnosis, and geographic area for these services. Electrodiagnostic testing, which assists in the diagnosis and treatment of nerve or muscle damage, includes the needle electromyogram and the nerve conduction test. Coverage for diagnostic testing is provided by the Social Security act, § 1861(s)(2), and 42 CFR § 410.32.) The use of electrodiagnostic testing for inappropriate financial gain poses a growing vulnerability to Medicare. *(OEI; 04-12-00420; expected issue date: FY 2013; work in progress)*

Part B Imaging Services—Payments for Practice Expenses

We will review Medicare payments for Part B imaging services to determine whether they reflect the expenses incurred and whether the utilization rates reflect industry practices. For selected imaging services, we will focus on the practice expense components, including the equipment utilization rate. Practice expenses are those such as office rent, wages, and equipment. 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 expenses. (Social Security Act, § 1848(c)(1)(B).) *(OAS; W-00-12-35219; W-00-13-35219; various reviews; expected issue date: FY 2013; work in progress and new start)*

Diagnostic Radiology—Medical Necessity of High-Cost Tests

We will review Medicare payments for high-cost diagnostic radiology tests to determine whether they were medically necessary and the extent to which the same diagnostic tests are ordered for a beneficiary by primary care physicians and physician specialists for the same treatment. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862 (a)(1)(A).) *(OAS; W-00-12-35454; W-00-13-35454; various reviews; expected issue date: FY 2013; work in progress and new start)*

Laboratory Tests—Billing Characteristics and Questionable Billing in 2010

We will describe billing characteristics for Part B clinical laboratory tests in 2010. We will also identify questionable billing for Part B clinical laboratory tests in 2010. 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. Medicare pays only for those laboratory tests that are ordered by a physician or qualified nonphysician practitioner who is

treating a beneficiary. *(42 CFR § 410.32(a). (OEI; 03-11-00730; expected issue date: FY 2013; work in progress)*

Laboratory Tests—Reasonableness of Medicare Payments Compared to Those by State Medicaid and Federal Employees Health Benefit Programs

We will determine how the methods for establishing Medicare laboratory test payment rates vary from those of State Medicaid and Federal Employees Health Benefits (FEHB) programs. Excessive payment rates for laboratory tests can be costly for Medicare. In 2009, Medicare paid nearly $10 billion for laboratory tests. We will compare Medicare laboratory payment rates for 20 laboratory tests, representing the most frequently ordered and most costly tests in terms of total dollars paid, with those of other public payers, including State Medicaid programs and FEHB plans. *(OEI; 07-11-00010; expected issue date: FY 2013; work in progress)*

Laboratory Tests—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 and determine the appropriateness of Medicare payments for these tests. Preliminary OIG work at two Medicare contractors showed variations in the contractors' procedures for screening the frequency of these tests. 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. (CMS's *Medicare National Coverage Determinations Manual*, Pub. 100-03, ch. 1, pt. 3, § 190.21.) *(OAS; W-00-12-35455; W-00-13-35455; various reviews; expected issue date: FY 2013; work in progress and new start)*

Physicians and Other Suppliers—Noncompliance With Assignment Rules and Excessive Billing of Beneficiaries

We will review the extent to which physicians and other suppliers fail to comply with assignment rules and determine to what extent beneficiaries are inappropriately billed in excess of amounts allowed by Medicare. We will also assess beneficiaries' awareness of their rights and responsibilities regarding potential billing violations and Medicare coverage guidelines. Physicians participating in Medicare agree to accept payment on "assignment" for all items and services furnished to individuals enrolled in Medicare. (Social Security Act, § 1842(h)(1).) 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 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. *(OEI; 07-12-00570; expected issue date: FY 2014; work in progress)*

Physicians—Error Rate for Incident-To Services Performed by Nonphysicians

We will review physician billing for "incident-to" services to determine whether payment for such services had a higher error rate than that for non-incident-to services. We will also assess Medicare's ability to monitor services billed as "incident-to." Medicare Part B pays for certain services billed by physicians that are performed by nonphysicians incident to a physician office visit. A 2009 OIG review found that when Medicare allowed physicians' billings for more than 24 hours of services in a day, half of the services were not performed by a physician. We also found that unqualified nonphysicians performed 21 percent of the services that physicians did not personally perform. Incident-to services are a program vulnerability in that they do not appear in claims data and can be identified only by reviewing the medical record. They may also be vulnerable to overutilization and expose beneficiaries to care that does not meet professional standards of quality. Medicare's Part B coverage of services and supplies that are performed incident to the professional services of a physician is in the Social Security Act, § 1861(s)(2)(A). Medicare requires providers to furnish such information as may be necessary to determine the amounts due to receive payment. (Social Security Act, § 1833(e).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Physicians—Place-of-Service Coding Errors

We will review physicians' coding on Medicare Part B claims for services performed in ambulatory surgical centers and hospital outpatient departments to determine whether they properly coded the places of service. Federal regulations provide for different levels of payments to physicians depending on where services are performed. (42 CFR § 414.32.) 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 ambulatory surgical center. *(OAS; W-00-11-35113; various reviews; expected issue date: FY 2013; work in progress)*

Evaluation and Management Services—Potentially Inappropriate Payments in 2010

We will determine the extent to which CMS made potentially inappropriate payments for E/M services in 2010 and the consistency of E/M medical review determinations. 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. Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service on the basis of the content of the service and have documentation to support the level of service reported. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 30.6.1.) *(OEI; 04-10-00181; 04-10-00182; expected issue date: FY 2013; work in progress)*

Evaluation and Management Services—Use of Modifiers During the Global Surgery Period

We will review the appropriateness of the use of certain claims modifier codes during the global surgery period and determine whether Medicare payments for claims with modifiers used during such a period were in accordance with Medicare requirements. Prior OIG work found that improper use of modifiers during the global surgery period resulted in inappropriate payments. The global surgery payment

includes a surgical service and related preoperative and postoperative E/M services provided during the global surgery period. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 40.1.) Guidance for the use of modifiers for global surgeries is in CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 30. *(OAS; W-00-13-35607; various reviews; expected issue date: FY 2013; new start)*

Chiropractors—Part B Payments for Noncovered Services

We will review Medicare Part B payments for chiropractic services to determine whether such payments were in accordance with Medicare requirements. Prior OIG work identified inappropriate payments for chiropractic services furnished during calendar year (CY) 2006. Medicare-covered chiropractic services include only treatment by means of manual manipulation of the spine to correct subluxations. (42 CFR § 440.60.) Chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. (CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 30.5B.) Medicare will not pay for items or services that are "not reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) *(OAS; W-00-12-35606; W-00-13-35606; various reviews; expected issue date: FY 2013; work in progress and new start)*

Organ Procurement Organizations—Compliance With Supporting Documentation and Reporting Requirements

We will review Medicare payments to organ procurement organizations (OPO) to determine whether payments were correct and were supported by documentation, including whether OPOs correctly reported organ statistics for purposes of proper allocation of costs in their cost reports. An OPO coordinates the retrieval, preservation, and transportation of organs for transplant and maintains a system to allocate available organs to prospective recipients. Medicare generally reimburses OPOs under 42 CFR § 413.200 in accordance with a cost-basis method set forth at 42 CFR § 413. *(OAS; W-00-11-35568; W-00-12-35568; various reviews; expected issue date: FY 2013; work in progress)*

Claims Processing Errors—Medicare Payments for Part B Claims With G Modifiers (New)

We will determine the extent to which Medicare improperly paid claims from 2002 to 2011 in which providers entered GA, GX, GY, or GZ service code modifiers, indicating that Medicare denial was expected. Providers may use GA or GZ modifiers on claims they expect Medicare to deny as not reasonable and necessary pursuant to CMS's *Claims Processing Manual*. They may use GX or GY modifiers for items or services that are statutorily excluded. A recent OIG review 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. *(OEI; 02-10-00160; expected issue date: FY 2013; work in progress)*

End Stage Renal Disease—Medicare's Oversight of Dialysis Facilities

We will assess Medicare's oversight of facilities that provide outpatient maintenance dialysis services to Medicare beneficiaries with end stage renal disease (ESRD. We will assess the performance of oversight functions as well as the complaint processes of dialysis facilities. Dialysis facilities must meet specific

conditions to participate in Medicare. (Social Security Act, § 1881(b)(1), and 42 CFR Part 494.) CMS monitors the quality of care delivered to dialysis patients. (Balanced Budget Act of 1997 (BBA), § 4558(b).) CMS contracts with State survey and certification agencies and ESRD Networks to conduct onsite inspections of dialysis facilities and initiate corrective actions. State agencies and ESRD Networks also respond to and resolve complaints and adverse events, and utilize data for dialysis facility oversight. *(OEI; 01-11-00550; expected issue date: FY 2013; work in progress)*

End Stage Renal Disease—Bundled Prospective Payment System for Renal Dialysis Services

We will review Medicare pricing and utilization related to renal dialysis services under the new bundled ESRD PPS for renal dialysis services. We will also determine whether Medicare payments under the new ESRD PPS were made in accordance with Medicare requirements. CMS was to establish a case-mix adjusted bundled PPS for renal dialysis services beginning January 1, 2011. (Social Security Act, § 1881(b)(14).) The ESRD PPS, to be phased in over 4 years, will replace the basic case-mix adjusted composite payment system and the methodologies for reimbursement of separately billable outpatient ESRD services and will combine the payments for composite rate and separately billable services into a single payment. *(OAS; W-00-12-35608; W-00-13-35608; various reviews; expected issue date: FY 2013; work in progress and new start)*

End Stage Renal Disease—Payments for ESRD Drugs Under the Bundled Rate System

We will review payments for ESRD drugs under the new bundled rate system. We will compare facilities' acquisition costs for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed since our last review. Effective January 1, 2011, Federal law required CMS to begin implementation of a new system that bundles all costs related to ESRD care (including drugs that were previously separately billable) into a single per-treatment payment. (Social Security Act, § 1881(b)(14)(A)(i).) The bundled rate must be updated annually to reflect changes in the price of goods and services used in ESRD care. CMS has based price updates on wage and price proxy data from the Bureau of Labor Statistics. (75 Fed. Reg. 49030 at page 49151 (Aug. 12, 2010).) Previous OIG work found that data from the Bureau did not accurately measure changes in facilities' acquisition costs for high-dollar ESRD drugs. *(OEI; 03-12-00550; expected issue date: FY 2013; work in progress)*

Prescription Drugs

Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price
ASP—average sales price
AWP—average wholesale price
FDA—Food and Drug Administration
LCD—local coverage determination
WAMP—widely available market price

Ethics—Conflicts of Interest Involving Prescription Drug Compendia (New)

We will determine the extent to which the prescription drug compendia oversee conflicts of interest through reporting requirements and/or mitigation policies and the number and nature of the compendia's reported conflicts. Generally, Medicare covers drugs that are approved by FDA and

supported by one or more drug compendia recognized by CMS. (*Benefits Policy Manual*, Pub. 100-02, ch. 1, § 30, and ch. 15, § 50.) Recent concerns have highlighted the issue of conflicts of interest involving the drug compendia; however, CMS does not require the compendia to regularly publish conflict information, and it is unclear whether CMS conducts any oversight of the strength of the compendia's policies or the nature of their conflicts. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Patient Safety and Quality of Care—Off-Label Use of Medicare Part B Drugs

We will review off-label (prescribed for a condition that is not listed on the product's label) and off-compendia use of certain Medicare Part B prescription drugs and determine the extent to which specified compendia provide support for coverage. We will also identify CMS oversight mechanisms related to off-label use of drugs. For prescription drugs to be covered, Federal law generally requires that they be prescribed according to medically accepted indications, such as those approved by the Food and Drug Administration (FDA) or supported in one or more of the authoritative drug compendia identified by the Secretary of Health and Human Services (HHS). Therefore, most drugs are covered when used off-label as long as one of the designated compendia has determined that there is sufficient evidence that the drug is safe and effective for treating the condition. *(OEI; 03-12-00270; expected issue date: FY 2013; work in progress)*

Patient Safety and Quality of Care—Physicians' Experiences With Drug Shortages (New)

We will determine the extent to which providers of selected Part B-covered drugs in short supply report difficulty acquiring those drugs. During shortages, physicians may have to ration their supplies of certain drugs; delay treatments; use different drugs, which may be less effective; or resort to potentially untrustworthy sources to acquire drugs. In addition, we will ask providers to describe their behavior when facing a drug shortage as well as any effect on pricing, quality of care, and market availability. *(OEI; 00-00-00000; various reviews; expected issue date: FY 2014; new start)*

Patient Safety and Quality of Care—Hospitals' Experiences With Drug Shortages (New)

We will determine hospitals' reported experiences with drug shortages. During shortages, hospitals may have to ration their supplies of certain drugs; delay treatments; use different drugs, which may be less effective; or resort to potentially untrustworthy sources to acquire drugs. In addition, we will ask providers to describe their behavior when facing a drug shortage as well as any effect on pricing, quality of care, and market availability. *(OEI; 00-00-00000; various reviews; expected issue date: FY 2014; new start)*

Patient Safety and Quality of Care—Manufacturer Sales of Prescription Drugs in Short Supply (New)

We will quantify the effect of drug shortages on manufacturer sales. According to FDA, a record number of drugs were in short supply in 2010 and the number of drug shortages continued to grow in 2011. We will also use data from CMS to determine the extent to which demand and average sales prices of drugs changed when the drugs were reportedly in shortage. For any drug that did not show substantial decline in unit during the shortage quarter, we will analyze Part B claims data to determine

whether there was an increase in Part B utilization during that period. *(OEI; 00-00-00000; various reviews; expected issue date: FY 2014; new start)*

Potential Savings From Manufacturer Rebates for Part-B Drugs (New)

We will determine the potential savings associated with requiring manufacturers to pay rebates to Medicare Part B for those drugs Part B pays for on behalf of beneficiaries who are not also eligible for Medicaid (i.e., are not dual eligibles). Pursuant to the Omnibus Budget Reconciliation Act of 1990, pharmaceutical manufacturers are required to remit rebates for prescription drugs paid under Medicaid. Because of the statutorily mandated rebates, Federal and State governments were able to recoup approximately $11 billion of the $29 billion that Medicaid spent on prescription drugs in 2010. Medicare Part B spent over $16 billion on covered prescription drugs that same year. However, a comparable rebate program does not exist for Medicare Part B. *(OEI; 12-12-00260; expected issue date: FY 2013; work in progress)*

Comparison of 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) and identify drug prices that exceed a designated threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Federal law requires OIG to 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. (Social Security Act, § 1847A(d).) *(OEI; 00-00-00000; various studies; expected issue date: FY 2013; new start)*

Comparison of Average Sales Prices to Widely Available Market Prices

We will periodically review widely available market prices (WAMP) for selected prescription drugs covered by Part B and compare them to ASPs for those drugs to identify a designated payment-related threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Federal law requires OIG to conduct studies that compare ASPs to WAMPs for Part B-covered drugs. (Social Security Act, § 1847A(d).) If OIG finds that the ASP of a drug exceeds the WAMP by a certain threshold (now 5 percent), Medicare is to base payment for the drug on the lesser of the WAMP or 103 percent of the AMP. *(OEI; 00-00-00000; various studies; expected issue date: FY 2013; new start)*

Payments for Immunosuppressive Drug Claims With KX Modifiers (New)

We will determine whether Medicare Part B payments for immunosuppressive drugs billed with a certain claims service code modifier ("KX" modifier) met Medicare documentation requirements. Medicare Part B covers FDA-approved immunosuppressive drugs and drugs used in immunosuppressive therapy when a beneficiary receives an organ transplant for which immunosuppressive therapy is appropriate. (Social Security Act, § 1861(s).) Entities that bill for immunosuppressive drugs are required to submit claims to a designated Medicare payment contractor. On or after July 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary annotate the claim with the KX modifier to signify that the supplier retains documentation of the beneficiary's transplant date and that such transplant

date preceded the date of service for furnishing the drug. (*Medicare Claims Processing Manual*, Pub. 100-04, ch. 17, § 80.3) *(OAS; W-00-13-35707; various reviews; expected issue date: FY 2013; new start)*

Payments for Multiuse Vials of the Drug Herceptin

We will review claims to Medicare for the drug Herceptin, which is used to treat breast cancer, to determine whether they were properly billed. For drug claims involving a single-use vial or package, if a provider must discard the remainder of a single-use vial or package after administering a dose/quantity of the drug or biological, Medicare provides payment for the amount discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. However, multiuse vials, such as those used for supplying Herceptin, are not subject to the rule for payment for discarded amounts of a drug or biological (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 17, § 40). Providers must bill accurately and completely for services provided. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) *(OAS; W-00-11-35325; W-00-12-35325; various reviews; expected issue date: FY 2013; work in progress)*

Payments for Outpatient Drugs and Administration of the Drugs

We will review Medicare outpatient payments to providers for certain drugs and the administration of the drugs (e.g., chemotherapy drugs) to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. Prior OIG reviews have identified certain drugs, particularly chemotherapy drugs, as vulnerable to incorrect coding. Providers must bill accurately and completely for services provided. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) Further, providers must report units of service as the number of times that a service or procedure was performed (ch. 5, § 20.2, and ch. 26, § 10.4.). *(OAS; W-00-12-35576; various reviews; expected issue date: FY 2013; work in progress)*

Payments for Physician-Administered Drugs and Biologicals

We will compare Medicare and Medicaid payments for commonly used physician-administered drugs and biologicals to determine whether changes in the reimbursement methodologies for the Part B drug program would result in significant savings. Medicare Part B covers drugs and biologicals that are usually administered by nonphysicians during a visit to a physician's office. Medicare Part B pays for most covered drugs and biologicals on the basis of the reimbursement methodology of ASP plus 6 percent. (Social Security Act, § 1847A.) Medicaid also covers physician-administered drugs and biologicals. However, under Medicaid, States have flexibility in determining reimbursement for covered drugs and biologicals as long as the ingredient cost approximates an estimated acquisition cost. In addition, manufacturers must provide rebates for Medicaid-covered drugs. (Social Security Act, § 1927(a)(1).) *(OEI; 00-00-00000; expected issue date: FY 2013; new start)*

Payments for Drugs Infused Through Medical Equipment Compared to Provider Acquisition Costs (New)

We will review provider acquisition costs for Part B-covered drugs infused through medical equipment. We will also determine the amount Medicare could have saved had payment amounts for these drugs

been based on ASP. Unlike most drugs covered under Medicare Part B, drugs infused through medical equipment are paid based on average wholesale prices (AWP). (42 CFR § 414.904(e).) Prior OIG reports found that the AWPs for Part B-covered drugs often greatly exceeded the drugs' actual costs. *(OEI; 12-12-00310; expected issue date: FY 2013; work in progress)*

Payments for Prostate Cancer Drugs Under Current Policy (New)

We will determine the financial impact of rescinding least costly alternative policies (LCA) for certain prostate cancer drugs covered under Medicare Part B. We will also determine how Medicare Part B utilization for those drugs changed after the LCA policies were rescinded. Between 1995 and 2010, certain prostate cancer drugs covered under Medicare Part B were subject to LCA policies, which based the payment amount for a group of clinically comparable products on that of the least costly one. However, in April 2010, LCA policies for Part B drugs were discontinued in response to a court ruling that found that the use of an LCA policy for certain prescription drugs was not authorized under Medicare law. *(OEI; 12-12-00210; expected issue date: FY 2013; work in progress)*

Part A and Part B Contractors

Acronyms and Abbreviations for Selected Terms Used in This Section:

CERT— Comprehensive Error Rate Testing [program]
FAR—Federal Acquisition Regulation
FI—fiscal intermediary
LCD—local coverage determination
MAC—Medicare Administrative Contractor
NSC—National Supplier Clearinghouse
RAC—Recovery Audit Contractor
ZPIC—Zone Program Integrity Contractor

Overview of CMS's Contracting Landscape (New)

This review will provide an overview of the contracting landscape at CMS. CMS relies extensively on contractors to help it carry out its basic mission, including administration, management, and oversight of its health programs. In fiscal year 2009, CMS awarded $4 billion in contracts. Recent Government Accountability Office (GAO) reports have found pervasive deficiencies in CMS's contract management internal control. Given the number of contracts and the obligated dollars for which CMS is responsible, oversight and monitoring are vital for ensuring effective programs and safeguarding taxpayer dollars. This review will determine the number, types, and dollar amount of active CMS contracts and examine how CMS maintains all of its contract information. *(OEI; 03-12-00680; expected issue date: FY 2013; work in progress)*

CMS's Compliance With Contract Documentation Requirements (New)

We will determine the extent to which CMS complies with contract documentation requirements. CMS relies on contractors to perform many of its program functions. Prior work by the Office of Inspector General has consistently identified vulnerabilities in CMS's oversight of its contractors, and reports by the Government Accountability Office have specifically identified contract file documentation as an area of concern. The Federal Acquisition Regulation (FAR) and HHS Regulations establish rules and standards for awarding and administering Government contracts, including requirements for contract file

documentation. We will also determine how CMS ensures that contract file documentation is maintained as required by regulation. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Preaward Reviews of Contractor Cost Proposals

We will review the cost proposals of various bidders for Medicare contracts. The reports produced by these reviews assist CMS in negotiating favorable and cost-beneficial contract awards. Criteria are in Office of Management and Budget (OMB) Circular A-122, *Cost Principles for Non-Profit Organizations*. *(OAS; W-00-13-35002; various reviews; expected issue date: FY 2013; new start)*

Administrative Costs Claimed by Medicare Contractors

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. We will coordinate with CMS the selection of the contractors we will review. Criteria include Appendix B of the Medicare contract with CMS and the Federal Acquisition Regulation (FAR) at 48 CFR pt. 31. *(OAS; W-00-10-35005; W-00-11-35005; W-00-12-35005; W-00-13-35005; various reviews; expected issue date: FY 2013; work in progress and new start)*

Contractor Pension Cost Requirements

We will determine whether Medicare contractors have calculated and claimed reimbursement for Medicare's share of various employee pension costs in accordance with their Medicare contracts and applicable Federal requirements. We will determine whether contractors have fully implemented contract clauses requiring them to determine and separately account for the employee pension assets and liabilities allocable to their contracts with Medicare. We will also review Medicare carriers and fiscal intermediaries whose Medicare contracts have been terminated. We will assess Medicare's share of future pension costs as well as determine the amount of excess pension assets as of the closing dates. Applicable requirements are found in the FAR at 48 CFR Subpart 31.2; Cost Accounting Standards (CAS) 412 and 413; and the Medicare contract, Appendix B, § XVI. *(OAS; W-00-12-35067; W-00-13-35067; W-00-13-35094; W-00-13-35148; various reviews; expected issue date: FY 2013; work in progress and new start)*

Contractor Postretirement Benefits and Supplemental Employee Retirement Plan Costs

We will review the postretirement health benefit costs and the supplemental employee retirement plans of FIs and carriers. Our reviews will determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts. Criteria are in the FAR at 48 CFR §§ 31.201 through 31.205. *(OAS; W-00-12-35095; various reviews; expected issue date: FY 2013; work in progress)*

Contractor Error Rate Reduction Plans

We will determine the extent to which Medicare contractors meet error rate reduction plan requirements. We will also assess CMS's oversight of the process and determine the extent to which it affects overall contractor evaluation. Each Medicare payment contractor must develop and submit an

error rate reduction plan 30 days after receipt of its annual Comprehensive Error Rate Testing program (CERT) results. Error rate reduction plans describe the corrective actions that contractors plan to take to lower the CERT paid-claims error rate and provider-compliance error rate in their jurisdictions. *(OEI; 09-12-00090; expected issue date: FY 2013; work in progress)*

Medicare Administrative Contractors—CMS's Assessment and Monitoring of Performance (New)

We will determine the extent to which CMS conducted performance assessment and monitoring of MACs. We will also describe the extent to which MACs met, did not meet, or exceeded performance standards and determine the extent to which CMS identified and MACs addressed performance deficiencies. Federal law requires the Secretary to administer Medicare Part A and Part B through contracts with MACs and to develop specific performance requirements and standards for measuring the extent to which MACs meet them. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 911.) Previous OIG and GAO work has identified vulnerabilities in CMS's oversight of its contractors. This evaluation will build upon this body of work. *(OEI; 03-11-00740; expected issue date: FY 2013; work in progress)*

Medicare Administrative Contractors—Use and Management of System of Edits (New)

We will determine whether MACs fulfilled their contractual obligations specific to system edits in 2010 and 2011. We will also describe how MAC error rates varied across regions compared to differences in MACs' implementation, application, and evaluation of edits in 2010 and 2011. MACs are responsible for consolidating all Part A and Part B edits within their jurisdiction, as well as developing and testing final edits; implementing and using initial, local system, and medical review edits; and evaluating edit effectiveness. Since these automated edits are one of the only safeguards for identifying improper payments before Medicare payment is made, it is important that MACs properly implement and use edits. *(OEI; 04-12-00140; expected issue date: FY 2014; work in progress)*

Claims Processing Contractors—Failure To Conduct Prepayment Reviews in Response to Edits (New)

We will determine the number of Part B claims that were suspended for manual prepayment review on the basis of system edits but on which the reviews were not conducted. Because manual review is more timely and costly to the contractor, some suspended claims might not receive the review and, therefore, may be paid inappropriately. When a medical review edit reveals a billing error or claim anomaly, Medicare claims processing contractors (MACs, carriers, and intermediaries) may conduct manual prepayment or postpayment reviews. (CMS's *Program Integrity Manual*, Pub. 100-08, ch. 3.) They may also request additional medical documentation from the provider/supplier or contact beneficiaries to verify that the services actually were provided. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Recovery Audit Contractors—Identification and Recoupment of Improper and Potentially Fraudulent Payments and CMS's Oversight and Response

We will review the extent that Recovery Audit Contractors (RAC) identified improper payments, identified vulnerabilities, and made potential fraud referrals in 2010 and 2011. We will also review the activities that CMS performed to resolve RAC-identified vulnerabilities, address potential fraud referrals, and evaluate RAC performance in 2010 and 2011. On completion of a 3-year demonstration project, Congress mandated nationwide implementation of a permanent RAC program for Medicare Part A and Part B. (Tax Relief and Health Care Act of 2006 (TRHCA), § 302.) Subsequently, Congress expanded the RAC program, giving it additional responsibilities to address improper payments in Medicare (including Part C and Part D) and Medicaid. (Affordable Care Act, § 6411.) *(OEI; 04-11-00680; expected issue date: FY 2013; work in progress; Affordable Care Act)*

Zone Program Integrity Contractors—CMS's Oversight of Task Order Requirements (New)

We will review CMS oversight of fraud and abuse task order requirements for Zone Program Integrity Contractors (ZPICs). Pursuant to the FAR, CMS is required to evaluate contracts issued under the Medicare Integrity Program. Prior OIG work on benefit integritycontractor evaluations found that evaluations contained little information about performance results related to the detection and deterrence of fraud and abuse. This review will build upon prior work by reviewing the methods used to evaluate ZPIC task orders and determining the extent to which these methods focus on fraud and abuse. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

National Supplier Clearinghouse—Performance and CMS Oversight

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 their results . We will also assess CMS's oversight of the NSC. CMS, through its contract with the NSC, verifies medical equipment suppliers' initial and continuing compliance with conditions for payment. Federal regulations require medical equipment suppliers to comply with the conditions for payment, which include, among other things, requirements relating to provider enrollment. (42 CFR pt. 424, subpart P, and 42 CFR § 424.57.) OIG work in 2007 and 2008 found that fraudulent suppliers continue to enroll and participate in Medicare. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Contractor Information Systems Security Programs— Annual Report to Congress

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and MACs. We will report to Congress on our assessment of the scope and sufficiency of the independent evaluations and summarize their results . Federal law requires independent evaluations of the security programs of FIs, carriers, and MACs and requires OIG to assess such evaluations and report the results of its assessments to Congress. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 912.) *(OAS; W-00-13-41010; expected issue date: FY 2013; new start)*

Contractor Closeout—Disposition of Government Systems and Data

We will review CMS's policies, instructions, and procedures designed to ensure adherence to Federal data privacy, information security, and contractual requirements and conduct information technology closeout audits at Medicare contractors that left the program during FYs 2007 and 2008. We will assess compliance with applicable Federal requirements. 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, the 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. Federal law required 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. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 911.) The plan the Secretary submitted to Congress called 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. *(OAS; W-00-13-41011; various reviews; expected issue date: FY 2013; 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 (PHI) 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. We will assess and test contractors' and hospitals' policies and procedures for electronic health information protections, access, storage, and transport. OMB 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. (OMB Memorandum M-06-16, issued June 23, 2006.) *(OAS; W-00-12-41014; various reviews; expected issue date: FY 2013; work in progress)*

Local Coverage Determinations—Impact on Physician Fee Schedule, Services, and Expenditures

We will determine to what extent Part B services and items paid under the Medicare Physician Fee Schedule are affected by Local Coverage Determinations (LCD) and the variation in coverage of these services and items as a result. We will also assess CMS's efforts to evaluate and adopt new LCDs for national coverage as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Medicare delegates the establishment of LCDs to third-party contractors. 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. (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) § 521 and Social Security Act, § 1862(a)(1)(A).) 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. *(OEI; 01-11-00500; expected issue date: FY 2013; work in progress)*

Other Part A and Part B Management and Systems Issues

Acronyms and Abbreviations for Selected Terms Used in This Section:

CERT— Comprehensive Error Rate Testing (program)
NPI—national provider identifier
PECOS—Provider Enrollment, Chain, and Ownership System
PSC—Program Safeguard Contractor

Medicare as Secondary Payer—Improper Medicare Payments for Beneficiaries With Other Insurance Coverage

We will identify improper Medicare payments made for services to beneficiaries who have certain types of other insurance coverage to assess the effectiveness of Medicare's controls to prevent such payments. (Social Security Act, § 1862(b).) We will determine whether selected non-Medicare health plans properly reported insurance coverage information to Medicare as required. (Medicare, Medicaid and SCHIP Extension Act of 2007, §111). *(OAS; W-00-13-35317; various reviews; expected issue date: FY 2013; new start)*

Payments for Incarcerated Beneficiaries (New)

We will determine whether Medicare payments for incarcerated beneficiaries complied with Federal requirements. Medicare, in general, does not pay for services rendered to incarcerated beneficiaries; however, the regulation does permit Medicare payment where an incarcerated beneficiary has an obligation for the cost of care. (Social Security Act, § 1862, and 42 CFR § 411.4.) The Common Working File will reject claims on which the dates of incarceration (as obtained from the Social Security Administration) and the dates of service on the claim overlap. (CMS's *Medicare Claims Processing Manual*, ch 1, § 10.4.) In addition, the *Medicare Claims Processing Manual* provides instructions for providers who render services to incarcerated beneficiaries who meet the criteria for exception. Our review will determine whether Medicare payments were made for incarcerated beneficiaries who did not meet the criteria for exception identified in the regulations. *(OAS; W-00-12-35624; various reviews; expected issue date: FY 2013; work in progress)*

Payments for Alien Beneficiaries Unlawfully Present in the United States on the Dates of Service (New)

We will determine whether Medicare payments were made on behalf of beneficiaries who were unlawfully present in the United States on the dates of services. Medicare payment may not be made for items and services furnished to alien beneficiaries who were not lawfully present in the United States. (CMS's *Medicare Claims Processing Manual*, ch 1, § 10.1.4.8.) Medicare prohibits payment for services rendered to individuals who are not "qualified aliens." (Personal Responsibility and Work Opportunity Reconciliation Act of 1996, § 401.) CMS relies on an auxiliary file based on enrollment data

maintained by the Social Security Administration to identify claims associated with alien beneficiaries. (BBA, § 5561.) *(OAS; W-00-12-35625; various reviews; expected issue date: FY 2013; work in progress)*

Payments for Services After Beneficiaries' Death (New)

We will review Medicare claims dates to determine whether Medicare payments were made for deceased beneficiaries in 2011. We will also identify trends of Medicare claims with service dates after beneficiaries' dates of death. According to a prior OIG report, Medicare paid $20.6 million in 1997 for Part A and Part B services that purportedly started after beneficiaries' dates of death. *(OEI; 04-12-00170; expected issue date: FY 2013; work in progress)*

Undelivered Medicare Summary Notices (New)

We will review the procedures that CMS and claims processors have for handling undelivered Medicare Summary Notices (MSN). It is important that beneficiaries review their MSNs to ensure that there are no errors and that all items and services listed on the MSNs were actually received. CMS urges beneficiaries to review their MSNs to help protect Medicare and themselves from fraud; however, if beneficiaries do not receive their MSNs, they are unable to review them and report errors. *(OEI; 03-12-00600; expected issue date: FY 2014; work in progress)*

Medicare Integrity Program—CMS's Overall Strategy (New)

We will review CMS's overall strategy to maintain the integrity of the Medicare. The Medicare Integrity Program (MIP) was established through 42 U.S.C. § 1395ddd and requires CMS to contract with entities to carry out various program integrity activities to safeguard against fraud, waste, and abuse in Medicare Parts A and B. Over the past few years, Congress has submitted multiple letters to CMS questioning the effectiveness of the program integrity efforts of these contractors. We will also determine how CMS allocates funds for MIP activities and review the measures CMS uses to evaluate the performance and overall effectiveness of the MIP. *(OEI-03-12-00690; expected issue date: FY 2013 work in progress)*

Comprehensive Error Rate Testing Program—Fiscal Year 2012 Error Rate Oversight

We will review certain aspects of the CERT Program to evaluate CMS's efforts to ensure the accuracy of the FY 2012 error rate and to reduce improper payments. Through CERT, national, contractor-specific, and service-type error rates are computed. The CERT program's national estimated improper payments for FY 2011 were $28.8 billion (8.6 percent-error rate). In November 2003, CMS assumed responsibility for estimating and reporting improper Medicare FFS payments and national error rates. The CERT Program was established by CMS to meet the requirements of the Improper Payments Elimination and Recovery Improvement Act of 2011 (IPERA) and to monitor the accuracy with which Medicare claims are billed and paid. (CMS's *Medicare Program Integrity Manual,* Pub. 100-08, ch. 12.) Effective August 1, 2008, the CERT program also samples inpatient records, replacing the Hospital Payment Monitoring Program. *(OAS; W-00-13-40048; various reviews; expected issue date: FY 2013; new start)*

National Provider Identifier 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 and assess CMS's supporting processes. Federal law requires the Secretary of HHS to establish a standard unique identifier for each health care provider, health care organization, and health plan for use in the health care system. (Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Secretary established the NPI to address this requirement. Separately, Federal regulations require providers to enroll to receive payment from Medicare. (42 CFR § 424.505.) PECOS is the system CMS uses to complete the enrollments online. *(OEI; 07-09-00440; expected issue date: FY 2013; work in progress)*

CMS Disclosure of Personally Identifiable Information

We will determine whether CMS's disclosures of individuals' records are in accordance with the Privacy Act of 1974 (Privacy Act). We will also determine whether CMS is accounting for the disclosures in accordance with the Privacy Act and describe CMS's policies and practices for implementing safeguards that protect individuals' records. A "record" means any item, collection, or grouping of information about an individual maintained by an agency, including, but not limited to, financial transactions and medical history, which contains a name or identifying information. The Privacy Act allows limited disclosure of individuals' records for routine uses necessary to accomplish an agency activity. The law's requirements include keeping an accurate accounting of the name or agency to which the records were disclosed and the date, nature, and purpose of each disclosure. (Privacy Act, 5 U.S.C. § 552a(c).) *(OEI; 09-11-00430; expected issue date: FY 2013; work in progress)*

CMS Oversight of 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 medical equipment supplier debt deemed CNC was $402 million. A prior OIG review found that overpayments referred for collection by program safeguard contractors (PSC) in 2007 did not result in substantial recoveries to Medicare. *(OEI; 03-11-00670; expected issue date: FY 2013; work in progress)*

Grant Management —Stabilization Grant in the Greater New Orleans Area (New)

HHS has played a central role in post-Katrina recovery efforts, including the funding of provider stabilization grants pursuant to the Deficit Reduction Act of 2005 (DRA), § 6201(a)(4). One such grant, the Primary Care Access Stabilization Grant, was awarded by CMS to the Louisiana Department of Health and Hospitals for public and not-for-profit clinics that provide primary care to low-income and uninsured residents in the Greater New Orleans area. We will determine whether the Federal grant requirements were met. *(OAS; W-00-12-35203; various reviews; expected issue date: FY 2013; work in progress)*

First Level of the Medicare Appeals Process

We will describe redeterminations (the first level of Medicare appeals) processed in 2008-2011 for Medicare Parts A and B. A Medicare contractor has 60 days to conclude a redetermination regarding a denied claim. We will also assess the processing of redeterminations by Medicare contractors and CMS's monitoring of redeterminations processing. (Social Security Act, § 1869(a)(3)(C)(ii).)
(OEI; 01-12-00150; expected issue date: FY 2013; work in progress)

The *Work Plan* is one of OIG's three core publications. The *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations from prior periods that when implemented, will save tax dollars and improve programs.

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Part II
Medicare Part C and Part D

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. Medicare's optional outpatient prescription drug benefit, known as Medicare Part D, took effect on January 1, 2006. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).) Part D is a voluntary benefit available to Medicare beneficiaries.

Acronyms and Abbreviations for Selected Terms Used in Work Plan Part II:

HCPP—Health Care Prepayment Plan
HMO—health maintenance organization
MA—Medicare Advantage
MEDIC—Medicare Drug Integrity Contractor
QIO—Quality Improvement Organization

Program Integrity Oversight of Part C and Part D

Benefit Integrity Activities by CMS Contractors in Medicare Part C and Part D (New)
We will determine the extent to which the National Benefit Integrity (NBI) program Medicare Drug Integrity Contractors (MEDIC) performed Medicare Parts C and D benefit integrity activities. We will also describe barriers that the NBI MEDICs encountered in performing their benefit integrity activities. In FY 2010, the Centers for Medicare & Medicaid Services (CMS) awarded contracts to two national MEDICs, one designated as the NBI MEDIC and the other as the Compliance and Enforcement MEDIC. The NBI MEDIC assumed responsibility for detecting and preventing Medicare Parts C and D fraud, waste, and abuse nationwide. *(OEI; 03-11-00310; expected issue date: FY 2013; work in progress)*

Part C – Medicare Advantage

Medicare Advantage (MA) 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 are often less than the coinsurance and deductibles under the original Medicare Part A and Part B. In most cases, these plans also offer Part D prescription drug coverage. Costs and benefits vary by plan.

Special-Needs Plans—CMS Oversight of Enrollment and Special-Needs Plans

We will review CMS's oversight of plans' enrollment practices and determine whether Special-Needs Plans' for beneficiaries with chronic or disabling conditions comply with enrollment requirements. Medicare restricts Special-Needs Plans to beneficiaries with chronic or disabling conditions. In 2010, the Secretary identified 15 conditions for 2010 that meet the requirements of being severe or disabling and needing specialized care management. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 164.) The Affordable Care Act extended Special-Needs Plans through 2013. (Affordable Care Act, § 3205.) *(OEI; 07-12-00170; expected issue date: FY 2013; work in progress ; Affordable Care Act)*

Provision of Services—Compliance With Medicare Requirements

We will review MA organizations' oversight of contractors that provide enrollee benefits, such as prescription drugs and mental health services. We will determine the extent to which MA organizations oversee and monitor their contractors' compliance with regulations and examine the processes they use to ensure that contractors fulfill their obligations. MA organizations are accountable for the performance of the entities with which they contract. MA organizations that delegate responsibilities under their contracts with CMS to other entities must specify in their contracts with those entities provisions that the entities must comply with all applicable Medicare laws, regulations, and CMS instructions. *(42 CFR § 422.504(i)(4)). (OEI; 00-00-00000; expected issue date: FY 2014, new start)*

Beneficiary Appeals—Beneficiary Requests for Reconsideration of Denied Services or Payments (New)

We will review notices of denied requests for services or payments that MA organizations sent to beneficiaries to determine whether the notices clearly explained beneficiaries' right to request reconsiderations and to appeal the ensuing determinations. We will also examine differences between denials of services and payments for which beneficiaries did and did not choose to appeal. MA organizations are required to explain beneficiaries' right to request reconsideration when their requests for medical services or payments for services are denied. (Social Security Act, § 1852(g)(2)(A).) A prior OIG report found that fewer than 1 in 10 beneficiaries requested reconsiderations when their MA organizations denied their requests for medical services. *(OEI; 00-00-00000; expected issue date: FY 2014, new start)*

MA Organization Bid Proposals—CMS Oversight of Data Quality and Accuracy

We will assess the extent to which CMS uses bid reviews to ensure that MA bids are accurate. We will assess 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 Medicare policies and procedures and that issues identified during reviews are sufficiently addressed before bid approval. Our audit will include a review of compliance with the desk review methodology as well as an assessment of the quality of that methodology. CMS's authority to review the aggregate bid amounts submitted by MA plans is at 42 CFR § 422.256. *(OAS; W-00-13-35555; various reviews; expected issue date: FY 2014; new start)*

Duplicate Payments—Cost-Based Health Maintenance Organization Plans Paid Under Capitation Agreements and Fee for Service

We will identify duplicate Medicare capitation and fee-for-service (FFS) payments to selected cost-based Health Maintenance Organization (HMO) plans. Medicare FFS billings that capitated providers submit for services provided to a cost plan's Medicare enrollees will result in duplicate payments to the providers. 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. Federal requirements for costs claimed for 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. *(OAS; W-00-13-35553; various reviews; expected issue date: FY 2013; new start)*

Encounter Data—CMS Oversight of Data Integrity (New)

We will review the extent to which MA encounter data reflecting the items and services provided to MA plan enrollees are complete, consistent, and verified for accuracy by CMS. In 2012, MA encounter data reporting requirements will expand from an abbreviated set of primarily diagnosis data to a more comprehensive set of data. (One Time Notification, Pub. 100-20, CR 7562.) Prior CMS and OIG audits have indicated vulnerabilities in the accuracy of risk adjustment data reporting by MA organizations. *(OEI; 00-00-00000; expected issue date: FY 2014, new start)*

Risk Adjustment Data—Sufficiency of Documentation Supporting Diagnoses

We will determine whether the diagnoses that MA organizations submitted to CMS for use in CMS's risk-score calculations complied with Federal requirements. We will review the medical record documentation to ensure that the documentation supports the diagnoses submitted to CMS. Payments to MA organizations are adjusted on the basis of the health status of each beneficiary. (Social Security Act, §§ 1853(a)(1)(C) and (a)(3).) MA organizations submit risk adjustment data to CMS in accordance with CMS instructions. (42 CFR § 422.310(b).) *(OAS; W-00-09-35078; W-00-10-35078; various reviews; expected issue date: FY 2013; work in progress)*

Risk Adjustment Data—Accuracy of Payment Adjustments

We will determine whether CMS properly adjusted payments to MA plans on the basis of the results of its data validation reviews. Risk adjustment data validation is an annual process of verifying diagnosis codes. (42 CFR §§ 422.308(c) and 422.310(e).) The process affects payments to MA plans. CMS contracts with Quality Improvement Organizations (QIO) or equivalent contractors to verify whether diagnosis codes are supported by medical record documentation. *(OAS; W-00-12-35554; various reviews; expected issue date: FY 2013; work in progress)*

Risk-Adjusted Payments—Medicare Advantage Organizations That Offer Prescription Drug Plans

We will review supporting data for beneficiary diagnosis codes submitted by MA organizations that offer prescription drug plans (MA-PD). We will determine the accuracy of the data and the validity of the diagnosis codes. We will also determine the accuracy of the resultant risk scores and risk-adjusted

monthly payments to MA-PDs. As an incentive to MA-PDs to accept less healthy and higher-risk beneficiaries, CMS uses a risk-adjusted payment methodology to pay a higher monthly subsidy for beneficiaries diagnosed as less healthy. (42 CFR § 423.329(b).) Sponsor-submitted diagnosis codes are used to determine beneficiaries' final risk scores for calculating monthly payments to MA-PDs. MA-PDs' collection of medical records and diagnoses from appropriate sources (i.e., hospital inpatient facilities, hospital outpatient facilities, and physicians) is critical in determining the appropriate diagnosis codes, risk scores, and monthly payments. Federal regulations require MA organizations that offer MA-PD plans to submit to CMS the risk-adjustment-related data that they obtain from those who provide services to the beneficiaries. (42 CFR §§ 422.310(b) and 423.329(b)(3)(ii).) In 2006, CMS adopted the prescription drug hierarchical condition category (RxHCC) model to calculate the risk scores of all Medicare beneficiaries eligible for Part D. *(OAS; W-00-13-35540; various reviews; expected issue date: FY 2013; new start)*

Cost Reports—Accuracy of Expenditures Claimed by Health Care Prepayment Plans

We will review expenditures claimed on cost reports by selected Health Care Prepayment Plans (HCPP). HCPPs are organization, union, or employer-sponsored plans that provide or arrange for some or all of Part B Medicare benefits on a prepayment basis. Payment for Part A services is made on a fee-for-service basis. We will determine whether selected HCPPs' expenditures were reasonable and allowable for reimbursement. HCPPs must submit a final cost report to CMS within 120 days after the close of the contract period. (42 CFR § 417.810(b).) CMS reconciles the final cost report to the monthly payments to determine any liability due CMS or the HCPP. HCPPs are entitled to reimbursement only for expenditures that are reasonable and necessary. (42 CFR § 417.802(a).) *(OAS; W-00-12-35563; various reviews; expected issue date: FY 2013; work in progress)*

Reporting Requirements—CMS Quality Oversight of MA Organization Reporting

We will review CMS's efforts to ensure MA organizations' compliance with CMS's Part C Reporting Requirements and improve the quality of the Part C Reporting Requirements data. We will also review how CMS has used the Reporting Requirements data to monitor, assess, and improve MA organizations' performance. The Part C Reporting Requirements are a group of measures that CMS established. CMS requires MA organizations to develop, compile, evaluate, and report these data to CMS and others (42 CFR 422.516(a)). The information is intended to serve as a resource for CMS to conduct the oversight, monitoring, compliance, and auditing activities that are necessary to ensure the quality of benefits provided by MA organizations. *(OEI; 03-11-00720; expected issue date: FY 2012; work in progress)*

Part D – Prescription Drug Program

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.

Acronyms and Abbreviations for Selected Terms Used in This Section:

HIV—human immunodeficiency virus
PBM—pharmacy benefit manager
PDE—prescription drug event
PDP—prescription drug plan
TrOOP—true out-of-pocket [costs]

Program Integrity—Beneficiary Use of Manufacturer Copayment Coupons (New)

We will identify safeguards pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D. The use of copay coupons in Federal health programs implicates the anti-kickback statute. Coupons may create an incentive for beneficiaries to choose more expensive brand-name drugs over lower-cost generic drugs. A recent survey suggests that beneficiaries are using copay coupons to obtain specific brand-name prescription drugs, causing Medicare to pay more than necessary when less costly versions of the same drugs are available. *(OEI; 05-12-00460; expected issue date: FY 2014; work in progress)*

Program Integrity—Voluntary Reporting of Fraud, Waste, and Abuse by Plan Sponsors (New)

We will review the extent to which plan sponsors offering Part D prescription drug coverage have voluntarily reported Part D antifraud activity data to CMS since 2010. Although the Part D program represents a significant portion of Medicare costs and beneficiary enrollment, little is known about the potential fraud and abuse identified by Part D plan sponsors. Beginning in 2010, sponsors may voluntarily report to CMS aggregate data about their anti-fraud, waste, and abuse activities related to Part D. The data will measure the types of incidents, the sources by which incidents are identified to Part D plan sponsors, as well as the activities taken by sponsors to respond to the incidents. (42 CFR § 423.504(b)(4)(vi)(G).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Pharmacy Benefit Managers—Part D Sponsors' Oversight of Pharmacy Benefit Managers' Administration of Plan Benefits (New)

We will assess Part D sponsors' abilities to oversee the ways in which pharmacy benefit managers (PBM) carry out their responsibilities to administer their formularies and manage prescription drug use. Formularies are listings of brand name and generic medications that are preferred by an insurance plan. Sponsors can delegate the administration of Part D plan benefits, including formularies and utilization management rules, to PBMs. PBMs are required to follow the same guidance and regulations as

sponsors concerning which drugs and therapeutic classes must be covered by the formulary, how the utilization management rules are applied, and which drugs are excluded under Part D. The sponsors remain responsible for the formularies and must ensure that the PBMs are in compliance with all Federal regulations and CMS guidance. (42 CFR § 423.505(i).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Patient Safety and Quality of Care—Part D Drugs Approved and Registered by FDA

We will determine whether the drugs used in the Part D program were previously found to be safe and effective by the Food and Drug Administration (FDA) and whether Part D beneficiaries were dispensed only drugs that FDA had deemed safe and effective. To ensure that drugs are safe and effective, FDA requires that drugs used by the public be approved and registered. (21 U.S.C. § 355). 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. *(OAS; W-00-13-35561; various reviews; expected issue date: FY 2013; new start)*

Drug Payments—Specialty Tier Formularies and Related Cost Sharing (New)

We will analyze the variation in prescription drug plans' (PDP) specialty tier formularies and beneficiary cost-sharing requirements. Drugs placed on specialty tiers are generally expensive; are used to treat rare, chronic conditions; and require special administration, distribution, and handling. A drug's inclusion on a specialty tier is based solely on its cost and not the patient's condition. If CMS sets the cost threshold too low or if PDP sponsors misclassify a drug as a specialty-tier drug, beneficiaries' plan choices, drug adherence, and drug choices could be affected. CMS's requirement for inclusion on specialty tiers is that the drug's monthly cost exceed a certain threshold ($600 in 2012). (*Medicare Prescription Drug Benefit Plan Manual*, Pub. 100-18, Ch. 6, § 30.2.4.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Drug Payments—Characteristics Associated With Atypically High Billing

We will review Part D drugs billed in 2009 to identify characteristics of associated prescribers and beneficiaries. We will identify the prescribers and beneficiaries associated with atypically high billing and determine what, if any, characteristics they have in common. Part D sponsors must submit the information necessary for the Secretary to determine payments to the plans, and the Department of Health and Human Services (HHS) has the right to inspect and audit the sponsors' records pertaining to the information. (Social Security Act, § 1860(D)-15(f)(1).) *(OEI; 02-09-00603; OEI; 02-09-00604; various reviews; expected issue date: FY 2013; work in progress)*

Drug Payments—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. We will also determine the extent to which payments for the sampled Part D claims were correct and were supported. A drug prescribed for a Part D beneficiary will not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. (Social Security Act, § 1860D-2(e)(2)(B).) Medicare Part A covers drugs for beneficiaries who are receiving treatment as

hospital inpatients. Drugs covered under Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with medical equipment, and some vaccines. Medicare Part A and Part B do not cover most outpatient prescription drugs that may be covered under Part D. *(OAS; W-00-11-35409; various reviews; expected issue date: FY 2013; work in progress)*

Drug Payments—Questionable Claims for HIV Drugs

We will describe billing for human immunodeficiency virus (HIV) drugs under Medicare Part D and determine the extent to which Part D billing for HIV drugs was questionable in 2010. Part D covers drugs that are prescribed and used for medically accepted indications. We will identify pharmacies, prescribers, and beneficiaries associated with the questionable Part D billing. *(OEI; 02-11-00170; expected issue date: FY 2013; work in progress)*

Drug Payments—Drugs Dispensed Through Retail Pharmacies With Discount Generic Programs

We will determine whether Part D is receiving the discount drug prices available at certain retail pharmacies. In 2006, several retail chain pharmacies began offering certain generic drugs at discounted prices (e.g., $4 for a 30-day supply). Typically, sponsors should also pay these discounted prices if their contracts include a "usual and customary" clause, which means they pay the lowest price that is consistently charged at a pharmacy. However, some retail pharmacies have restrictions in their discount generic programs that may negate the "usual and customary" requirement and prevent Part D from sharing in these discounted prices. This review will determine the number and percentage of Part D claims that were paid above the discount prices and the dollars associated with these claims. *(OEI; 03-11-00460; expected issue date: FY 2013; work in progress)*

Coverage Gap—Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts

We will review data submitted by Part D sponsors used in calculating the coverage gap discount. We will review the accuracy of the sponsor-submitted data to ensure that beneficiary payments are correct and amounts paid to sponsors are supported. Federal law requires the Secretary to establish a Medicare coverage gap discount program. (Social Security Act, § 1860D-14A, as amended by the Affordable Care Act.) This program provides relief to beneficiaries who are responsible for paying all drug costs during their coverage gaps. Sponsors track beneficiary payment information and the drug cost data necessary to calculate eligibility for the program. *(OAS; W-00-13-35611; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)*

Coverage Gap—Accuracy of Sponsors' Tracking of True Out-of-Pocket Costs

We will review the accuracy of Part D sponsors' tracking of beneficiaries' true out-of-pocket (TrOOP) costs. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. We will determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify to be included to meet thresholds for catastrophic coverage. For 2010, for example, once an enrollee had reached $4,550 in annual TrOOP costs (or $6,440 in total

drug spending), the enrollee had met the annual out-of-pocket threshold and the enrollee's cost sharing was capped—referred to as the catastrophic coverage phase). (Social Security Act, § 1860D-2(b)(4).) *(OAS; W-00-12-35234; various reviews; expected issue date: FY 2013; work in progress)*

Prescription Drug Event Data—Data Submitted for Incarcerated Individuals

We will review PDE data to determine the extent to which sponsors submitted data for prescription drugs for incarcerated individuals under the Medicare Part D program and whether CMS accepted such data. Individuals must live in the service area of a Part D plan to be eligible for benefits under the Part D program. (42 CFR § 423.30(a)(ii).) However, a "Service area" does not include facilities in which individuals are incarcerated. (42 CFR § 423.4.) *(OAS; W-00--12-35577; various reviews; expected issue date: FY 2013; work in progress)*

Sponsors' Bid Proposals—Documentation of Administrative Costs

We will review the sufficiency of Part D sponsors' documentation supporting administrative costs included in their annual bid proposals to CMS. Part D sponsors submit bids for the costs of providing prescription drug coverage, including administrative costs. (Social Security Act, § 1860D-11(b) and 42 CFR § 423.265(c)(1).) Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. *(OAS; W-00-13-35506; various reviews; expected issue date: FY 2013; new start)*

Sponsors' Bid Proposals—Documentation of Investment Income

We will determine the appropriateness of Part D sponsors' documentation supporting investment income included in their annual bid proposals to CMS. Federal regulations require Part D sponsors to submit bids for the costs of providing prescription drug coverage, including returns on investment and profits. (42 CFR § 423.265(c)(1).) 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 2013; work in progress)*

Reconciliation of Payments to Sponsors—Discrepancies Between Negotiated and Actual Rebates

We will compare the rebate amounts negotiated between Part D sponsors (or PBMs) and pharmaceutical manufacturers with the actual rebates paid and analyze any discrepancies. Medicare calculates certain payments to sponsors on the basis of amounts actually paid by the Part D sponsors, net of direct or indirect remunerations (DIR). (42 CFR pt. 423, subpart G.) 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. CMS requires that Part D sponsors submit DIR reports for use in the payment reconciliation process. *(OAS; W-00-11-35508; W-00-12-35508; various reviews; expected issue date: FY 2013; work in progress)*

Reconciliation of Payments to Sponsors—Reopening Final Payment Determinations

We will review CMS's processes for reopening final payment determinations. We will review the data received and CMS's policies, procedures, and instructions. CMS may reopen and revise an initial or reconsidered final payment determination, within time limitations that apply depending on the reason for reopening. (42 CFR § 423.346(a).) CMS reopened final payment determinations for 2006 for all Part D sponsors. In December 2010, CMS announced that it will reopen previous years' Part D payment reconciliations. CMS allowed sponsors to request reopening and to submit additional PDE data and DIR data. *(OAS; W-00-13-35621; various reviews; expected issue date: FY 2013; new start)*

Risk Sharing and Risk Corridors—Savings Potential of Adjusting Risk Corridors

We will analyze risk-sharing payments between the Government and Part D sponsors to determine whether cost savings could have been realized had the existing risk corridor thresholds remained at 2006 and 2007 levels. Risk corridors determine the amount of unexpected profits or losses that the Federal Government and sponsors share. CMS has the authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. (Social Security Act § 1860D-15.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Information Systems—Supporting Systems at Small- and Medium-Size Plans and Plans New to Medicare

We will review the implementation of systems that support Part D prescription drug benefit plans and the 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 the general and application controls that are critical to support these systems' 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, true out-of-pocket (TrOOP) costs, and PDE operations. This is a followup on issues identified in prior reviews of larger plans. *(OAS; W-00-13-41013; various reviews; expected issue date: FY 2013; new start)*

The *Work Plan* is one of OIG's three core publications. The *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

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Part III
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) 2013 address prescription drugs, long-term and community care, other services, program integrity and accountability, administration, information systems, and managed care.

Medicaid Prescription Drug Reviews

Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price
FUL—Federal upper limit
MCO—managed care organization
State MAC—State Maximum Allowable Cost
URA—unit rebate amount

Patient Safety and Quality of Care—Claims for and Use of Atypical Antipsychotic Drugs Prescribed to Children in Medicaid (New)

We will determine the extent to which children ages 18 and younger had Medicaid claims for atypical antipsychotic drugs during the selected timeframe. On the basis of medical record reviews, we will also determine the extent to which the atypical antipsychotic drug claims were for off-label uses and for indications not listed in one or more of the approved drug compendia. *(OEI; 07-12-00320; expected issue date: FY 2014; work in progress)*

Drug Pricing—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 the Medicaid drug rebate program and for drug reimbursement. We will also determine whether the methodologies are consistent with statutes, regulations, and manufacturers' rebate agreements and the CMS *Drug Manufacturer Release(s)*. Several changes to the Medicaid drug rebate statute and to Medicaid reimbursement for multiple-source drugs involve revisions in the calculation of the AMP and the best price. The changes will affect amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program and will affect the Federal upper limit (FUL) for drug reimbursement. (Deficit Reduction Act of 2005 (DRA), § 6001.) CMS uses the AMP and the best price to determine Unit Rebate Amounts (URA). Manufacturers must pay

rebates to States based on the URAs. *(OAS; W-00-11-31202; various reviews; expected issue date: FY 2013; work in progress)*

Drug Pricing—State Maximum Allowable Cost Programs

We will review State Maximum Allowable Cost (State MAC) programs to determine how State MAC lists are developed, how State MAC prices are set, and how State MAC prices compare to the FUL amounts. This review will compare State MAC programs to determine which ones are most successful in reducing Medicaid expenditures. To take advantage of lower market prices for certain generic products, States use the FUL list and/or State MAC programs in determining reimbursement amounts. State MAC programs are designed to ensure that Medicaid pays appropriate prices for generic drugs. In 2004, a CMS-contracted study looked at State MAC programs in five States and found considerable variation between these programs and the FUL program. The study concluded that expansion of existing State MAC programs and implementation of new ones could contribute to cost containment efforts nationwide. *(OEI; 03-11-00640; expected issue date: FY 2013; work in progress)*

Drug Pricing—Manufacturer Compliance With AMP Reporting Requirements

We will review manufacturer compliance with AMP reporting requirements and determine what percentage of manufacturers complied with the requirements in 2011. We will determine whether stepped-up enforcement actions by CMS and OIG are reflected in increased compliance by manufacturers. A previous OIG review found that in 2008 more than half of the drug manufacturers that were required to submit quarterly AMPs to CMS failed to comply with reporting requirements in at least one quarter. Manufacturers were even less likely to comply with monthly AMP reporting requirements, with more than three-fourths submitting late, incomplete, or no AMPs in at least 1 month of 2008. After the release of this report, CMS and the Office of Inspector General (OIG) worked to increase manufacturer compliance. Price-reporting obligations for certain drug manufacturers, including the obligation to report AMP data to CMS quarterly and monthly, are set forth in the Social Security Act, § 1927(b)(3), and 42 CFR §§ 447.510(a) and (d). *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Drug Pricing—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. We will also examine CMS's policies and procedures for ensuring that Medicaid is billed properly under 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 require, with certain exceptions, that each State Medicaid agency's reimbursement for covered generic outpatient drugs without established upper limits 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. (42 CFR § 447.512.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Manufacturer Rebates—States Collection of Rebates on Physician-Administered Drugs (New)

We will determine whether States have established adequate accountability and internal controls for collecting Medicaid rebates on physician-administered drugs. We will assess States' processes for collecting national drug code information on claims for physician-administered drugs and subsequent processes for billing and collecting rebates. To be eligible for Federal matching funds, States are required to collect rebates on covered outpatient drugs. (Social Security Act, § 1927(a).) Pursuant to the Deficit Reduciton Act of 2005 (DRA), States collect and submit data to CMS, including national drug codes that identify drug manufacturers, thereby allowing them to invoice manufacturers responsible for paying rebates. The DRA provision was phased in beginning January 1, 2006. Prior OIG audit and evaluation work identified concerns with certain States' implementation of the provision. *(OAS; W-00-12-31400; various reviews; expected issue date: FY 2013; work in progress)*

Manufacturer Rebates—States' Collection of Supplemental Rebates (New)

We will determine whether increases in the basic Federal minimum rebate amount required by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act)are being collected from drug manufacturers by States. We will also determine the dollar amount of supplemental drug rebates States negotiated and collected between 2008 and 2011. State Medicaid agencies negotiate supplemental rebate agreements (SRA) with drug manufacturers to further reduce expenditures. Pursuant to SRAs, drug manufacturers agree to pay States rebates higher than (i.e., in addition to) the rebates required under the basic Federal rebate agreement. On the basis of annual rebate data, we estimated that between 2006 and 2011, SRAs saved Medicaid an additional $1 billion per year, on average. Supplemental rebates might be reduced because manufacturers may be less willing to pay them because of the increases in the basic Federal rebates. *(OEI; 03-12-00520; expected issue date: FY 2013; work in progress)*

Manufacturer Rebates—Impact of the Deficit Reduction Act of 2005 on Rebates for Authorized Generic Drugs

We will review drug-pricing and rebate data that drug manufacturers report to State Medicaid agencies to determine the extent to which manufacturers are reporting pricing data and paying rebates for authorized generic drugs. Federal regulations define "authorized generics" 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. (42 CFR § 447.506.) We will also determine to what extent Medicaid rebates have changed since the implementation of certain provisions and whether the number of new authorized generics changed after implementation. 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 might increase the amount of rebates due from single-source drugs' primary manufacturers. Rebates to States from manufacturers are based in part on the difference between the AMP of a drug and the best price of the drug. (Social Security Act, § 1927.) The definition of "best price" was clarified to include the lowest

price available to any entity for any such drug sold under a new drug application. (DRA, § 6001.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Manufacturer Rebates—Zero-Dollar Unit Rebate Amounts

We will determine whether States have procedures to track and collect drug rebates for drugs with zero-dollar URAs. We will determine each State's rebate collection rate for high-dollar drugs with zero-dollar URAs in the fourth quarter of 2010 and the first quarter of 2011. Previous OIG work found that States may not be collecting all possible drug rebates from manufacturers when CMS is unable to calculate URAs. URAs are based on pricing data reported by drug manufacturers. 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. If manufacturers have not reported the necessary data for the calculations, the URAs for such products are listed as $0, i.e., zero-dollar URAs. In those cases, manufacturers are responsible for calculating URAs and the appropriate rebate payments for the drugs. *(OEI; 03-11-00470; expected issue date: FY 2013; work in progress)*

Manufacturer Rebates—New Formulations of Existing Drugs

We will review drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs. We will also determine whether manufacturers have correctly identified all their drugs that are subject to a new provision in law. A recent change increases the additional rebate for drugs that are new formulations of existing drugs if certain conditions are met. (Social Security Act, § 1927(c)(2)(C), as amended by the Affordable Care Act, § 2501.) Manufacturers pay the additional rebate that is based on the existing drug if it is higher than the additional rebate that is based on the new formulation. *(OAS; W-00-13-31451; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)*

Manufacturer Rebates—States' Efforts and Experiences With Resolving Rebate Disputes

We will review the causes of and resolutions to Medicaid rebate disputes and the methods States use to resolve them. In 2008, Medicaid spent approximately $24 billion on prescription drugs and received approximately $8 billion in rebates. Previous OIG reports have found large amounts in uncollected rebates. Federal law requires drug manufacturers to enter into drug rebate agreements as a prerequisite to coverage of their drugs under Medicaid State plans. (Social Security Act, § 1927(a).) *(OEI; 05-11-00580; expected issue date: FY 2013; work in progress)*

Manufacturer Rebates—Federal Share of Rebates

We will review States' reporting of the Federal share of Medicaid rebate collections. We will determine whether States are correctly identifying and reporting the increases in rebate collections. Three new provisions in law should result in increased rebate payments by drug manufacturers to the States. The provisions will increase the minimum rebate percentages, increase the additional rebate on new formulations of existing drugs, and allow for rebates on drugs dispensed through Medicaid managed care organizations (MCO). (Social Security Act, §§ 1927(b) and (c), as amended by the Affordable Care Act, § 2501.) Any increase in rebate collections that results from these new provisions is not shared with

the States but is considered 100 percent Federal. (Social Security Act, § 1927(b)(1)(C).)
(OAS; W-00-13-31450; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)

Home, Community, and Personal Care Services

Acronyms and Abbreviations for Selected Terms Used in This Section:

CDT—continuing day treatment
FFP—Federal financial participation
HCBS—home and community-based services
HHA—home health agency
PCS—personal care services

Home Health Services—Duplicate Payments by Medicare and Medicaid (New)

We will review Medicaid payments by States for Medicare-covered home health services to determine the extent to which both Medicare and Medicaid have paid for the same services. States are required to offer home health services to Medicaid beneficiaries who meet the States' criteria for nursing home coverage. (Social Security Act, § 1902(a)(10)(D).) Medicaid is the payer of last resort, paying only after all other third-party sources have met their legal obligation to pay. (Social Security Act, § 1902(a)(25).)
(OAS; W-00-13-31305; various reviews; expected issue date: FY 2014; new start)

Home Health Services—Screenings of 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. Examples of health screenings can include vaccinations for hepatitis and influenza. Home health agencies (HHA) provide health care services to Medicaid beneficiaries while visiting beneficiaries' homes. HHAs 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. (Social Security Act, §1891(a)(5).) 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; W-00-12-31387; various reviews; expected issue date: FY 2013; work in progress)*

Home Health Services—Provider Compliance and Beneficiary Eligibility

We will review HHA claims to determine whether providers have met applicable criteria to provide services and whether beneficiaries have met eligibility criteria. 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. The standards and conditions for HHAs' participation in Medicaid are at 42 CFR § 440.70 and 42 CFR pt. 484. *(OAS; W-00-10-31304; W-00-11-31304; W-00-12-31304; various reviews; expected issue date: FY 2013; work in progress)*

Home Health Services—Homebound Requirements

We will review CMS policies and practices for reviewing the sections of Medicaid State plans related to eligibility for home health services and describe how CMS intends to enforce compliance with appropriate eligibility requirements for home health services. We will also identify the number of States that violate Federal regulations by inappropriately restricting eligibility for home health services to homebound recipients. States must ensure that the services available to any individual in a categorically or medically needy group are comparable to the services available to the entire group. (42 CFR § 440.240(b).) States may not arbitrarily deny or reduce the amount, duration, or scope of a required service because of a beneficiary's diagnosis, type of illness, or condition. (42 CFR § 440.230(c).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Medicaid Waivers—Quality of Care Provided Through Waiver Programs

We will determine the extent to which Medicaid home and community-based services (HCBS) beneficiaries have service plans, receive the services in their plans, and receive services from qualified providers. Pursuant to the Social Security Act, § 1915(c), States are permitted to waive certain Medicaid requirements to provide a wide range of services to persons who would otherwise receive institutional care. In addition, States offering HCBS waiver programs must provide adequate planning for services and provide those services through qualified providers, as well as ensure the health and welfare of beneficiaries. Prior OIG work found vulnerabilities in State systems to ensure the quality of care provided to HCBS beneficiaries. (Social Security Act, §§ 1915 (c)(1) and 1902(a)(23).) *(OEI; 02-11-00700; expected issue date: FY 2013; work in progress)*

Medicaid Waivers—Supported Employment Services (New)

We will review Medicaid payments by States for supported employment services to determine whether such services were rendered in accordance with Federal and State requirements. With approval from CMS, States are authorized to waive certain Medicaid requirements, allowing a State to offer home and community-based services to State-specified target group(s) of Medicaid beneficiaries. (Social Security Act § 1915(c).) Supported employment helps individuals with the most significant disabilities to become competitively employed. Authorized services include vocational or job-related discovery or assessment, person-centered employment planning, job placement, training, and other workplace support services. (CMS Informational Bulletin, Sept. 16, 2011). Prior OIG work has identified significant unallowable Medicaid payments made by a State for supported employment services not covered under the waiver. *(OAS; W-00-12-31463; various reviews; expected issue date: FY 2013; work in progress)*

Medicaid Waivers—Adult Day Health Care Services (New)

We will review Medicaid payments by States for adult day care services to determine whether the payments complied with certain Federal and State requirements. Adult day health care programs provide health, therapeutic, and social services and activities to program enrollees. Beneficiaries enrolled in adult day health care programs must meet eligibility requirements, and services must be furnished in accordance with a plan of care. Medicaid allows payments for adult day health care

through various authorities, including HCBS waivers. (Social Security Act, § 1915, and 42 CFR § 440.180.) *(OAS; W-00-12-31386; various reviews; expected issue date: FY 2013; work in progress)*

Medicaid Waivers—Unallowable Room and Board Costs (New)

We will determine whether selected State Medicaid agencies claimed Federal reimbursement for unallowable room and board costs for home and community-based services (HCBS) provided pursuant the Social Security Act, § 1915(c). We will determine whether payments made by States for HCBS included the cost of room and board and the method used. Medicaid covers the cost of HCBS provided under a written plan of care to individuals in need of the services but does not allow for payment of room and board costs. (42 CFR §§ 441.301(b) and 441.310(a).) States may use various methods to pay for these services, such as a settlement process based on annual cost reports, or prospective rates with rate adjustments based on cost report data and cost trending factors. *(OAS; W-00-13-31465; various reviews; expected issue date: FY 2014; new start)*

School-Based Services—Students With Special Needs

We will review Medicaid payments by States for school-based services to determine whether the costs claimed for such services are reasonable and properly allocated. Medicaid may pay for medical services provided to students with special needs pursuant to individualized education plans. (Social Security Act, § 1903(c).) Direct medical services may include physical therapy; occupational therapy; speech therapy; and nursing, personal care, psychological, counseling, and social work services. Some States use random moment time studies to develop school-based health service payment rates. Costs claimed must be reasonable and be allocated according to the benefit received. (OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*.) *(OAS; W-00-11-31391; W-00-12-31391; various reviews; expected issue date: FY 2013; work in progress)*

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 FFP. Previous OIG work in one State found improperly claimed Medicaid reimbursement for individuals who were no longer residing in a community residence. To be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. (Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Attachment A, § C.1.c.) *(OAS; W-00-10-31087; W-00-11-31087; various reviews; expected issue date: FY 2013; work in progress)*

Continuing Day Treatment Mental Health Services

We will review Medicaid payments to continuing day treatment (CDT) providers in one State to determine whether Medicaid payments by the State to CDT providers in that State are adequately supported. 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. 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. To be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. (Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Att. A, § C.1.c.) *(OAS; W-00-11-31128; W-00-12-31128; various reviews; expected issue date: FY 2013; work in progress)*

Personal Care Services—Compliance With Payment Requirements

We will review Medicaid payments by States for personal care services (PCS) to determine whether States have appropriately claimed the FFP. Medicaid covers PCS only for those who are not inpatients or residents of hospitals, nursing facilities, institutions for mental diseases, or intermediate care facilities for individuals with developmental disabilities. (Social Security Act, § 1905(a)(24).) PCS must be authorized by a physician or (at the option of the State) 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. Beginning January 1, 2007, States are allowed to pay individuals for self-directed personal assistance services for the elderly and disabled, including PCS that could be provided by a family member. (DRA, § 6087.) *(OAS; W-00-10-31035; W-00-11-31035; W-00-12-31035; various reviews; expected issue date: FY 2013; work in progress)*

Other Medicaid Services, Equipment and Supplies

Acronyms and Abbreviations for Selected Terms Used in This Section:

EPSDT—Early and Periodic Screening, Diagnostic, and Treatment (services)
FFP—Federal financial participation
OMB—Office of Management and Budget

Nursing Facility Services—Communicable Disease Care (New)

We will review claims by nursing facilities for communicable disease care to determine whether they complied with Federal and State requirements. We will also examine patient safety consequences associated with nursing homes' failure to comply with related communicable disease requirements. Nursing facilities are required to establish and maintain infection control programs designed to provide safe, sanitary, and comfortable environments and to help prevent the development and transmission of diseases and infections. The facilities' infection control programs, under which they investigate, control, and prevent infections, decide what procedures, such as isolation, should be applied to individual residents and maintain records of incidents and corrective actions related to infections. (42 CFR § 483.65). A prior audit indicated that States are paying nursing facilities for unallowable claims related to communicable disease care. *(OAS; W-00-13-31466; various reviews; expected issue date: FY 2014; new start)*

Dental Services for Children—Inappropriate Billing (New)

We will review Medicaid payments by States for dental services to determine whether States have properly claimed Federal reimbursement. 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. (Social Security Act, §§ 1905(a)(4)(B) and 1905(r).) Federal regulations define "dental services" as diagnostic, preventative, or corrective procedures provided by or under the supervision of a dentist. (42 CFR § 440.100.) 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. Prior work indicates that some dental providers may be inappropriately billing for services. *(OAS; W-00-10-31135; W-00-11-31135; W-00-12-31135; various reviews; expected issue date: FY 2013; work in progress)*

Dental Services for Children—Billing Patterns in Five States (New)

We will review billing patterns of pediatric dentists and their associated clinics in five selected States. Medicaid covers comprehensive dental care for approximately 30 million low-income children through the EPSDT benefit. Under EPSDT, States must cover dental services and dental screening services for children. OIG investigations have identified numerous vulnerabilities with pediatric dental care, particularly with the care provided by certain for-profit dental chains. *(OEI; 02-12-00330; expected issue date: FY 2014; work in progress)*

Hospice Services—Compliance With Reimbursement Requirements

We will determine whether Medicaid payments by States for hospice services complied with Federal reimbursement requirements. Medicaid may cover hospice services for individuals with terminal illnesses. (Social Security Act, § 1905(o)(1)(A).) 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 patients' illness and death. An individual, having been certified as terminally ill, may elect hospice coverage and waive all rights to certain otherwise covered Medicaid services. (CMS's *State Medicaid Manual*, Pub. 45, § 4305.) In FY 2010, Medicaid payments for hospice services totaled more than $816 million. *(OAS; W-00-11-31385; W-00-12-31385; various reviews; expected issue date: FY 2013; work in progress)*

Family Planning Services—Claims for Enhanced Federal Funding

We will review family planning services in several States to determine whether States improperly claimed enhanced Federal funding for such services and the resulting financial impact on Medicaid. Previous OIG work found improper claims for enhanced funds for family planning services. States may claim Federal reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. (Social Security Act, § 1903(a)(5).) *(OAS; W-00-10-31078; W-00-11-31078; W-00-12-31078; various reviews; expected issue date: FY 2013; work in progress)*

Transportation Services—Compliance With Federal and State Requirements

We will review Medicaid payments by States to providers for transportation services to determine the appropriateness of the payments for such services. Federal regulations require States to ensure necessary transportation for Medicaid beneficiaries to and from providers. (42 CFR § 431.53.) Each State may have different Medicaid coverage criteria, reimbursement rates, rules governing covered services, and beneficiary eligibility for services. *(OAS; W-00-11-31121; W-00-12-31121; various reviews; expected issue date: FY 2013; work in progress)*

Health-Care-Acquired Conditions—Prohibition on Federal Reimbursements

We will determine whether selected States made Medicaid payments for health-care-acquired conditions and provider-preventable conditions and quantify the amount of Medicaid payments for such conditions. As of July 1, 2011, Federal payments to States under the Social Security Act, § 1903, are prohibited for any amounts expended for providing medical assistance for health-care-acquired conditions. (Affordable Care Act, § 2702.) Federal regulations prohibiting Medicaid payments by States for services related to health-care-acquired conditions and provider-preventable conditions are at 42 CFR § 447.26. *(OAS; W-00-13-31452; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)*

Medical Equipment and Supplies—Potential Savings From the Competitive Bidding Program (New)

We will determine cost savings for Medicare and Medicaid that could result from expanded use of competitive bidding for medical equipment and supplies. Medicare has authority to expand beyond the largest metropolitan statistical areas currently covered by the Medicare's competitive bidding to program. (Social Security Act, § 1847(a)(1)(B)(i).) Use of payment rates established through competitive bidding could result in costs savings for State Medicaid programs, which establish their own payment rates for medical equipment and supplies. (Social Security Act, § 1902(a)(30)(A).) *(OEI; 06-12-00470; 00-00-0000; expected issue date: FY 2014; work in progress)*

Medical Equipment and Supplies—Opportunities To Reduce Medicaid Payment Rates for Selected Items (New)

We will determine whether opportunities exist for lowering Medicaid payments for selected items of medical equipment and supplies. We will also determine the amount of Medicaid savings that could be achieved for selected items through the use of rebates, competitive bidding, or other means. Prior work found that State Medicaid programs negotiated rebates with manufacturers that reduced net payments for home blood-glucose test strips. Similarly, CMS reduced Part B rates of payment in selected areas through competitive bidding. *(OAS; W-00-12-31390; various reviews; expected issue date: FY 2013; new start)*

Medical Equipment and Supplies—Opportunities To Reduce Medicaid Payment Rates for Blood-Glucose Test Strips (New)

We will determine whether opportunities exist for lowering payments for home blood-glucose test strips provided under the Medicaid program. We will also review the rebates that some States collected on test strips to determine whether the States properly reimbursed the Federal share of the rebates. Prior work found that State Medicaid programs negotiated rebates with manufacturers that reduced net payments for test strips. Similarly, CMS reduced Part B rates of payment in selected areas through competitive bidding. We will determine the amount of Medicaid savings that could be achieved through a reduction in payments for blood-glucose test strips through rebates, competitive bidding, or other means. *(OAS; W-00-12-31390; W-00-13-31390; various reviews; expected issue date: FY 2013; work in progress and new start)*

Medical Equipment and Supplies—States' Efforts To Control Costs for Disposable Incontinence Supplies (New)

We will review the extent to which State Medicaid programs have implemented measures aimed at controlling costs for disposable incontinence supplies. We will also determine the cost savings created by these measures and the potential cost savings for States that have not yet implemented them.
A State Medicaid plan must provide for the inclusion of home health services (and related supplies) to Medicaid beneficiaries who meet the States' criteria for nursing home coverage. (Social Security Act, § 1902(a)(10)(D).) Federal regulations state that medical supplies, equipment, and appliances suitable for use in the home are required home health services. (42 CFR § 440.70(b)(3).) *(OEI; 07-12-000710 expected issue date: FY 2014; work in progress)*

State Management of Medicaid

Acronyms and Abbreviations for Selected Terms Used in This Section:

CPE—certified pubic expenditures
Form CMS-64—Quarterly Medicaid Statement of Expenditures
MIP—Medicaid Integrity Program
RAC—recovery audit contractor

State Use of Provider Taxes To Generate Federal Funding

We will review State health-care-related taxes imposed on various Medicaid providers to determine whether the taxes comply with applicable Federal requirements. Our work will focus on the mechanism States use to raise revenue through provider taxes and determine the amount of Federal funding generated. Previous OIG work has raised concerns about States' use of health-care-related taxes.
Many States finance a portion of their Medicaid spending by imposing taxes on health care providers. Health-care-related taxes are defined by Federal regulations that set forth the standard for permissible health-care-related taxes. (42 CFR §§ 433.55 and 433.68.) *(OAS; W-00-12-31455; various reviews; expected issue date: FY 2013; work in progress)*

State-Operated Facilities—Reasonableness of Payment Rates

We will determine whether Medicaid payment rates to State-operated facilities are reasonable and are in accordance with Federal and State requirements. We will determine in selected States the extent to which payments to providers may be excessive. Payments for services must be consistent with efficiency, economy, and quality of care. (Social Security Act, §1902(a)(30)(A).) Federal regulations state that a cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. (2 CFR § 225, Appendix A, § C. 2.) *(OAS; W-00-12-31398; various reviews; expected issue date: FY 2013; work in progress)*

State Upper-Payment-Limit-Related Supplemental Payments to Private Hospitals

We will review supplemental payments by States to private hospitals to determine whether errors exist involving such payments. Federal funds are not available for Medicaid payments that exceed applicable upper payment limits (UPL). Prior OIG work involving supplemental payments to public facilities found errors. Federal regulations 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. (42 CFR § 447.272.) States are permitted to make payments under their approved plans to hospitals up to the applicable aggregate UPL, and many States use this flexibility to make lump-sum supplemental payments based on the difference between the ordinary rate and the UPL. Medicaid agencies pay for inpatient hospital and long-term-care services using rates determined in accordance with methods and standards specified in their approved State plans. (42 CFR § 447.253(i).) *(OAS; W-00-10-31126; W-00-11-31126; various reviews; expected issue date: FY 2013; work in progress)*

State Use of Incorrect FMAP for Federal Share Adjustments (New)

We will review States' Medicaid claims records to determine whether the States used the correct Federal Medical Assistance Percentage (FMAP) when processing claim adjustments reported on the Medicaid Quarterly Expenditure Report (Form CMS-64). We reviewed the claim adjustments reported on Form CMS-64 for one State and determined that it did not use the correct FMAP for the majority of adjustments. The Federal Government is required to reimburse a State at the FMAP rate in effect at the time the expenditure was made (Social Security Act, §1903(a)(1).) *(OAS; W-00-12-31460; various reviews; expected issue date: FY 2013; work in progress)*

State Allocation of Medicaid Administrative Costs

We will review administrative costs claimed by several States to determine whether they were properly allocated and claimed or directly charged to Medicaid. Prior reviews in one State noted problems with the State's administrative costs. The Federal share of Medicaid administrative costs is typically 50 percent, with enhanced rates for specific types of costs. Federal cost sharing for the proper and efficient administration of Medicaid State plans is provided by the Social Security Act, § 1903(a)(7). Administrative costs are 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; W-00-12-31123; various reviews; expected issue date: FY 2013; work in progress)*

State Quarterly Expenditure Reporting on Form CMS-64—CMS Oversight

We will examine CMS's oversight of State quarterly expenditure reporting on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64). We will also identify opportunities to improve the accuracy of such reporting. Previous OIG and Government Accountability Office (GAO) studies have shown significant inaccuracies in the reporting of State expenditures, thus affecting the Federal reimbursement match. The Form CMS-64 is a detailed accounting of expenditures that the Federal Government uses to reimburse States under Title XIX of the Social Security Act. Federal regulations require each State to submit the Form CMS-64 as a report of actual quarterly expenditures. (42 CFR § 430.30(c).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

State Medicaid Monetary Drawdowns—Reconciliation With Form CMS-64

We will review the Medicaid monetary drawdowns that States received from the Federal Reserve System to determine whether they were supported by actual expenditures reported by the States on the Form CMS-64. States draw monetary advances against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee throughout a quarter. (42 CFR § 430.30(d)(4).) After the end of each quarter, States must submit the Form CMS-64, which shows the disposition of Medicaid funds used to pay for actual medical and administrative expenditures for the reporting period. (42 CFR § 430.30(c).) The amounts reported on the Form CMS-64 should reconcile the monetary advances for a quarter. *(OAS; W-00-12-31456; various reviews; expected issue date: FY 2013; work in progress)*

State Reporting of Medicaid Collections on Form CMS-64

We will determine whether States accurately captured Medicaid collections on their Form CMS-64, as well as returned the correct Federal share related to those collections. Previous OIG work revealed multiple errors in compiling collection amounts on the Form CMS-64, particularly errors related to the calculation of the Federal share returned. The States should report collections on lines 9a-9e of the Form CMS-64. These collections decrease the total expenditures reported for the period. (42 CFR §§ 433.154 and 433.320.) Instructions for line 9 indicate that States should compute the Federal share of collections at the rate at which CMS matched the original expenditures. (CMS's *State Medicaid Manual*, § 2500.1(B).) *(OAS; W-00-12-31457; various reviews; expected issue date: FY 2013; work in progress)*

State Actions To Address Vulnerabilities Identified During CMS Reviews

We will review corrective actions that State Medicaid agencies have implemented to address the findings and recommendations from State Medicaid program integrity reviews conducted by CMS. We will determine why States have not implemented all corrective actions, examine the followup CMS performed to ensure that corrective actions were taken by States, and examine the evidence CMS reviews to ensure that corrective actions were implemented. As part of the Medicaid Integrity Program (MIP), CMS conducts a triennial review of each State's program integrity functions to assess their effectiveness and compliance with Federal requirements. CMS issues to the State a final report of findings and recommendations and requires the State to provide a corrective action plan within 30 days

of the report issuance. The MIP was established by the Deficit Reduction Act of 2005 (DRA), § 6034. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

State Buy-In of Medicare Coverage—Eligibility Controls

We will review States' Medicaid buy-in programs for Medicare Part B to 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. States may enroll dual-eligible beneficiaries in Part B. States that operate buy-in programs pay the Part B premium for each dual-eligible individual that they enroll in Part B. (Social Security Act, § 1843, and 42 CFR §§ 407.40 through 407.42.) *(OAS; W-00-10-31220; W-00-11-31220; W-00-12-31220; various reviews; expected issue date: FY 2013; work in progress)*

State Medicaid Payments for Medicare Deductibles and Coinsurance (New)

We will determine whether States claimed Federal reimbursement for Medicaid payments for Medicare deductibles and coinsurance in excess of amounts authorized in the State plans. State Medicaid plans require coordination of Medicaid with Medicare and provide methods and standards for claim payments. Claims payment is based on the eligibility group of a dual-eligible individual and a comparison between Medicare's payment and the State Medicaid plan rate. (Social Security Act, § 1902(a)(10)(E), § 1902(n)(2), and § 1902(a)(30)(A), and State plan Supplement 1 to Attachment 4.19-B). Prior OIG audits found problems with Medicaid payments for Medicare deductibles and coinsurance. *(OAS; W-00-13-31464; various reviews; expected issue date: FY 2014; new start)*

State Cost Allocations That Deviate From Acceptable Practices (New)

We will review public assistance cost allocation plans and processes for selected States to determine whether the States claimed Medicaid costs that were supported and allocated on the basis of random moment sampling systems (RMSS) that deviated from acceptable statistical sampling practices. RMSSs must be documented so as to support the propriety of the costs assigned to Federal awards. (OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Attachment A, §C.1.j.) A State must claim FFP for costs associated with a program only in accordance with its approved cost allocation plan (45 CFR § 95.517(a).) Prior OIG reviews of school-based and community-based administrative claims found significant unallowable payments when payments were based on RMSS. *(OAS; W-00-12-31467; various reviews; expected issue date: FY 2014; work in progress)*

State Recovery Audit Contractor Performance and Results (New)

We will review the early performance and results of Recovery Audit Contractors (RAC) in State Medicaid programs. States were required to establish programs to contract with RACs to audit Medicaid payments by the end of 2010. (Affordable Care Act, § 6411.) The RACs were initially established to conduct postpayment reviews to identify Medicare overpayments and underpayments. The Affordable Care Act expanded the use of RACs to Medicaid. Previous OIG and GAO work identified problems with Medicare RACs' process for identifying and reporting potential fraud and with CMS's handling of vulnerabilities identified by RACs. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

State Enrollment and Monitoring of Medical Equipment Suppliers (New)

We will review State Medicaid agencies' processes for enrolling and monitoring medical equipment suppliers. We will conduct site visits to determine whether such suppliers complied with their State Medicaid agencies' enrollment standards. In a recent OIG review of Medicaid medical equipment suppliers, more than 15 percent of the suppliers failed to meet at least one enrollment standard. *(OAS; W-00-12-31468; various reviews; expected issue date: FY 2014; work in progress; Affordable Care Act)*

State Determinations of Hospital Provider Eligibility and Program Participation (New)

We will determine whether States appropriately determined hospital providers' eligibility for Medicaid reimbursement. Hospital providers are required to meet Medicare program participation requirements to receive Medicaid funding. (42 CFR § 440.10.) Previous reviews have found significant unallowable Medicaid payments to hospitals that did not meet Medicare program eligibility requirements as part of the disproportionate share hospital (DSH) program, which assists hospitals serving a high proportion of low-income patients. *(OAS; W-00-12-31301; W-00-13-31301; various reviews; expected issue date: FY 2013; work in progress)*

State Compliance With Estate Recovery Provisions of the Social Security Act (New)

We will determine whether States complied with requirements for recoveries from deceased Medicaid beneficiaries' estates. We will also determine whether States properly reported any such recoveries on Form CMS-64. States must, with certain exceptions, recoup medical assistance costs from the estates of deceased beneficiaries who were institutionalized. (Social Security Act, § 1917(b)(1).) 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. Beneficiaries' estates include the real and personal property in the estates under the State's probate laws. (Social Security Act, § 1917(b)(4).) CMS requires that the amounts collected from deceased Medicaid beneficiaries' estates be reported on Form CMS -64 as reductions to total Medicaid expenditures. (CMS's *State Medicaid Manual*, Pub. No. 45, pt. 2, § 2500.1.) *(OAS; W-00-12-31113; W-00-13-31113; various reviews; expected issue date: FY 2013; work in progress)*

State Compliance With the Money Follows the Person Demonstration Program (New)

We will review selected States' compliance with the Money Follows the Person (MFP) rebalancing demonstration program. The MFP program was authorized by the Deficit Reduction Act of 2005 (DRA), § 6071, and was extended by the Affordable Care Act, § 2403. The MFP program was designed to assist States in rebalancing their long-term-care systems and to help Medicaid enrollees transition from institutions to the community. The MFP program is authorized through September 30, 2016, at up to $4 billion. We will determine whether States followed applicable requirements for participating in the MFP program, such as providing qualified services to eligible participants. *(OAS; W-00-12-31461; various reviews; expected issue date: FY 2013; work in progress)*

State Terminations of Providers Terminated by Medicare or by Other States

We will review States' compliance with a new requirement that State Medicaid agencies terminate providers that have been terminated under Medicare or by another State. We will determine whether such providers are terminated by all States, assess the status of the supporting information-sharing system, determine how CMS is ensuring that States share complete and accurate information, and identify obstacles States face in complying with the termination requirement. This new requirement became effective January 1, 2011. (Social Security Act, § 1902(a)(39), as amended by the Affordable Care Act, § 6501.) (Affordable Care Act, § 6401(b)(2).) *(OEI; 06-12-00030; expected issue date: FY 2014; work in progress; Affordable Care Act)*

State Payments to Federally Excluded Providers and Suppliers

We will review Medicaid payments by States to providers and suppliers to determine the extent to which payments were made for services rendered during periods of exclusion from Medicaid. Excluded providers and suppliers are not permitted to receive payments for services rendered during periods of exclusion. (Social Security Act, §§ 1128, 1128A, and 1156, and 42 CFR § 1001.1901.) *(OAS; W-00-11-31337; W-00-12-31337; various reviews; expected issue date: FY 2013; work in progress)*

State Compliance With Federal Certified Public Expenditures Regulations

We will determine whether States are complying with Federal regulations for claiming certified public expenditures (CPE), which are normally generated by local governments as part of their contribution to the coverage of Medicaid services. States may claim CPEs to provide the States' shares in claiming Federal reimbursement as long as the CPEs comply with Federal regulations and are being used for the required purposes. (42 CFR § 433.51 and 45 CFR § 95.13.) *(OAS; W-00-12-31110; various reviews; expected issue date: FY 2013; work in progress)*

State Procedures for Identifying and Collecting Third-Party Liability Payments

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. Many Medicaid beneficiaries may have additional health insurance through third-party sources, such as employer-sponsored health insurance. OIG work in 2006 described problems that State Medicaid agencies had in identifying and collecting third-party payments. States are to take all reasonable measures to ascertain the legal liabilities of third parties with respect to health care items and services. (Social Security Act, § 1902(a)(25).) The DRA, § 6035, clarified the provision for entities defined as third-party payers. *(OEI; 05-11-00130; expected issue date: FY 2013; work in progress)*

State Collection and Verification of Provider Ownership Information

We will determine the extent to which State Medicaid agencies and CMS collect and verify required ownership information for enrolled providers. Federal regulations require Medicaid and Medicare providers to disclose ownership information, such as the name, address, and date of birth of each person with an ownership or control interest in the provider. (42 CFR § 455.104.) We will also review States' and CMS' practices for collecting and verifying provider ownership information and determine whether

States and CMS had comparable provider ownership information for providers enrolled in both Medicaid and Medicare. *(OEI; 04-11-00590, 04-11-00591, 04-11-00592; expected issue date: FY 2013; work in progress)*

Children's Health Insurance Program for Medicaid-Eligible Individuals

Acronyms and Abbreviations for Selected Terms Used in This Section:

CHIP—Chidren's Health Insurance Program
FFP—Federal financial participation

State Claims for Federal Reimbursement Under the Children's Health Insurance Program for Medicaid-Eligible Individuals

We will assess the appropriateness of a State's claims for federal financial participation (FFP) under the State's Children's Health Insurance Program (CHIP) program for individuals who were enrolled in the State's Medicaid 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 Medicaid. 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. (Social Security Act, § 2105(c)(6)(B).) *(OAS; W-00-11-31314; W-00-12-31314; various reviews; expected issue date: FY 2013; work in progress)*

State Compliance With Eligibility and Enrollment Notification and Review Requirements for the Children's Health Insurance Program

We will review State compliance with the CHIP eligibility and enrollment notification and review requirements. We will also determine whether beneficiaries remain enrolled during reviews of suspension or after termination of enrollment. Federal regulations contain requirements relating to applicant and enrollee protections. (42 CFR pt. 457, subpart K.) Requirements include, among other things, that eligibility determinations be timely and be in writing, 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. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Medicaid Data Systems, Controls, and Claims Processing

Acronyms and Abbreviations for Selected Terms Used in This Section:

MMIS—Medicaid Management Information System
MSIS—Medicaid Statistical Information System
NPI—National Provider Identifier
PARIS—Public Assistance Reporting Information System
PHI—protected health information

Early Review of the Transformed Medicaid Statistical Information System Pilot Project (New)

We will review CMS's implementation of the Transformed Medicaid Statistical Information System (T-MSIS) pilot project. Much of the efforts around Medicaid program integrity at a national level rely on the use of the Medicaid Statistical Information System (MSIS), which is a database of Medicaid claims and encounter information collected from States by CMS. MSIS data are used by Medicaid Integrity Contractors and other Federal and law enforcement agencies to identify and pursue providers that are defrauding States and the Federal Government. Timely, accurate, and comprehensive Medicaid data are necessary for program integrity oversight and the identification of potential fraud, waste, and abuse. CMS is implementing a pilot project, called T-MSIS, to begin collecting higher quality timely data. T-MSIS is scheduled for national implementation in 2014. We will also determine whether the pilot project is achieving results that will make the new T-MSIS database useful for detecting fraud, waste, and abuse. *(OEI; 05-12-00610; expected issue date: FY 2013; work in progress)*

Claims With Inactive or Invalid Provider Identifier Numbers

Given the vulnerabilities identified in the Medicare program, 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 National Prover Identifiers (NPI), 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 medical equipment and supplies claims with inactive or invalid NPIs 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 medical claims contained NPIs of deceased physicians. *(OAS; W-00-11-31338; various reviews; expected issue date: FY 2013; work in progress)*

Beneficiaries With Multiple Medicaid Identification Numbers

We will review duplicate payments made by States on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and States' 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. *(OAS; W-00-11-31374; W-00-12-31374; various reviews; expected issue date: FY 2013; work in progress)*

Use of the Public Assistance Reporting Information System To Reduce Instances of Payments by 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. 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. PARIS is a computer matching and information exchange system operated by the Administration for Children and 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. Federal law requires States' Medicaid eligibility determination systems to provide data matching through PARIS. (Social Security Act, § 1903, as amended by the Qualifying Individual Program Supplemental Funding Act of 2008 (QI).) *(OEI; 09-11-00780; expected issue date: FY 2013; work in progress)*

Management Information Systems Business Associate Agreements

We will review CMS's oversight activities related to data security requirements of State Medicaid Management Information Systems (MMIS), which process and pay claims for Medicaid benefits. We will determine whether business associate agreements have been properly executed to protect beneficiary information, including safeguards implemented pursuant to Federal standards. 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 established minimum requirements for contracts with business associates to protect the security of electronic-protected health information. (Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rules at 45 CFR pt. 164, subpart C.) *(OAS; W-00-13-41015; various reviews; expected issue date: FY 2013; new start)*

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 to determine whether they contain any vulnerabilities that could affect the confidentiality, integrity, and availability of the Medicaid claims' protected health information (PHI). Electronic claims transactions may contain PHI as defined under regulations that also define "health plan" to include Medicaid. (45 CFR § 160.103.) 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. We will use an application security assessment tool in conducting this review. *(OAS; W-00-13-41016; various reviews; expected issue date: FY 2013; new start)*

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. We will focus on security controls, such as access controls over the mainframe operating system and security software. We will also review some limited general controls, such as disaster recovery plans and physical security. The Office of Management and Budget (OMB) requires that agencies implement and maintain programs to ensure that adequate security is provided for all agency information that is collected, processed, transmitted, stored, or disseminated in general support systems and major applications. OMB also established a minimum set of controls to be included in Federal automated information security programs. (OMB Circular A-130, *Management of Federal Information Resources*, Appendix III.) *(OAS; W-00-12-40019; W-00-13-40019; various reviews; expected issue date: FY 2013; work in progress and new start)*

Medicaid Managed Care

Acronyms and Abbreviations for Selected Terms Used in This Section:

MCE—managed care entities
MCO—managed care organizations
MSIS—Medicaid Statistical Information System
OMB—Office of Management and Budget

Beneficiary Access to Medicaid Managed Care (New)

We will review how extensive managed care provider networks are for Medicaid managed care beneficiaries. According to Federal regulations (42 CFR §§ 438.202-210), States must ensure that managed care plans maintain and monitor a network of providers that is sufficient to provide adequate access to all Medicaid services. In establishing and maintaining this network, managed care plans must consider the anticipated Medicaid enrollment, the expected utilization of services, the number and types of providers accepting new patients, and the geographic location of providers and beneficiaries. We will also describe State standards for primary and specialty care and will determine beneficiaries' access to certain primary and specialty care providers. *(OEI; 02-11-00320; expected issue date: FY 2014; work in progress)*

Beneficiary Grievances and Appeals Process (New)

We will review the extent to which States monitor Medicaid managed entities' (MCE) grievances and appeals systems for compliance with Federal requirements. States are required to provide an opportunity for a fair hearing to any beneficiary whose Medicaid claim for assistance is denied or not acted upon promptly. (Social Security Act, § 1902(a)(3).) Medicaid MCEs are required to establish internal grievance procedures under which beneficiaries, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical services. (Social Security Act, § 1932(b)(4).) CMS promulgated more detailed requirements at 42 CFR Part 438, Subpart F. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

State Oversight of Provider Credentialing by Managed Care Entities

We will determine how States ensure that Medicaid MCEs (specifically managed care organizations) prepaid inpatient health plans, and prepaid ambulatory health plans comply with credentialing and recredentialing requirements. We will also determine how CMS ensures that States comply with provider credentialing requirements. Each entity must document its process for credentialing and recredentialing providers and not discriminate against providers that serve high-risk populations or specialize in high-cost treatment. Federal regulations require States to ensure that entities serving the Medicaid population implement written policies and procedures for selection and retention of providers. (42 CFR 438.214.) *(OEI; 09-10-00270; expected issue date: FY 2013; work in progress)*

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 MCEs' marketing practices and compliance with Federal and

State contractual marketing requirements. We will also determine the extent to which CMS ensures States' compliance with Federal requirements involving Medicaid MCE marketing practices. No marketing materials may be distributed by Medicaid MCEs without first obtaining States' approval. (Social Security Act, § 1932(d)(2).) States are permitted to impose additional requirements in contracts with MCEs about marketing activities. (42 CFR § 438.104.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Completeness and Accuracy of Managed Care Encounter Data

We will determine the extent to which Medicaid managed care encounter data included in Medicaid Statistical Management Systems (MSIS) submissions to CMS accurately represent all services provided to beneficiaries. We will also determine the extent to which CMS acted to enforce Federal requirements that Medicaid managed care encounter data be included in MSIS. A prior OIG review of 2007 data found that although all 40 States with Medicaid managed care were collecting encounter data and most of those States used the data, only 25 States included the data in their MSIS submissions to CMS. Of the 25 States that included encounter data in their MSIS submissions, the MSIS files containing encounter data varied by service (e.g., inpatient, pharmacy, long-term care) and eligibility, as did the data elements reported in each file. Federal law requires States and MCEs to submit data elements deemed necessary by the Secretary for use in program integrity, program oversight, and administration. (Affordable Care Act, § 6504.) Federal Medicaid matching funds for the operation of an MSIS are authorized pursuant to the Social Security Act, § 1903(a)(3)(B). Such matching funds can be withheld from States that fail to submit required Medicaid data, including encounter data. (Social Security Act, §§ 1903(m)(2)(A) and 1903(r)(1).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start; Affordable Care Act)*

Program Integrity—Excluded Individuals Employed by Managed Care Networks

We will determine the extent to which OIG-excluded individuals were employed by entities that provide services through MCE provider networks in 2009. 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. The Department of Health and Human Services (HHS) and OIG have authority to exclude individuals and entities from all Federal health care programs pursuant to the Social Security Act, §§ 1128, 1156, and 1892. Medicaid and any other Federal health care programs are precluded from paying for any items or services furnished, ordered, or prescribed by an excluded individual or entity, except under specific limited circumstances. (Social Security Act, § 1862(e)(1), and 42 CFR § 1001.1901(b).) 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. *(OEI; 07-09-00632; expected issue date: FY 2013; work in progress)*

Program Integrity—Medicaid Managed Care Organizations' Identification of Fraud and Abuse (New)

We will determine whether managed care organizations (MCO) identified and addressed potential fraud and abuse incidents in 2011. We will also describe how States oversee MCOs' efforts to identify and address fraud and abuse. All MCOs are required to have processes to detect, correct, and prevent fraud, waste, and abuse. However, the Federal requirements surrounding these activities are general in nature (42 CFR § 438.608), and MCOs vary widely in how they deter fraud, waste, and abuse. A prior OIG report found that over a quarter of the MCOs surveyed did not report a single case of suspected fraud and abuse to their State Medicaid agencies in 2009. The report also found that although MCOs and States are taking steps to address fraud and abuse in managed care, they remain concerned about their prevalence. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Program Integrity—Managed Care Organizations' Use of Prepayment Review To Detect and Deter Fraud and Abuse

We will determine the extent to which Medicaid MCOs use prepayment reviews to detect and deter fraud and abuse. We will also examine the results of MCO prepayment reviews, the challenges addressed in developing and implementing the prepayment programs, and lessons MCOs learned about them. Federal regulations require Medicaid MCOs to have administrative and management arrangements or procedures that are designed to guard against fraud and abuse and that include mandatory compliance plans and provisions for internal monitoring and auditing. (42 CFR § 438.608.) Prepayment reviews can serve as effective fraud and abuse safeguards because they occur during the claims processing phase before claim payment. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Medical Loss Ratio—Medicaid Managed Care Plans' Refunds to States

We will review managed care plans with contract provisions that require a minimum percentage of total costs to be expended for medical expenditures (medical loss ratio) to determine whether a refund was made to the State agency when the minimum medical loss ratio threshold was not met. Prior OIG work found that, although the minimum medical loss ratios were not met, the managed care plans did not make the required refund to the State agency. State Agencies must properly report expenditures and apply any applicable credits. (OMB Circular A-87.) *(OAS; W-00-11-31372; W-00-12-31372; various reviews; expected issue date: FY 2013; work in progress)*

Other Medicaid-Related Reviews

Acronyms and Abbreviations for Selected Terms Used in This Section:

FFS—fee for service
MDS—Minimum Data Set
MFCU—Medicaid Fraud Control Unit
PERM—Payment Error Rate Measurement (process)
PPS—prospective payment system
SNF—skilled nursing facility

Medicaid Overpayments—Credit Balances in Medicaid Patient Accounts

We will review patient accounts of providers to determine whether there are Medicaid overpayments in accounts with credit balances. Previous OIG work found Medicaid overpayments in patients' accounts with credit balances. Medicaid is the payer of last resort and providers are to identify and refund overpayments received. (Social Security Act, § 1902(a)(25); 42 CFR pt. 433, subpart D; various State laws; and CMS's *State Medicaid Manual,* Pub. No. 45, pt. 3, § 3900.1.) *(OAS; W-00-11-31311; W-00-12-31311; various reviews; expected issue date: FY 2013; work in progress)*

Payment Error Rate Measurement Program—Error Rate Accuracy and Health Information Security

We will review CMS's implementation of the Payment Error Rate Measurement (PERM) process to determine whether it has produced valid and reliable error rate estimates for Medicaid and Children's Health Insurance Program (CHIP) fee for service, managed care, and eligibility. We will also review the physical and data security of health information transmitted by various States for use in the PERM. We will also verify CMS's actions to implement recommendations from a March 2010 OIG review. Annually, Federal agencies must develop statistically valid estimates of improper payments under programs with a significant risk of erroneous payments, including Medicaid and CHIP. (Improper Payments Elimination and Recovery Act of 2011 (IPERA) and OMB's implementation of IPERA.) CMS developed the PERM process to comply with IPERA. The process includes conducting FFS, managed care, and eligibility reviews. (42 CFR, pt. 431, subpart Q.) OMB's instructions on protecting sensitive information and reporting incidents involving potential and confirmed breaches of personally identifiable information (PII) are provided by OMB Memorandums M-06-16 and M-07-16. OIG has oversight and monitoring responsibilities related to CMS's error rate process pursuant to the Chief Financial Officers Act of 1990. *(OAS; W-00-13-40046; various reviews; expected issue date: FY 2013; new start)*

Nursing Home Minimum Data Set—Accuracy and CMS Oversight

We will review CMS's oversight of Minimum Data Set (MDS) data submitted by nursing homes certified to participate in Medicare or Medicaid. We will also review CMS's processes for ensuring that nursing homes submit accurate and complete MDS data. MDS data include the residents' physical and cognitive functioning, health status and diagnoses, preferences, and life care wishes. Nursing homes must conduct accurate comprehensive assessments for residents using an instrument that includes the MDS. (Social Security Act, §§ 1819(b)(3)(A)(iii) and 1819(e)(5), and corresponding sections of Title XIX of the Social Security Act.) Federal regulations specify the requirements of the assessment instrument. (42 CFR § 483.20.) CMS implemented a skilled nursing facility (SNF) prospective payment system (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. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Reviews of State Medicaid Fraud Control Units

We will review the overall management, operations, and performance of selected Medicaid Fraud Control Units (MFCU). We will also determine the extent to which a State MFCU operates in accordance with the 12 published performance standards and identify effective practices and areas for improvement in the MFCU's management and operations. The Secretary has delegated to OIG the responsibility for administering the MFCU grants and providing oversight and guidance to the MFCUs. Part of that oversight responsibility, as required by 42 CFR § 1007.15(d), includes certifying and then annually recertifying every State MFCU. The Social Security Act, §1902(a)(61), required the Secretary to establish performance standards that could be used in evaluating a MFCU's performance for recertification purposes; the 12 standards were published at 59 Fed. Reg. 49080. Periodically, OIG conducts an in depth, on-site review of each State MFCU as part of the recertification process. *(OEI; 00-00-00000; various reviews; expected issue date: FY 2013; work in progress)*

The *Work Plan* is one of OIG's three core publications. The *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

Part IV
Legal and Investigative Activities Related to Medicare and Medicaid

Acronyms and Abbreviations for Selected Terms Used in Part IV:

CIA—corporate integrity agreement
CMP—civil monetary penalty
CMS— Centers for Medicare & Medicaid Services
CPG—compliance program guidance
DOJ—Department of Justice
FBI—Federal Bureau of Investigation
IRS—Internal Revenue Service
MFCU—[State] Medicaid Fraud Control Unit

Legal Activities

The Office of Inspector General's (OIG) resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalities (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 antikickback statute, and provides 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

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. (Social Security Act, § 1128, § 1156, and other statutes.) 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) 2011, OIG excluded 2,662 individuals and entities from participation in Federal health care programs. The total for FY 2012 will be published in OIG's Fall FY 2011 *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, on the basis of 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 MedicalTreatment 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.

False Claims Act Cases and 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 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 on the basis of 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, 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: https://oig.hhs.gov/fraud/cia/cia_list.asp.

Review of Entities That Do Not Enter Into Corporate Integrity Agreements

We will review entities, including providers and/or suppliers that settled fraud cases with the Government but declined to enter into CIAs with OIG. CIAs promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all Federal health care programs, as defined in 42 U.S.C.§ 1320a-7b(f). OIG reviews may be similar to or more extensive than those that would be performed by Independent Review Organizations (IRO) under CIAs to assess the entity's compliance with Federal health care program requirements. (OAS; W-00-12-30070; various reviews; expected issue date: FY 2013; work in progress)

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 antikickback 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. Examples are available on OIG's Web site at:

- Advisory Opinions: https://oig.hhs.gov/fraud/advisoryopinions.asp
- Fraud Alerts: https://oig.hhs.gov/compliance/alerts/index.asp

- Compliance Guidance: https://oig.hhs.gov/fraud/complianceguidance.asp
- Open Letters: https://oig.hhs.gov/fraud/openletters.asp
- Other Guidance: https://oig.hhs.gov/compliance/alerts/guidance/index.asp

Provider Compliance Training

In spring 2011, OIG and its government partners provided in-person provider compliance training in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C. The sessions focused on the realities of Medicare and Medicaid fraud and the importance of implementing an effective compliance program. To expand access to providers nationwide, we broadcasted a free online live Webcast of the May 18 training in Washington. These and other training materials are available on OIG's Provider Compliance Training Web site along with corresponding slides and written handouts. Also available are 13 educational video and audio podcasts covering various topics to help prevent fraud, waste, and abuse. Our provider compliance training effort continues.

Provider Self-Disclosure

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraud and abuse. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. In doing so, the self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in being overpaid by a Federal program). After making an initial disclosure, the provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG Web site at https://oig.hhs.gov/fraud/selfdisclosure.asp.

In 2012, OIG published a Solitication for Information and Recommendations for revising the Provider Self-Disclosure Protocol. 77 Fed. Reg. 36281 (June 18, 2012). OIG will consider those comments and expects to publish a revised Protocol in FY 2013.

Investigative Activities

The Office of Investigations (OI) conducts and coordinates criminal, civil, and administrative investigations of fraud, waste, abuse, and misconduct related to more than 300 HHS programs and operations. The investigations include Medicare and Medicaid fraud, failure-of-care cases, child support

enforcement violations, grant and contract fraud, computer intrusions, and employee misconduct. Investigations can 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: https://oig.hhs.gov/publications.asp. See also OIG's Consumer Alerts at: https://oig.hhs.gov/fraud/consumer-alerts/index.asp.

Medicare Strike Force Teams and Other Collaboration

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, the Internal Revenue Service (IRS), and State Medicaid Fraud Control Units (MFCU).

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by the Department of Health and Human Services (HHS) and DOJ to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. Using a collaborative model, Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud. The Strike Force teams were formed in March 2007 and are operating in nine major cities. The effectiveness of the Strike Force model is enhanced by interagency collaboration within HHS. For example, we refer credible allegations of fraud to CMS so it can suspend payments to perpetrators. During Strike Force operations, OIG and CMS work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets.

- 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.

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

- OIG also examines quality-of-care issues 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 investigation include Medicare and Medicaid drug benefit issues and assisting CMS in identifying program vulnerabilities and schemes, such as prescription shorting (a pharmacy's

dispensing of 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 Medicare and Medicaid from making improper payments, deter the illegal use of prescription drugs, and curb the danger associated with street distribution of highly addictive medications.

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 the National Association for Medicaid Program Integrity.

Highlights of recent enforcement actions to which OIG has contributed are posted to OIG's Web site at: https://oig.hhs.gov/fraud/enforcement/criminal/.

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https://oig.hhs.gov

Part V
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. Our reviews of public health agencies within the Department of Health and Human Services (HHS) generally 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 health surveillance system 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 have low income or are 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 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 functions of the Office of the Assistant Secretary for Health (OASH) include overseeing the protection of volunteers involved in research.

Acronyms and Abbreviations for Selected Organizations and Terms Used in Part V:

AIDS—acquired immunodeficiency syndrome
CHS—Contract Health Services (program)
FAR—Federal Acquisition Regulation
HIV—human immunodeficiency virus
IND—investigational new drug
OMB—Office of Management and Budget
PSO—Patient Safety Organizations
SBIR—Small Business Innovation Research (program)

Descriptions of the Office of Inspector General's (OIG) work in progress and work planned for fiscal year (FY) 2012 follow.

Agency for Healthcare Research and Quality

AHRQ—Early Implementation of Patient Safety Organizations

We will review the policies and activities of Patient Safety Organizations (PSO) to determine the extent of participation among hospitals, PSO's practices in receiving and analyzing adverse event reports, and the extent to which PSOs provide information to health care providers and the Network of Patient Safety Databases maintained by AHRQ. We will evaluate PSOs' efforts to identify and resolve patient safety problems in hospitals and identify any barriers to the full and effective implementation of the PSO program. PSOs are nongovernmental entities certified by HHS to collect and analyze reports of adverse events from hospitals and other health care settings. (Patient Safety and Quality Improvement Act of 2005.) Adverse events are harm caused to patients during medical care, such as infections or injury. A prior OIG review found that hospitals did not identify all serious adverse events, suggesting that hospital incident-reporting systems may be an unreliable source of information for PSOs. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Centers for Disease Control and Prevention

CDC—Oversight of Security of the Strategic National Stockpile for Pharmaceuticals (New)

We will review efforts by CDC to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss. We will use the guidelines established in the Department of Homeland Security's *Physical Security Manual* to assess security risks at selected stockpiles. The Strategic National Stockpile Program, for which CDC and the Department of Homeland Security (DHS) share management responsibility, is designed to supplement and restock State and local public health agency pharmaceutical supplies in the event of a biological or chemical incident in the United States or its territories. These stockpiles are stored at strategic locations for the most rapid distribution response possible, and CDC is responsible for ensuring that the materials in these facilities are adequately protected and stored. *(OAS; W-00-13-58310; expected issue date: FY 2013; new start)*

CDC—Award Process for the President's Emergency Plan for AIDS Relief Cooperative Agreements (New)

We will review the award process for cooperative agreements that CDC awarded under the President's Emergency Plan for AIDS Relief (PEPFAR) program to ensure compliance with applicable laws, regulations, and departmental guidance. The review will include awards made to both foreign and domestic recipients. The *Grants Policy Directive*, Part 2, § 04, specifies the process for competitive review, ranking applications, approval of applications, and the award policy. During previous reviews of the award monitoring process, we noted possible deficiencies, such as conflicting, missing or inaccurate

information in the Funding Opportunity Announcement and the Notice of Award. *(OAS; W-00-13-58311; expected issue date: FY 2013; new start)*

CDC—Oversight of HIV/AIDS Prevention and Research Grants (New)

We will assess whether CDC's oversight of HIV/AIDS prevention and research grants was conducted in accordance with Federal regulations and HHS policies. During FYs 2007 through 2011, CDC used more than $3.6 billion to award grants for HIV/AIDS prevention and research. These grants are important tools in carrying out CDC's mission of meeting the goals of the National HIV/AIDS Strategy for the United States. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

CDC—Grantees' Use of Funds (New)

We will determine the allowability of costs funded with FY 2012 HHS appropriations and claimed by Centers for Disease Control and Prevention (CDC) grantees using the funds to reduce chronic disease and promote healthy lifestyles. Grantees receiving such funds must ensure that the funds are used for authorized purposes, including whether funds were spent on lobbying, and in compliance with the purposes outlined in Federal laws, Office of Management and Budget (OMB) circulars, and other directives. *(OAS; W-00-13-59014; expected issue date: FY 2013; new start)*

CDC—Oversight of High-Risk Grantees

We will examine current CDC processes for designating and monitoring high-risk grantees. We will determine the extent to which CDC designates its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) grantees as high risk, whether CDC includes special conditions and restrictions in high-risk grantees' contracts, and the extent to which CDC high-risk grantees comply with special conditions and restrictions in their contracts. Increased funding through the American Recovery and Reinvestment Act of 2009 (Recovery Act) for NCCDPHP increases potential vulnerabilities in CDC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal regulations, special conditions and restrictions may be included in the contracts of grantees designated as high risk if the grantees meet certain criteria (e.g., history of poor performance, financial instability). (42 CFR § 74.14 and 45 CFR § 92.12.) *(OEI; 04-12-00240; expected issue date: FY 2012; work in progress)*

Food and Drug Administration

FDA—Oversight of Wholesale Prescription Drug Distributors (New)

We will assess the adequacy of FDA's oversight of wholesale prescription drug distributors and determine the extent to which FDA ensures that States are licensing wholesalers according to applicable State and Federal laws. All drug wholesalers must be licensed under State licensing systems, which must in turn meet the FDA guidelines under 21 CFR Part 205. (Prescription Drug Marketing Act of 1987, § 6.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

FDA—Complaint Investigation Process

We will determine the adequacy of FDA's complaint investigation process. We will determine whether complaints are properly recorded in the Consumer Complaint System and investigated expeditiously. We will also review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries. FDA relies on its complaint investigation process to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Guidelines for such investigations are in FDA's *Investigations Operation Manual*, ch. 8, § 8.2. *(OAS; W-00-13-51010; expected issue date: FY 2013; new start)*

FDA—Oversight of Investigational New Drug Applications

We will review FDA's process for evaluating investigational new drug (IND) applications. To begin clinical studies on a new drug product for human use, the sponsor (usually a manufacturer or research organization) must submit to FDA an IND application with all the known information about the new drug and describe how the proposed human clinical trials will be conducted. We will assess FDA's timeliness and identify challenges in the IND review process. FDA has 30 days from receipt of the applications to review them, after which the sponsors may start clinical trials without FDA's approval. Federal law governs FDA's authority to oversee INDs used in clinical trials to assess their safety and effectiveness. (Food, Drug, and Cosmetic Act (FDCA) of 1938, § 505(i).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

FDA—Implementation of the Risk Evaluation and Mitigation Strategies Program

We will examine the extent to which FDA ensures drug manufacturer compliance with the requirements of the Risk Evaluation and Mitigation Strategies (REMS) program, designed to identify risks and benefits of drugs. FDA may require a REMS plan for a drug associated with risks that may outweigh its benefits. We will also review drug manufacturer assessments of the REMS program's efficacy in minimizing risk to consumers. Drug manufacturers are required to submit assessments of the effectiveness of the REMS plan at scheduled intervals. Ensuring the effectiveness of REMS plans is an important component of drug safety oversight, which is one of the Top Management and Performance Challenges that OIG identified for HHS. *(OEI; 04-11-00510; expected issue date: FY 2013; work in progress)*

FDA—510(k) Process for Device Approval

We will determine FDA's progress in either reclassifying or requiring the more stringent "Premarket Approval" process for certain types of high-risk medical devices. FDA clears lower-risk devices through the "Premarket Notification," (510(k), process), which is a faster and less expensive method. We will determine the extent to which FDA documented its decision to clear devices through the less stringent 510(k) process in 2010 in accordance with 21 CFR § 10.70. (FDCA, §§ 510(k) and 513(f), and 21 CFR § 807.92.) *(OEI; 04-10-00480; expected issue date: FY 2013; work in progress)*

Health Resources and Services Administration

HRSA—Health Center Adoption of Routine Testing for Human Immunodeficiency Virus Testing

We will determine the extent to which HRSA-funded health centers have adopted CDC's recommendation for routine HIV testing. We will review health center service sites to determine their HIV testing practices. 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 disproportionately affected by HIV. However, HRSA estimates that only 5.8 percent of health center patients were tested in 2010, and little information exists regarding health center HIV testing practices. *(OEI; 06-10-00290; expected issue date: FY 2013; work in progress)*

HRSA—Community Health Centers' Compliance With Grant Requirements of the Affordable Care Act

We will determine whether community health centers that received funds pursuant to the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), § 10503, are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems that assess and account for program income. The review is based in part on requirements of the Public Health Service Act, § 330, and Federal regulations. *(OAS; W-00-13-58303; various reviews, expected issue dates: FY 2013; new start; Affordable Care Act)*

HRSA—Monitoring of Recipients' Fulfillment of National Health Services Corps Obligations

We will determine the effectiveness of National Health Service Corps (NHSC) monitoring of recipients to ensure timely fulfillment of their contract obligations or timely recognition and referral of defaults to a Treasury-designated Debt Collection Center (HHS Program Support Center) when recipients breach their obligations. We will assess the accuracy of HRSA's default rate (2 percent) and the adequacy of its followup with health care professionals who default on their service commitments. Pursuant to the PHS Act, NHSC provides loan repayments and scholarships for health professionals who agree to work for a specified period in Health Professional Shortage Areas. In FY 2010, NHSC received $141 million in discretionary funding. In addition to its annual appropriation, the NHSC had received $300 million in funding through the Recovery Act in FY 2009, of which $160 million was available in FY 2010. The Affordable Care Act, § 10503, and the Recovery Act provided increased annual funding for the NHSC Loan Repayment and Scholarship Programs, totaling $1.5 billion over five years (FYs 2011 – 2015). *(OAS; W-00-13-58205; expected issue date: FY 2013; new start; Affordable Care Act)*

Indian Health Service

IHS—Contract Health Services Program's Compliance With Appropriations Laws (New)

We will determine whether IHS has adequate controls in place to ensure that it is appropriately funding its Contract Health Services (CHS) program and whether the program is complying with the purpose, time, and amount requirements specified in appropriations statutes. IHS can provide health care directly or by funding tribes to independently deliver health care. When an IHS or tribal facility is not available or does not provide required emergency or specialty care, IHS and tribes rely on the CHS program to purchase services from private health care providers. (42 CFR Part 136.) The rising cost of health care services and transportation and increased need have led to greater demands for services provided by CHS. Recently, the Government Accountability Office (GAO) noted that IHS/CHS had inadequate controls and identified potential Antideficiency Act violations. If IHS and CHS do not have adequate internal controls to properly monitor the costs of CHS services, the programs may incur Antideficiency Act violations by not complying with appropriations statutes while administering the program. *(OAS; W-00-13-50041; expected issue date: FY 2013; new start)*

IHS—Medicaid Reimbursements

We will review IHS's expenditure of Medicaid reimbursements. Federal law allows IHS and tribal facilities to bill State Medicaid programs for services provided to Indian beneficiaries enrolled in Medicaid. (Social Security Act, § 1911.) Tribal 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 Federal Government reimburses 100 percent of the services provided to Indian beneficiaries enrolled in Medicaid. (Social Security Act, § 1905(b).) States may lack incentive to require accountability for expenditures of Medicaid reimbursements that, according to law, must be used exclusively to make improvements in IHS and tribal health care facilities. *(OAS; W-00-13-55065; expected issue date: FY 2013; new start)*

National Institutes of Health

NIH—Extramural Construction Grants at NIH Grantees (New)

We will perform reviews at facilities that received extramural construction grants to determine whether Recovery Act funds were spent in accordance with Federal requirements. (42 CFR Part 52b, 45 CFR Part 74, 2 CFR Part 215, 2 CFR Part 220, and 2 CFR Part 225.) We will determine whether appropriate bidding procedures were followed and whether expenditures were allowable under the terms of the grants and applicable Federal requirements. The Recovery Act provided $1 billion to be invested in extramural construction projects to build, renovate, or repair non-Federal biomedical and behavioral research facilities. The intended recipients of these awards were institutions of higher education as well as nonprofit and regional organizations across the country. *(OAS; W-00-13-50042; expected issue date: FY 2013; new start)*

NIH—Equipment Claims by Grantees (New)

We will determine whether NIH grantees' claims for equipment purchases are in compliance with the special terms and conditions set forth by the Recovery Act and applicable Federal requirements. We will conduct reviews at selected schools based on the dollar value of Federal grants received and on input from NIH. Capital expenditures for special-purpose equipment are addressed by OMB Circular A-81, *Cost principles for Educational Institutions*, and at 2 CFR Part 220, App. A, § J.18(b)(2). *(OAS; W-00-12-50037; various reviews; expected issue date: FY 2013; work in progress)*

NIH—Human Subjects Protection Practices of National Cancer Institute Extramural Grantees Collecting Biospecimens (New)

We will determine the extent to which informed consent documents for research that includes the collection of biospecimens comply with human subjects protection regulations. Further, we will determine the extent to which Institutional Review Boards (IRB) overseeing this type of research comply with regulations. We will also determine the extent to which principal investigators and IRBs take measures to address unique risks associated with this type of research. Biospecimens are biological materials (i.e. blood, plasma, tissue) taken from clinical trial human subjects or remaining from a clinical procedure. With research involving the collection of biospecimens, informational risks, such as a breach of privacy, are magnified because of the long-term electronic storage of the subjects' personally identifiable information and the potential for the biospecimens to be used in research not specified at the time of collection. No current regulations directly address human subjects' protections in research that includes the collection of human biospecimens. Regulations at 45 CFR Part 46, subpart A address human subject protections, including informed consent, for HHS-funded research. *(OEI; 01-11-00520; expected issue date: FY 2013; work in progress)*

NIH—Superfund Financial Activities for Fiscal Year 2011

We will review payments, obligations, reimbursements, and other uses of Superfund amounts by NIH's National Institute of Environmental Health Sciences. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities. (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k).) *(OAS; W-00-12-56030; W-00-13-56030; expected issue date: FY 2013; new start)*

NIH—Colleges' and Universities' Compliance With Cost Principles

We will assess 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 on the basis of the dollar value of Federal grants received and on input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration. *(OAS; W-00-13-50037; various reviews; expected issue date: FY 2013; new start)*

NIH—Extra Service Compensation Payments Made by Educational Institutions

We will determine whether payments for extra compensation charged to federally sponsored grants, contracts, and cooperative agreements by educational institutions complied with Federal regulations.

We will determine whether extra compensation payments were properly calculated and approved by the sponsoring agency. Recent OIG work has identified problems with extra compensation payments charged to federally sponsored agreements at several colleges and universities. Pursuant to OMB requirements, charges for work performed on sponsored agreements by an individual faculty member will be based on the faculty member's regular compensation. (OMB Circular A-21, *Cost Principles for Education Institutions*, Att., § J.8.d(1).) 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. *(OAS; W-00-13-50040; expected issue date: FY 2013; new start)*

NIH—Use of Data and Safety Monitoring Boards in Clinical Trials

We will determine the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. 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. A DSMB is made up of individuals who have pertinent expertise and who regularly review accumulated data from one or more clinical trials to ensure the safety of participants and the validity and integrity of scientific data generated. A variety of types of monitoring, including DSMBs, are used, depending on the risk, nature, size, and complexity of the clinical trial. NIH requires that all NIH-funded clinical trials establish data- and safety-monitoring plans. (NIH's "Policy for Data and Safety Monitoring," June 1998.) This requirement sets minimum responsibilities that sponsoring institutes and centers must meet to ensure and oversee data and safety monitoring. *(OEI; 12-11-00070; expected issue date: FY 2013; work in progress)*

NIH—Oversight of Grants Management Policy Implementation

We will examine the NIH Office of Extramural Research's (OER) oversight of the grants administration processes implemented by the 24 institutes and centers (IC) that award extramural grants. We will also examine OER's oversight of each IC's compliance with regulations, department directives, and agency policies. NIH is the largest Federal funder of health research and development, having awarded $22.2 billion in FY 2010 for extramural research awards. Regulations at 45 CFR Parts 74 and 92 establish uniform administrative requirements governing HHS grants. The HHS Grants Policy Directives and the NIH Grants Policy Statement provide guidance on implementing these regulations. OER issues grants administration policy to the ICs and has oversight responsibility for ICs' compliance with Federal regulations and departmental guidance. Each IC maintains a Grants Administration Office that is responsible for implementing its own procedures. *(OEI; 07-11-00190; expected issue date: FY 2013; work in progress)*

NIH—Inappropriate Salary Draws From Multiple Universities

We will determine whether faculty members working on NIH grants were inappropriately drawing salaries from multiple universities. A recent indictment alleged that two professors were each inappropriately drawing salaries from two universities. Extensive and swift funding under the Recovery Act may have provided an opportunity for similar actions by other researchers. The

Recovery Act provided $10.4 billion in new funding for NIH. *(OAS; W-00-13-58206; expected issue date: FY 2013; new start)*

NIH—Cost Sharing Claimed by Universities

We will determine how universities are meeting cost-sharing requirements. During a recent audit, we noted that to meet cost-sharing requirements, a university waived its claim for Facilities and Administrative (F&A) costs. The university then relied on a Cost Accounting Standards (CAS) exemption to directly claim costs that are normally treated as F&A costs. A CAS exemption allows, in exceptional circumstances, normally indirect costs, such as clerical salaries, postage, memberships, subscriptions, telephone charges, and office supplies, to be charged as direct costs. However, by waiving F&A costs to meet cost-sharing requirements and claiming the costs directly, the university is not complying with the intent of cost sharing. Indirect costs may be claimed in matching or cost-sharing instances only with the prior approval of the Federal awarding agency. (OMB Circular A-110, *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Non-Profit Organizations*, subpart C, § 23(b).) *(OAS; W-00-13-58207; expected issue date: FY 2013; new start)*

NIH—Awardee Eligibility for Small Business Innovation Research Awards

We will determine the extent to which HHS ensures that Small Business Innovation Research (SBIR) awardees meet eligibility requirements and awards are not duplicative. We will also determine the extent to which SBIR award funding amounts comply with program guidance and whether HHS assesses the commercialization success of SBIR-funded projects. Within HHS, NIH manages SBIR applications for awards from NIH, CDC, FDA, and the Administration for Children and Families (ACF). The SBIR Program, created by the Small Business Innovation Development Act of 1982, is a highly competitive, three-phase award system providing qualified small businesses with opportunities to propose innovative ideas that meet the specific research and development needs of the Federal Government. Eligible awardees must meet the definition of a small business and not already receive Federal funding for the proposed research. The Small Business Innovation Research Program Reauthorization Act of 2000 required creation of a Governmentwide database to assist with monitoring of SBIR awards across Departments. *(OEI; 04-11-00530; expected issue date: FY 2013; work in progress)*

Substance Abuse and Mental Health Services Administration

SAMHSA—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 and determine the extent to which States are reporting and meeting the goals. The program's purpose is to improve access, reduce barriers, and promote effective treatment and recovery services for people who have alcohol and drug abuse problems. Federal law requires Federal agencies to develop long-term strategic plans defining goals and objectives for their programs. (Government

Performance and Results Act of 1993 (GPRA).) *(OEI; 04-12-00160; expected issue date: FY 2013; new start)*

SAMHSA—Grantees' Use of Funds From the Prevention and Public Health Fund

We will review grantees' use of Prevention and Public Health Fund awards to determine whether the funds were properly used for the purposes outlined in Federal award letters, program requirements, and Affordable Care Act regulations. The Affordable Care Act, § 4002, authorized funds for the Prevention and Public Health Fund. From these funds, SAMHSA awarded $20.9 million in FY 2010 to help 43 community behavioral health agencies integrate primary care into their services. Up to $500,000 per year will be available for 4 years to each grantee, depending on the availability of funds, need, and the progress achieved by the grantee. Pursuant to 45 CFR §§ 74.21(b)(3) and 92.20(b)(3), grantees receiving Affordable Care Act funds must ensure that the funds are used for authorized purposes. *(OAS; W-00-12-59005; W-00-13-59005; A-07-12-04191; expected issue date: FY 2013; work in progress and new start; Affordable Care Act)*

Other Public-Health-Related Reviews

Select Agent Shipments To and From Foreign Countries (New)

We will review exports and imports of select agents between U.S.-based entities and foreign countries. Select agents are biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health or to animal or plant products. Federal regulations direct entities that possess, use, or transfer HHS select agents to, among other requirements, restrict access to select agents to approved individuals; develop and implement security plans; and maintain detailed select agent inventory and access records. (42 CFR Part 73.) Prior OIG reviews of domestic select agent transfers noted deficiencies in these and other areas of select agent management. We will examine imports and exports of select agents made from October 1, 2009, through September 30, 2011, for compliance with these and related requirements. *(OAS; W-00-13-50043; expected issue date: FY 2013; new start)*

Protections of Human Research Subjects (New)

We will review the Office for Human Research Protections' (OHRP) oversight of institutional compliance with Federal requirements designed to protect human research subjects. OHRP, a component of the HHS Office of the Assistant Secretary for Health, provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by HHS. OHRP derives compliance authority from the PHS Act, § 289, and 45 CFR part 46. At OHRP's discretion, it evaluates written substantive indications of noncompliance with 45 CFR part 46. This review is being conducted in followup to a series of OIG reports issued in 1998 that identified vulnerabilities in Federal oversight of human research subjects. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Federal Response Capabilities for Public Health and Medical Services Emergency Support

We will determine the extent to which HHS has prepared to fulfill its public health and medical services emergency support responsibilities. The Department of Homeland Security's National Response Framework's (NRF presents guiding principles that enable all response partners to prepare for and provide a unified national response to disasters and emergencies. The NRF is used by the Federal Government to coordinate designated agencies' response efforts when an incident occurs. The NRF established fifteen emergency support functions, and Federal agencies are assigned to fulfill responsibilities as the Coordinator, Primary, and/ or Support agency for each function. HHS serves as the Primary and Coordinator agency for public health and medical services. *(OEI; 04-11-00260; expected issue date: FY 2013; work in progress)*

Pandemic Influenza Response Planning

We will review HHS's implementation of key areas in its pandemic influenza plan. We will also determine the extent to which States are reporting and meeting performance goals and determine how CDC's Division of Strategic National Stockpile provides vaccines and antivirals to the States. We will review areas pertaining to appropriate supplies of prepandemic vaccines, postpandemic vaccines and antivirals, and distribution of vaccines and antivirals. HHS's pandemic-related activities are coordinated by CDC and ASPR. HHS's pandemic influenza plan is the blueprint for responding to the next pandemic, which has the potential to overwhelm current public health and medical care capabilities. In the 2009-H1N1 pandemic, during which 11 million doses of antivirals were released, many doses of antivirals remained unused because they weresent to areas that already had enough doses of vaccine. *(OAS; W-00-13-57229; expected issue date: FY 2013; new start)*

Oversight of Laboratory-Developed Tests (New)

We will determine HHS agencies' oversight of the clinical effectiveness of laboratory-developed tests (LDT). We will determine the extent and nature of LDT use for health care decisions and describe the challenges in regulating LDTs. The Medical Devices Amendments Act of 1976 provided FDA with the authority to regulate all medical devices, including in vitro diagnostics, for clinical effectiveness. LDTs, a category of in vitro diagnostics, have traditionally been used in research settings only. Because of this limited use, FDA has chosen to use regulatory discretion with respect to these tests and does not oversee them. LDTs are also subject to CMS oversight through its enforcement of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). However, CLIA addresses laboratory practices rather than the clinical effectiveness of the tests they conduct. (Clinical Laboratory Improvement Amendments of 1988 (CLIA), § 493, and Medical Device Amendments Act of 1976. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Public Health Legal Activities

OIG assists the Department of Justice (DOJ) in resolving civil and administrative fraud cases and promoting compliance of HHS grantees. We assist DOJ in developing and pursuing Federal False Claims

Act cases against institutions that receive grants from NIH and other public health service agencies. We also assist DOJ prosecutors in litigation and in settlement negotiations.

Public Health Investigations

Violations of Select Agent Requirements

In 2005, HHS issued a final regulation on possession, use, and transfer of select (biological) agents and toxins that applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. (70 Fed. Reg. 13294 (March 18, 2005), 42 CFR Part 73.) The rule authorizes OIG to conduct investigations and to impose civil monetary penalties (CMP) against individuals or entities for violations of these requirements. We are continuing to coordinate efforts with CDC, the FBI, and the Department of Agriculture (USDA) to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

The *Work Plan* is one of OIG's three core publications. OIG's *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations that when implemented will save tax dollars and improve programs.

Part VI
Human Services Reviews

Human Services Agencies

The principal Department of Health and Human Services (HHS) agencies that administer human services programs are the:

- Administration for Community Living (ACL),which includes the Administration on Aging (AoA) that provides 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

- Administration for Children and Families (ACF) that 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.

Acronyms and Abbreviations for Selected Terms Used in Part VI:

ACF—Administration for Children and Families
AoA—Administration on Aging
CCDF—Child Care and Development Fund
CSE—child support enforcement
LIHEAP—Low Income Home Energy Assistance Program
TANF—Temporary Assistance for Needy Families [program]

Descriptions of the Office of Inspector General's (OIG) human services work in progress and planned new starts for fiscal year (FY) 2012 follow.

Administration for Community Living

AoA—Senior Medicare Patrol Projects Performance Data

We will review Medicare and Medicaid monetary recoveries attributable to the Administration on Aging (AoA) Senior Medicare Patrol projects, including documentation supporting amounts recovered for the Medicare and Medicaid programs, beneficiaries, and providers. This information will support AoA's efforts to evaluate and improve the performance of the projects. In 1997, 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. The initiative stemmed from recommendations in a congressional committee report accompanying the Omnibus Consolidated Appropriations Act of 1997. *(OEI; 00-00-00000; expected issue date: FY 2013; new start)*

AoA—State Long-Term-Care Ombudsman Programs' Efforts To Identify, Investigate, and Resolve Elder Abuse Cases

We will determine whether ombudsmen follow statutory requirements to identify, investigate, and resolve elder abuse cases. (42 U.S.C. § 3058g(a)(3)(A).) We will also assess AoA's oversight of the ombudsman programs. Ombudsman responsibilities include identifying, investigating, and resolving cases made by or on behalf of residents in long-term-care facilities, including cases involving elder abuse. (42 U.S.C. § 3058g(a)(3)(A).) AoA's data on elder abuse show significant variation between State Long-Term-Care Ombudsman programs. AoA administers the State Long-Term-Care Ombudsman programs pursuant to 42 U.S.C. § 3058g, as set forth by the Older Americans Act Amendments of 2000, § 704. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Administration for Children and Families

Child Care and Development Fund—Monitoring of Licensing and Health and Safety Requirements for Childcare Providers

We will describe childcare-licensing and health and safety requirements for each State, States' monitoring of providers' compliance in each State, and the Administration for Children and Families' (ACF) monitoring of licensing and health and safety requirements for each State. Also, we will review outcomes in selected States in more detail (i.e., deficiencies, complaints, and safety issues). A previous OIG review of one Head Start grantee that also provided Child Care and Development Fund (CCDF) daycare services found several instances in which childcare facilities did not comply with health and safety requirements. Federal Head Start performance standards require that Head Start facilities comply with State and local childcare-licensing requirements. (45 CFR pt. 1304 and pt. 1306.) If States do not have licensing requirements or the States' requirements are less stringent than Federal standards, the facilities must comply with Head Start health and safety requirements in regulations at 45 CFR § 1304.53(a). Federal regulations for CCDF require States to certify that they have licensing and health and safety requirements applicable to childcare services pursuant to 45 CFR §§ 98.40 and 98.41. (45 CFR § 98.15(b)(4)-(6).) *(OEI; 07-10-00230; expected issue date: FY 2013; work in progress)*

Child Care Development Fund—Licensing, Health, and Safety Standards at Federally Funded Facilities (New)

We will review licensing, health, and safety standards at childcare facilities that received Federal funding from CCDF to determine the extent to which the facilities have complied with applicable State and Federal requirements. We will also assess ACF's oversight of States' licensing, health, and safety requirements for CCDF-funded childcare facilities. Federal regulations for the CCDF require States to certify that they have licensing and health and safety requirements applicable to childcare services pursuant to 45 CFR §§ 98.15, 98.40 and 98.41. *(OAS; W-00-12-25052; W-00-13-25052; various reviews; expected issue date: FY 2013; work in progress and new start)*

Child Care Development Fund—Direct Services (New)

We will review States' CCDF programs, which are developed based on the approved CCDF State plan and State regulations, to determine the extent to which States have established controls for determining eligibility of the family to receive services, regulating and monitoring the childcare providers, and ensuring proper payment for services. We will also review the extent to which States complied with Federal regulations (45 CFR Part 98) when developing their CCDF programs. Pursuant to the Child Care and Development Block Grant Act of 1990 and the Social Security Act, § 418, the CCDF assists low-income families, families receiving temporary public assistance, and families transitioning from public assistance in obtaining childcare so that family members can work or attend training or education. *(OAS; W-00-12-25053; W-00-13-25053; various reviews; expected issue date: FY 2013; work in progress and new start)*

Child Care Development Fund—Targeted Funds (New)

We will review CCDF targeted funds to determine the extent to which States comply with Federal regulations (45 CFR 98.60(d)) in the expenditure of those funds. The targeted funds are authorized in the Child Care and Development Block Grant Act, § 658B, and in annual appropriations. These activities are 100 percent federally funded. *(OAS; W-00-12-25054; W-00-13-25054; various reviews; expected issue date: FY 2013; work in progress and new start)*

Adoption Assistance Subsidies

We will review States' claims for Federal reimbursement of adoption assistance subsidies to determine compliance with eligibility requirements. A previous OIG review of one State's adoption assistance subsidies found payments to families that did not meet 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. *(OAS; W-00-13-24009; expected issued date: FY 2013; new start)*

Head Start—Reviews at Selected Grantees (New)

At ACF's request, we will review four Head Start agencies that have used the services of the same public accounting firm over the past 13 years. The accounting firm has developed a pattern of producing audit reports with no audit findings in the last 13 years even though significant items are discussed in the management letter for each these Head Start grantees. In 2008, the accounting firm began working with three other Georgia Head Start grantees, bringing the total to seven grantees using the firm's auditing services. Our review will determine whether costs claimed by the grantees were allowable under the terms of the grants and applicable Federal regulations. *(OAS; W-00-13-25060; various reviews; expected issue date: FYs 2013 and 2014; new start)*

Foster Care—State Oversight and Coordination of Health Services for Children in Foster Care (New)

We will determine the extent to which States provide oversight and coordination of health services for children in foster care, as required. The Fostering Connections to Success and Increasing Adoptions Act of 2008 requires each State to develop a plan for ongoing oversight and coordination of health care services for children in foster care. States' plans must include certain elements, such as a schedule for initial and followup health screening and oversight of prescription medicines. *(OEI; 00-00-00000; expected issue date: FY 2014; 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 to determine whether current and retroactive claims were allowable and reasonable and were supported in accordance with laws and regulations and States' cost allocation plans. 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. (Social Security Act, §§ 474(a)(3)(A) – (B) and 474(a)(3)(E).) *(OAS; W-00-12-24100; W-00-13-24100; various reviews; expected issue date: FY 2013; work in progress and new start)*

Foster Care—Per Diem Rates

We will determine whether State agencies claimed foster care maintenance payments and administrative costs under Title IV-E of the Social Security Act in accordance with Federal requirements. A prior OIG review found that some services included in per diem rates were not eligible for Title IV-E foster care maintenance payments. Federal law 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. (Social Security Act, § 475(4)(A).) *(OAS; W-00-13-24101; expected issue date: FY 2013; new start)*

Foster Care—Group Home and Foster Family Agency Rate Classification

We will review one State's foster care payment rates for group homes and/or foster family agency treatment programs to determine whether the rates were accurate. Federal regulations provide that Federal financial participation is available for allowable costs of foster care maintenance payments and that States must review the amount of the payments to ensure the continued appropriateness of the amounts. (45 CFR §§ 1356.60(a)(1)(i) and 1356.71(d)(2).) 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. *(OAS; W-00-13-24111; expected issue date: FY 2013; new start)*

TANF—Oversight of Work Participation and Verification Requirements

We will review ACF oversight of States' compliance with requirements for verifying TANF program work participation. We will also assess ACF oversight of tribes' compliance with Tribal Family Assistance Plan requirements under TANF. 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 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. (45 CFR pts. 261-265.) *(OEI; 09-11-00490; 09-11-00491; expected issue date: FY 2013; work in progress)*

Refugee Resettlement—Services for Recently Arrived Refugees

We will determine whether grantees have met the terms and conditions of grants and contracts. Federal law 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. (The Refugee Act of 1980, § 412(c).) *(OAS; W-00-13-25042; expected issue date: FY 2013; new start)*

Community Action Agencies—Pension Costs Claimed on HHS-Funded Programs

We will determine whether costs for retirement benefits for Community Action Agency employees have been appropriately charged to ACF-sponsored grants. We will also determine whether retirement benefit costs claimed are reasonable and allowable and comply with Federal requirements. (2 CFR § 225 (applicable to State and local governments) and 2 CFR § 230 (applicable to nonprofit organizations).) *(OAS; W-00-13-28020; expected issue date: FY 2013; new start)*

Low-Income Home Energy Assistance Program (New)

We will review States' controls for assessing and monitoring the Low-Income Home Energy Assistance Program (LIHEAP) funds provided to community action agencies (CAA). We will also review CAAs to assess whether LIHEAP funds are being used in accordance with Federal requirements. States are required to establish appropriate systems and procedures to prevent, detect, and correct waste, fraud, and abuse in activities funded under LIHEAP. (45 CFR 96.84(c).) Such systems and procedures are to address possible waste, fraud and abuse by clients, vendors, and administering agencies. *(OAS; W-00-13-25061; expected issue date: FY 2013; new start)*

Low-Income Home Energy Assistance Program—Duplicate Payments

We will examine the extent to which LIHEAP grantees made duplicate payments or payments that exceeded benefit thresholds. We will also review ACF's oversight of LIHEAP grantees. LIHEAP provides States, territories, and tribal organizations with funding to assist low-income households in meeting their immediate home energy needs. On September 30, 2008, Federal law appropriated $5.1 billion to LIHEAP. (The Consolidated Appropriations Act for FY 2009, § 155, appropriated the amount under the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009.) Program

requirements codified in the statute include the purpose of LIHEAP funds, eligibility criteria, and annual application requirements. (42 U.S.C. §§ 8621 et seq.) *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Child Support Enforcement—State and Local Protection of Child-Support Information (New)

We will determine whether selected State and local child-support enforcement programs complied with Federal regulations to protect child-support information. We will also determine the extent to which State and local child support enforcement programs monitor access to data in child support enforcement systems and penalties administered as a result of unauthorized access or use. States are required to establish safeguards to prevent unauthorized access or use of child-support information in their computerized child support enforcement systems. (Social Security Act, § 454(26) and 45 CFR 307.13.) These safeguards must include developing written policies, monitoring access to the system, training employees to protect the information, and administering penalties for unauthorized access to or disclosure of child-support information. *(OEI; 04-12-00050; expected issue date: FY 2013; work in progress)*

Child Support Enforcement—Increasing Collections

We will review States' procedures for collecting child support 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 legislation to identify earnings and collect child-support from self-employed individuals whose families are receiving TANF. A prior review in one State disclosed that the State increased child support collections by more than $1 million as a result of enacting legislation to identify earnings from self-employed noncustodial parents. *(OAS; W-00-13-20032; expected issue date: FY 2013; new start)*

Child Support Enforcement—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. In FY 2013, we will continue to encourage and coordinate enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases. The project brings together OIG, the U.S. Marshals Service, the Departments of Justice (DOJ) and State, local law enforcement agencies and prosecutors, State child-support agencies, and others to enforce Federal and State criminal child-support statutes.

The *Work Plan* is one of OIG's three core publications. OIG's *Semiannual Report to Congress* summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual *Compendium of Unimplemented Recommendations* (Compendium) describes open recommendations that when implemented will save tax dollars and improve programs.

Part VII
Other HHS-Related Reviews

Certain financial, performance, and investigative issues cut across Department of Health and Human Services (HHS) programs. The Office of Inspector General's (OIG) work in progress and its 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 in residential settings who have disabilities.

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).

Acronyms and Abbreviations for Selected Terms Used in Part VII:

ACF—Administration for Children and Families
AICPA—American Institute of Certified Public Accountants
AIDS—acquired immunodeficiency syndrome
CMS—Centers for Medicare & Medicaid Services
FAR—Federal Acquisition Regulation
FISMA—Federal Information Security Management Act of 2002
OMB—Office of Management and Budget
PEPFAR—President's Emergency Plan for AIDS Relief

Financial Statement Audits

Audits of Fiscal Years 2012 and 2013 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 the Chief Financial Officers Act of 1990, as amended by the Government Management Reform Act of 1994; Government Auditing Standards; and OMB Circular 07-04, "Audit Requirements for Federal Financial Statements." 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 FY 2012 financial statements for the Department of Health and Human Services (HHS) are due to the

Office of Management and Budget (OMB) by November 15, 2012; for FY 2013, they are due by November 15, 2013.

The following FY 2012 financial statement audits will be completed and reports will be issued during FY 2013:

- Consolidated HHS – This audit covers all operating divisions, including CMS, which will also receive a separate audit report (listed below). *(OAS; W-00-12-40009; A-17-12-00001)*

- CMS – *(OAS; W-00-12-40008; A-17-12-02012)*

The following FY 2013 financial statement audits will be completed and reports will be issued during FY 2014:

- Consolidated HHS – This audit will cover all operating divisions, including CMS, which will also receive a separate audit report (listed below). (*OAS; W-00-13-40009; A-17-13-00001)*

- CMS – *(OAS; W-00-13-40008; A-17-13-02012)*

Fiscal Year 2013 Statement on Standards for Attestation Engagements No. 16

We will review an independent auditor's workpapers to determine whether examinations of HHS's service organizations were conducted in accordance with laws and regulations. Such examinations are conducted in accordance with Generally Accepted Government Auditing Standards and the American Institute of Certified Public Accountants' (AICPA) *Statement on* Standards *for Attestation Engagements (SSAE) No. 16*, *Reporting on Controls at a Service Organization*, commonly referred to as SSAE 16 examinations. SSAE 16 examinations report on the controls of service organizations that may be relevant to the user organizations' internal control structures. The following SSAE 16 examinations of HHS service organizations will support FY 2013 financial statement audits and will be issued during FY 2013:

- Center for Information Technology (National Institutes of Health Computer Center) *(OAS; W-00-13-40012; A-17-13-00010)*

- Division of Payment Management Grants Management System *(OAS; W-00-13-40012; A-17-13-00009)*

Fiscal Years 2012 and 2013 Financial-Related Reviews

The purpose of the financial-related reviews is to fulfill requirements in Office of Management and Budget (OMB) Bulletin No. 07-04, *Audit Requirements for Federal Financial Statements*, §§ 6.11 and 13. The FY 2012 financial-related reviews that will be issued during FY 2013 are:

- Audit Reports on the HHS Special Purpose Financial Statements entered into the Governmentwide Financial Report System. These audit reports are intended to support the preparation of Governmentwide financial statements and reports. *(OAS; W-00-12-40009; A-17-12-00006)*

- Department of State Agreed Upon Procedures. These procedures focus on reviewing certain financial information for allocation transfers from the Department of State to HHS under the President's Emergency Plan for AIDS Relief (PEPFAR). OMB 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. (OMB Bulletin 07-04, paragraph 6.05.) The procedures are performed in accordance with the AICPA's attestation standards. *(OAS; W-00-12-40009; A-17-12-00015)*

The FY 2013 financial-related review that will be issued in FY 2013 is:

- Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the Department of Defense (DOD) OIG in performing the OMB Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, § 11, Agreed-Upon Procedures. *(OAS; W-00-13-40009; A-17-13-00008)*

The FY 2013 financial-related reviews that will be issued during FY 2014 are:

- Department of State Agreed Upon Procedures. These procedures focus on reviewing certain financial information for allocation transfers from the Department of State to HHS under PEPFAR. OMB 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. (OMB Bulletin 07-04, paragraph 6.05.) The procedures are performed in accordance with the AICPA's attestation standards. *(OAS; W-00-13-40009; A-17-13-00015)*

- Audit Reports on the HHS Special Purpose Financial Statements entered into the Governmentwide Financial Report System. These audit reports are intended to support the preparation of Governmentwide financial statements and reports. *(OAS; W-00-13-40009; A-17-13-00006)*

Financial Accounting Reviews

Certification of Predictive Analytics (New)

We will certify certain aspects of HHS's reporting of actual and projected savings for improper payments avoided and recovered and the relative return on investment for using technology authorized under the Small Business Jobs Act. The Small Business Jobs Act requires HHS to implement over a 4-year period predictive analytic technology for reducing improper payments in Medicare fee-for-service. Pursuant to the Act, HHS is required to report annually on the progress of these programs and to certify certain

amounts reported by the Department. OIG is required to perform this review through 2014. We will assess the data presented in the reports and provide HHS any recommendations for modifying its methodology. *(OAS; W-00-13-40060; various reviews; expected issue date: FY 2013; new start)*

HHS Contract Management Review (New)

We will review controls the Program Support Center has in place to ensure compliance with requirements specified in appropriations statutes when awarding contracts. We will review the quality assurance procedures implemented by the Department by selecting two contract samples (contracts not reviewed by the Department to ensure compliance with its quality assurance procedures and contracts reviewed by the Department) to determine the accuracy and completeness of the internal control reviews to ensure full compliance with appropriations laws. The Department, in its July 2011 Antideficiency Report to the President, noted that it implemented corrective actions, including adopting quality assurance procedures and conducting procurement management and internal control reviews to validate full compliance with appropriations laws and regulations to ensure no future violations of the Anti-Deficiency Act (31 U.S.C. § 1341(a)(1)) and bona fide need rule (31 U.S.C. § 1502.) *(OAS; W-00-13-52313; expected issue date: FY 2013; new start)*

Compliance With Improper Payment Elimination and Recovery Act

We will review certain aspects of HHS's compliance with the Improper Payment Elimination and Recovery Act of 2011 (IPERA) on the reporting of improper payments. We will assess HHS' compliance with IPERA and the data presented in HHS's Annual Financial Report (AFR) and provide recommendations for modifying the reporting as needed. IPERA requires the head of a Federal agency with programs or activities 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. Pursuant to the OMB Circular accompanying IPERA, OIG is required to review how HHS is assessing the programs it reports as well as the accuracy and completeness of the reporting in the AFR. *(OAS; W-00-12-40047; expected issue date: FY 2013; work in progress)*

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 PEPFAR. HHS received PEPFAR funds from the annual HHS appropriation and the Foreign Operations appropriation. PEPFAR funds support international programs for AIDS prevention, treatment, and care. *(OAS; W-00-12-52300;* W-00-13-52300; *expected issue date: FY* 2013; *work in progress and new start)*

Annual Accounting of Drug-Control Funds

We will review HHS agencies' compliance with the requirement that agencies expending funds on National Drug Control Program activities submit to the Office of National Drug Control Policy an annual accounting of the expenditure of drug-control funds. (21 U.S.C. § 1704.) The policy also requires that an

agency submit with its annual accounting an authentication by the agency's OIG in which OIG expresses a conclusion on the reliability of the agency's assertions in its accounting. We will submit this authentication with respect to HHS's FY 2011 annual accounting. *(OAS; W-00-13-52312; various reviews; expected issue date: FY 2013; new start)*

Reasonableness of Prime Contractor Fees

We will determine whether the Government negotiated reasonable fees for prime contracts that involve significant subcontractor efforts, taking into consideration any fees the prime contractor expected to pay subcontractors. Federal acquisition laws and regulations limit the amount of the fee that can be negotiated with a contractor. (10 U.S.C. 2306(d), 41 U.S.C. 254(b), and Federal Acquisition Regulation (FAR) 15.404-4(b)(4)(i).) 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. *(OAS; W-00-13-52321; expected issue date: FY 2013; new start)*

Non-Federal Audits

We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations.* As part of our reviews of A-133 audits, we will ensure that the auditors have audited and reported in compliance with the American Recovery and Reinvestment Act of 2009 (Recovery Act). 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. 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 reported by non-Federal auditors for use by HHS managers. Our reviews assure HHS managers 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-agency 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 HHS OIG as the cognizant audit organization for

audits that HHS OIG performs of non-HHS funds. *(OAS; W-00-13-50012; various reviews; expected issue date: FY 2013; new start)*

Requested Audit Services

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

- contract and grant closeouts,
- indirect cost audits,
- bid proposal audits, and
- other reviews designed to provide specific information requested by management.

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.

Automated Information Systems

Information System Security Audits

We will review the reliability of the Information System Security Program at several operating divisions. HHS and its components are responsible for administering and implementing this security program in compliance with the Federal Information Security Management Act of 2002 (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 security program requirements. *(OAS; W-00-11-42000; W-00-13-42000; various reviews; expected issue date: FY 2013; work in progress and new start)*

Federal Information Security Management Act of 2002

We will review various HHS operating divisions' compliance with FISMA. We will also follow up on the unresolved findings from prior reviews of information systems controls. FISMA and OMB Circular A-130, *Management of Federal Information Resources*, Appendix III, require that agencies and their contractors maintain programs that provide adequate security for all information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. *(OAS; W-00-12-42001; W-00-13-42001; various reviews; expected issue date: FY 2013; work in progress and new start)*

Information Technology Systems' General Controls

We will review the adequacy of information technology security general controls of selected HHS systems using Departmental, OMB, and FISMA guidance and regulations. Recent legislation and OMB directives have focused on safeguards for critical systems' assets and infrastructures. *(OAS; W-00-12-42002; W-00-13-42002; various reviews; expected issue date: FY 2013; work in progress and new start)*

Fraud Vulnerabilities Presented by Electronic Health Records

We will identify fraud and abuse vulnerabilities in electronic health records (EHR) systems as articulated in literature and by experts and determine how certified EHR systems address these vulnerabilities. The Health Information Technology for Economic and Clinical Health Act provides $36 billion in incentives for adopting EHRs. Medicare and Medicaid EHR incentive programs require providers to use EHR systems that have been certified by a Department-authorized testing and certification body. The Office of the National Coordinator establishes the requirements and oversees the certification process. Regulations at 45 CFR part 170 provide the initial set of standards, implementation specifications, and certification criteria for EHR systems. *(OEI; 01-11-00570; expected issue date FY 2012; work in progress)*

Other HHS-Related Issues

HHS Programs' Vulnerabilities to Grant Fraud (New)

We will review HHS programs that are vulnerable to grant fraud and assess how HHS awarding agencies mitigate the potential risks of grant fraud, abuse, and mismanagement. We will also identify grantees that have exhibited fraudulent or abusive behavior in one HHS program and determine whether they receive funds from other HHS programs and whether awarding programs are aware of the grantees' past problems. Federal regulations incorporate uniform administrative requirements governing HHS awards. Guidance in implementing those regulatory requirements is contained in the *HHS Grants Policy Directives*, which apply across HHS. Under certain circumstances an agency may suspend or debar a grantee. (45 CFR Part 76.) *(OEI; 07-12-00110; expected issue date: FY 2014; work in progress)*

HHS Compliance with the Reducing Over-Classification Act (New)

We will assess HHS policies and practices concerning the classification of materials. The Reducing Over-Classification Act of 2009 requires the Inspector General of each department or agency with delegated original classification authority to carry out evaluations to determine whether applicable classification policies, procedures, rules, and regulations have been adopted, followed, and effectively administered and to identify policies, procedures, rules, regulations, or management practices that may be contributing to persistent misclassification of material within such department, agency, or component. *(OEI; 07-12-00400; expected issue date: FY 2013; work in progress)*

Review of Calendar Year 2011 Purchase Card Purchases (New)

We will review the extent to which purchases made with HHS purchase cards complied with Federal laws and departmental guidance. The Federal Acquisition Regulation and HHS Purchase Card Program Guide govern the use of purchase cards. Prior OIG reports found vulnerabilities in HHS employees' use of purchase cards. This review will build on previous OIG work. *(OEI; 00-00-00000; expected issue date: FY 2014; new start)*

Use of HHS Grant Funds for Lobbying Activities (New)

We will determine the extent to which the Department of Health and Human Services (HHS) agencies notify grantees of lobbying prohibitions. It will also examine the extent to which HHS grantees are aware of lobbying prohibitions. The FY 2012 Consolidated Appropriations Act, § 503, prohibits appropriations from being used for activities "designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body…." Section 503 makes exceptions for activities "for normal and recognized executive-legislative relationship or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government." This review will also explore the extent to which HHS agencies have mechanisms in place to identify and address lobbying violations. *(OEI; 07-12-00620; expected issue date: FY 2014; work in progress)*

State Protections for People in Residential Settings Who Have Disabilities

We will review actions taken by CMS, ACF, the Substance Abuse and Mental Health Services Administration, and the Food and Drug Administration on OIG recommendations to work cooperatively to provide information and technical assistance to States for strengthening State protections for people in residential settings who have disabilities. 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 funds, 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-00-13-58126; expected issue date: FY 2013; new start)*

The *Work Plan* is one of OIG's three core publications. OIG's *Semiannual Report to Congress* summarizes OIG's most significant findings from audits and evaluations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual *Compendium of Unimplemented Recommendations* (Compendium) provides descriptions of open recommendations that when implemented will save tax dollars and improve programs.

Appendix A
Affordable Care Act Reviews

The reviews described in Appendix A address:

- New programs and initiatives created by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act) as they relate to responsibilities of the Department of Health and Human Services (HHS).
- Existing HHS programs and operations (Medicare, Medicaid, and public health) as they relate directly or indirectly to Affordable Care Act provisions.

New Programs and Initiatives

Acronyms and Abbreviations for Selected Terms Used in This Section:

CCIIO—Center for Consumer Information and Insurance Oversight
Exchanges—Affordable Insurance Exchanges
PHI—protected health information

The Affordable Care Act created new programs and initiatives and expanded and modified a number of existing HHS programs. The Secretary of HHS is responsible for many of the new programs in the Affordable Care Act. HHS programs created by the Affordable Care Act for which the Office of Inspector General (OIG) has work in progress or plans to start reviews in fiscal year (FY) 2012 are:

- Pre-existing Condition Insurance Plans (PCIP), § 1101
- Early Retiree Reinsurance Program (ERRP), § 1102
- Health Insurance Web Portal, § 1103
- Affordable Insurance Exchanges, §§ 1311 and 1413
- Consumer Operated and Oriented Plan (CO-OP) Program, § 1322 (New)

Pre-Existing Condition Insurance Plans, § 1101

Why was the program created? The PCIP program was created to provide a temporary high-risk health insurance pool program for eligible individuals with pre-existing conditions. PCIPs will operate until 2014, when individuals and small businesses will be able to purchase private health insurance through

insurance exchanges called Affordable Insurance Exchanges (Exchanges). Insurance plans offered under the Exchanges may not discriminate on the basis of a pre-existing condition.

What does the program do? The law appropriated $5 billion of Federal funds to support PCIPs that offer comprehensive insurance coverage to individuals with pre-existing conditions. A State may operate its own PCIP or to be covered under the Federal PCIP.

Who is responsible? The Center for Consumer Information and Insurance Oversight (CCIIO), part of the Centers for Medicare & Medicaid Services (CMS), is responsible for administering the PCIP program. HHS, through arrangements with the Office of Personnel Management (OPM) and the Department of Agriculture's National Finance Center, operates a Federal PCIP for those States that choose not to operate their own PCIPs.

How is the related assistance received and used? Funding for PCIPs became available on July 1, 2010, and States applied to CCIIO for funding. Funds are used to pay claims. To ensure the integrity of the program, each PCIP is required to develop, implement, and execute procedures to prevent, detect, and recover inappropriate payments, as well as to promptly report to HHS incidences of waste, fraud, and abuse.

The objective of our initial review of the PCIP program follows.

Controls Over Pre-Existing Condition Insurance Plans and Collaborative Administration

We will review the controls HHS and States have in place to prevent and identify fraudulent health care claims for individuals covered by PCIPs. We will also examine the effectiveness of Federal agencies in working together to administer the PCIP program. *(OEI; 07-12-00300; expected issue date: FY 2013; new start; Affordable Care Act)*

Early Retiree Reinsurance Program, § 1102

Why was the program created? The ERRP is a temporary reinsurance program to reimburse participating employment-based plans for a portion of the cost of providing health insurance to early retirees (and to certain eligible family members) with high health care costs. The ERRP will end no later than January 1, 2014, when the Affordable Insurance Exchanges under § 1311 of the Affordable Care Act are implemented.

What does the program do? Congress appropriated $5 billion for the ERRP. The ERRP reimburses participating employment-based plans for a portion of health care costs incurred by the plans for certain early retirees and family members. Reimbursable claims are those between$15,000 and $90,000 (indexed for plan years starting October 1, 2011).

Who is responsible? The program is administered by CCIIO, a part of CMS.

How is the assistance received and used? Employment-based plans applied to CCIIO to participate in the ERRP. CCIIO ceased accepting applications on May 6, 2011, and is not accepting claims incurred after December 31, 2011. Employers may use ERRP payments to reduce premium costs for employment-based plans or to reduce premium contributions, co-payments, deductibles, co-insurance, or other out-of-pocket costs for plan participants. CMS has notified participants that they must use ERRP funds no later than December 31, 2014.

The objectives for our initial ERRP-related reviews follow.

CCIIO's Internal Control Structure for the Early Retiree Reinsurance Program

We will determine whether CCIIO's internal controls for the ERRP provide reasonable assurance that the program is in compliance with the requirements of the Affordable Care Act.
(OAS; W-00-12-59008; W-00-13-59008; expected issue dates: FYs 2013-14; work in progress; Affordable Care Act)

CCIIO's Certification Procedures for Employment-Based Plans and Plan Sponsor's Use of Federal Funds

We will determine whether CCIIO's procedures for certifying employment-based plans for participation in the ERRP and plans' use of ERRP reimbursements are in compliance with the requirements of the Affordable Care Act. *(OAS; W-00-12-59009; W-00-13-59009; expected issue dates: FYs 2013-14; new start; Affordable Care Act)*

CCIIO's System Security Controls Over Protected Health Information

We will review CCIIO's system security controls over claims that employment-based plans submit for reimbursement to determine whether CCIIO's claims system contains vulnerabilities that could affect the confidentiality, integrity, and availability of the claims' protected health information (PHI).
(OAS; W-00-13-59010; expected issue dates: FYs 2013-14; new start; Affordable Care Act)

CCIIO's Reimbursements to Plans

We will review CCIIO's ERRP reimbursements to participating employment-based plans to determine whether CCIIO's payments for the costs of health benefits for early retirees complied with Federal requirements. A plan receives reimbursement for 80 percent of the costs net of negotiated price concessions for health benefits within certain cost thresholds. *(OAS; W-00-12-59011; W-00-13-59011; expected issue dates: FYs 2013-14; work in progress; Affordable Care Act)*

Employment-Based Plans' Costs for Items and Services Reimbursed

We will determine whether the costs for items and services that employment-based plans reported on their claims for reimbursement complied with Federal requirements. Claims are to be based on the actual amount expended by the plans for the health benefits provided to early retirees and eligible spouses, surviving spouses, and dependents. *(OAS; W-00-12-59012; W-00-13-59012; expected issue dates: FYs 2013-14; work in progress; Affordable Care Act)*

Employment-Based Plan Sponsors' Use of Early Retiree Reinsurance Program Funds

We will determine whether employment-based plans sponsors' use of ERRP Federal funds complied with Federal requirements. *(OAS; W-00-12-59013; W-00-13-59013; various reviews; expected issue dates: FYs 2013-14; new start; Affordable Care Act)*

Health Insurance Web Portal, § 1103

Why was the program created? The portal provides a mechanism through which residents of, and small businesses in, any State may identify affordable health insurance coverage options in that State and receive information about coverage options. The Affordable Care Act required the portal to be available July 1, 2010.

What does the program do? The program enables individuals and consumers to access information on coverage options, including private health insurance, Medicaid coverage, State high-risk pools, and other types of insurance.

Who is responsible? CCIIO, a part of CMS, is responsible for operating the portal.

The objective of our initial review of the Health Insurance Web Portal follows.

Oversight of Private Health Insurance Submissions to the HealthCare.gov Plan Finder

We will assess CCIIO's oversight of the HealthCare.gov Plan Finder. Specifically, we will determine the extent to which CCIIO oversees private insurers' compliance with Plan Finder reporting requirements. We will also determine whether data displayed on the Plan Finder are complete and consistent with consumer information provided by private insurers. The Plan Finder is one of several components of the HealthCare.gov Web site. The Affordable Care Act, § 1103, required the HHS Secretary to establish a health insurance Web site portal that presents a central database of health insurance information in a standardized format and enables comparison of coverage options. The Plan Finder can be found at http://finder.healthcare.gov/. *(OEI; 03-11-00560; expected issue date: FY 2013; work in progress; Affordable Care Act)*

Affordable Insurance Exchanges, §§ 1311, 1321, and 1413

Why was the program created? Starting in 2014, individuals and small businesses will be able to purchase qualified health plans through State-based insurance Exchanges. The Affordable Care Act requires HHS and States to streamline the procedures for enrolling through an Exchange and State Medicaid, Children's Health Insurance Program (CHIP), and health insurance subsidy programs.

What will the program do? The program provides funding for States for activities related to planning and establishing Exchanges. Exchanges will assist consumers with shopping for, and enrolling in, private

insurance. Exchanges will also help coordinate eligibility for premium tax credits and other subsidies. The streamlined eligibility procedures will ensure that individuals using an Exchange will be enrolled in the State Medicaid or CHIP if they qualify or will be able to purchase insurance on the Exchange and access related benefits for which they are eligible.

Who is responsible? States have flexibility in operating Exchanges for their States. HHS must establish an Exchange in States that choose not to establish one or will not have one operable by January 1, 2014. HHS's Exchange responsibilities are being implemented by CCIIO.

How is related assistance received and used? States have applied to CCIIO for grants that can be used in a variety of initial planning activities, including planning the coordination of eligibility and enrollment systems across Medicaid, CHIP, and the Exchanges.

The objectives for our initial reviews of Affordable Insurance Exchanges follow.

CCIIO Oversight of Health Insurance Exchange Establishment Grants (New)

We will review the health insurance Exchange establishment grant program and States' plans for preventing fraud, waste, and abuse in their Exchanges. We will also assess CCIIO's procedures for determining compliance with grant criteria. The Affordable Care Act, § 1311(a), requires the Secretary to award such grants, which are being administered by CCIIO. *(OEI; 00-00-00000; expected issue date: FY 2014; new start; Affordable Care Act)*

States' Readiness To Comply With Exchange and Medicaid Eligibility and Enrollment Requirements

We will review States' progress in complying with new eligibility and enrollment requirements for the Exchanges, Medicaid, CHIP, and health subsidy programs. We will also identify what steps States have already taken to meet these requirements, what additional steps States plan to take, and challenges or barriers that States report regarding the implementation of eligibility and enrollment systems. We will also determine the extent to which CMS has provided guidance and technical assistance to States to meet the streamlined eligibility and enrollment requirements. *(OEI; 07-10-00530; expected issue date: FY 2013; work in progress; Affordable Care Act)*

Consumer Operated and Oriented Plan Program, § 1322

Why was the program created? The program is intended to foster the creation of qualified nonprofit health insurance issuers (qualified nonprofit issuers) that will offer qualified health plans in the individual and small group markets. These issuers are known as Consumer Operated and Oriented Plans, or CO-OPs.

What does the program do? The Affordable Care Act provides $3.4 billion in new funding for organizations applying to become qualified nonprofit issuers. Starting January 1, 2014, these issuers will be able to offer health plans through the Exchanges and may also offer plans outside the Exchanges.

Who is responsible? CCIIO, a part of CMS, is responsible for administering this program.

How is the related assistance received and used? The program will make loans (repayable in 5 years) to assist in funding startup costs for qualified nonprofit issuers and will award loans (repayable in 15 years) to assist such issuers in meeting State solvency requirements. The Secretary must award the loans and grants and begin funding distribution no later than July 1, 2013. (76 Fed. Reg. 5774, February 2, 2011.) HHS has made loans to 20 entities totally approximately $1.6 billion.

The objectives of our initial reviews of the CO-OP program follow.

Assessment of the CO-OP Program Award Process (New)

We will review the process CMS uses to identify and select the best qualified recipients of Consumer Operated and Oriented Plan (CO-OP) program funds in compliance with the Affordable Care Act and Federal procurement regulations. The Affordable Care Act provides $3.4 billion in new funding for the CO-OP program. The CO-OP funds are awarded to organizations applying to become qualified nonprofit health insurance issuers. The funds are to be used to establish loans to help organizations meet their startup costs and to help organizations meet any solvency requirements of States in which the organizations seek to be licensed to issue qualified health plans. The Affordable Care Act, § 1322, directs CMS to establish the CO-OP program. *(OAS; W-00-12-59025; W-00-13-59025; expected issue date: FY 2013; work in progress; Affordable Care Act)*

Affordable Care Act: Early Implementation of the Consumer Operated and Oriented Plan (CO-OP) Loan and Grant Program (New)

We will describe how early loan recipients under the CO-OP program will meet program requirements and CCIIO's oversight of the CO-OPs. Given the substantial amount of Federal funding, CCIIO must effectively monitor CO-OPs to ensure appropriate use of loans and enforce program requirements. CCIIO must implement this program in a short timeframe so that CO-OPs will be ready to enter the State Exchanges in 2014. In addition, CO-OPs are new entrants to a competitive insurance market and therefore face significant operational and financial challenges that could increase their risk of loan default. *(OEI; 01-12-00290; expected issue date: FY 2013; work in progress; Affordable Care Act)*

Existing Programs

Acronyms and Abbreviations for Selected Terms Used in This Section:

HRSA—Health Resources and Services Administration MA—Medicare Advantage

The major Parts of the OIG *Work Plan* for FY 2013 that precede the appendixes include descriptions of Affordable Care Act-related reviews in progress or planned to start in FY 2013. Below are shortened descriptions of those reviews and the major Part in which each one appears in full.

Medicare

Hospitals—Same-Day Readmissions

We will review Medicare claims to determine trends in the number of same-day hospital readmissions. This work, which pertains to an existing system edit, may also be helpful to CMS in implementing provisions of the Affordable Care Act. *(OAS; W-00-13-35439; various reviews; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part I, p.2)*

HHAs—Home Health Face-to-Face Requirement (New)

We will determine the extent to which home health agencies (HHA) are complying with a statutory requirement that physicians (or certain practitioners working with physicians) who certify beneficiaries as eligible for Medicare home health services have face-to-face encounters with the beneficiaries. (*Affordable Care Act, § 6407.) (OEI; 01-12-00390; expected issue date: FY 2013; work in progress; Affordable Care Act) (Work Plan Part I, p. 11)*

Power Mobility Devices—Supplier Compliance With Payment Requirements (New)

We will conduct a series of reviews related to power mobility devices (PMD). These reviews will focus on whether Medicare payments for PMD claims submitted by medical equipment suppliers were made in accordance with requirements at 42 CFR § 410.38(c)(2) and whether savings can be achieved by Medicare for rentals rather than lump-sum purchases of certain PMDs. The Affordable Care Act, § 3136, eliminated the option of a lump-sum purchase for certain PMDs. *(OAS; W-00-13-35703; various reviews; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part I, p. 14)*

Program Integrity—Onsite Visits for Medicare Provider and Supplier Enrollment and Reenrollment (New)

We will determine how often onsite visits occur as part of the Medicare enrollment and reenrollment process. CMS is authorized to expand the role of unannounced preenrollment site visits. (Affordable Care Act, § 6401.) CMS implemented the Affordable Care Act provider and enrollment provisions by requiring onsite visits for provider and supplier types identified by CMS as moderate risk or high risk. (76

Fed. Reg. 5862 (February 2, 2011).) *(OEI; 00-00-00000; expected issue date: FY 2014; new start; Affordable Care Act) (Work Plan Part I, p. 18)*

State Health Insurance Assistance Programs' Provision of Medicare Fraud Information (New)

We will review the extent to which State Health Insurance Assistance Programs (SHIP) provide Medicare fraud information. CMS provides grants to States so they can provide information, counseling, and assistance relating to the procurement of adequate and appropriate health insurance coverage to Medicare beneficiaries. (42 USC § 1395b-4.) Additional funding for SHIPs was provided by the Affordable Care Act, § 3306. For FYs 2011 and 2012, CMS included objectives related to increasing the awareness about Medicare fraud in the Basic Program Announcement and Grant Renewal Application. *(OEI; 00-00-00000; expected issue date: FY 2014; new start; Affordable Care Act)*

Recovery Audit Contractors—Identification and Recoupment of Improper and Potentially Fraudulent Payments and CMS's Oversight and Response

We will determine the extent that Recovery Audit Contractors (RAC) identified improper payments, identified vulnerabilities, and made potential fraud referrals in 2010 and 2011. We will also review the activities that CMS performed to resolve RAC-identified vulnerabilities, address potential fraud referrals, and evaluate RAC performance in 2010 and 2011. (Affordable Care Act, § 6411.) *(OEI; 04-11-00680; expected issue date: FY 2013; work in progress; Affordable Care Act) (Work Plan Part I, p. 34)*

Part C: Special-Needs Plans—CMS Oversight of Enrollment and Special-Needs Plans

We will review Special-Needs Plans' compliance with chronic condition enrollment requirements and will assess CMS's oversight of the enrollment practices. (Affordable Care Act, § 3205.) *(OEI; 07-12-00170; expected issue date: FY 2013; work in progress; Affordable Care Act) (Work Plan Part II, p. 42)*

Parat D: Coverage Gap—Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts

We will review data submitted by Part D sponsors used in calculating the coverage gap discount. We will determine the accuracy of the sponsor-submitted data to ensure that beneficiary payments are correct and amounts paid to sponsors are supported. The Affordable Care Act, § 3301, established the coverage gap discount program. *(OAS; W-00-13-35611; various reviews; expected issue date: FY 2013; Affordable Care Act) (Work Plan Part II, p. 47)*

Medicaid

Manufacturer Rebates—Federal Share of Rebates

We will review States' reporting of the Federal share of Medicaid rebate collections to determine whether States are correctly identifying and reporting the increases in rebate collections. The Affordable Care Act, § 2501, amended the Medicaid rebate requirements. *(OAS; W-00-13-31450; various reviews; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part III, p. 54)*

Manufacturer Rebates—New Formulations of Existing Drugs

We will review drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs. We will also determine whether manufacturers have correctly identified all their drugs that are subject to a new provision in law. The Affordable Care Act, § 2501, amended the Medicaid rebate requirements. *(OAS; W-00-13-31451; various reviews; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part III, p. 54)*

Health-Care-Acquired Conditions—Prohibition on Federal Reimbursements

We will determine whether selected State agencies made Medicaid payments for health-care-acquired conditions and provider-preventable conditions and will quantify the amount of Medicaid payments for such conditions. The Affordable Care Act, § 2701, changed Medicaid requirements to preclude Federal payments related to health-care-acquired conditions. *(OAS; W-00-13-31452; various reviews; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part III, p. 60)*

State Terminations of Providers Terminated by Medicare or by Other States

We will review States' compliance with a new requirement that State Medicaid agencies terminate providers that have been terminated under Medicare or by another State. We will also determine whether such providers are terminated by all States, assess the status of the supporting information-sharing system, determine how CMS is ensuring that States share complete and accurate information, and identify obstacles States face in complying with the termination requirement. (Affordable Care Act, § 6401(b)(2).) *(OEI; 06-12-00030; expected issue date: FY 2014; work in progress; Affordable Care Act) (Work Plan Part III, p. 66)*

Completeness and Accuracy of Managed Care Encounter Data

We will determine the extent to which Medicaid managed care encounter data included in Medicaid Statistical Information System (MSIS) submissions to CMS accurately represent all services provided to beneficiaries. We will also determine the extent to which CMS acted to enforce Federal requirements that mandate the inclusion of Medicaid managed care encounter data in MSIS. The Affordable Care Act, § 6504, requires submission of data elements necessary for program integrity, program oversight, and administration. *(OEI; 00-00-00000; expected issue date: FY 2014; new start; Affordable Care Act) (Work Plan Part III, p. 71)*

State Enrollment and Monitoring of Medicaid Medical Equipment Suppliers (New)

We will review State Medicaid agencies' processes for enrolling and monitoring medical equipment suppliers. We will conduct site visits to determine whether such suppliers complied with their State Medicaid agencies' enrollment standards. In a recent OIG report on Medicaid suppliers, more than 15 percent of the suppliers failed to meet at least one enrollment standard. *(OAS; W-00-12-31468; various reviews; expected issue date: FY 2014; work in progress; Affordable Care Act) (Work Plan Part III, p. 65)*

Public Health

HRSA—Community Health Centers' Compliance With Grant Requirements of the Affordable Care Act

We will determine whether community health centers that received Affordable Care Act funds though the Health Resources and Services Administration (HRSA) are complying with Federal laws and regulations. (Affordable Care Act, § 10503) The review will include determining the allowability of expenditures and the adequacy of accounting systems and assessing the accounting for program income. *(OAS; W-00-13-58303; various reviews, expected issue dates: FY 2013; new start; Affordable Care Act) (Work Plan Part V, p. 85)*

HRSA—Monitoring of Recipients' Fulfillment of National Health Services Corps Obligations

We will determine the effectiveness of HRSA's monitoring of recipients to ensure timely fulfillment of their National Health Service Corps contract obligations and the timeliness of HRSA's recognition and referral of defaults to a Treasury-designated Debt Collection Center (HHS Program Support Center) if the recipients breach their obligations. We will determine the accuracy of HRSA's default rate (2 percent) and the adequacy of its followup with health care professionals who default on their service commitments. The Affordable Care Act, § 10503, and the Recovery Act provided increased funding for National Health Service Corps Loan Repayment and Scholarship Programs. *(OAS; W-00-13-58205; expected issue date: FY 2013; new start; Affordable Care Act) (Work Plan Part V, p. 85)*

SAMHSA—Grantees' Use of Funds From the Prevention and Public Health Fund

We will review Substance Abuse and Mental Health Services Administration (SAMHSA) grantees' use of funds from the Prevention and Public Health Fund to determine whether such funds were properly used for the purposes outlined in Federal laws and directives. The Prevention and Public Health Fund was established pursuant to the Affordable Care Act, § 4002. *(OAS; W-00-12-59005; W-00-13-59005; expected issue date: FY 2013; work in progress and new start; Affordable Care Act) (Work Plan Part V, p. 90)*

Appendix B
Recovery Act Reviews

Medicare and Medicaid

Acronyms and Abbreviations for Selected Terms Used in the Medicare and Medicaid Section:

HIT—health information technology

PHI—protected health information

Medicare Part A and Part B

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) authorized Medicare incentive payments over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology. (§§ 4101 and 4102.) Incentive payments were scheduled to begin in 2011 and continue through 2016, with payment reductions to health care professionals who fail to become meaningful users of EHRs beginning in 2015. (§ 4101(b).) 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 selected 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; 05-11-00250; expected issue date: fiscal year (FY) 2013; work in progress; OAS; W-00-13-31352; expected issue date: FY 2013; new start; Recovery Act)*

Medicaid Administration

Medicaid—Incentive Payments for Electronic Health Records

We will review Medicaid incentive payments to Medicaid providers and hospitals for adopting EHRs and CMS's safeguards to prevent erroneous incentive payments. The Recovery Act establishes 100-percent Federal financial participation for allowable expenses for eligible Medicaid providers to purchase, implement, and operate certified EHR technology. (§ 4201.) The section 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 erroneous 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-00-12-31351; various reviews; expected issue date: FY 2013; work in progress; Recovery Act)*

Medicare and Medicaid Information Systems and Data Security

Health Information Technology System Enhancements

We will review HIT enhancements to CMS systems to ensure that they include standards adopted by the Department of Health and 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 Medicare and Medicaid 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 technology. CMS systems require modification to manage the new requirements. *(OAS; W-00-12-27109; various reviews; expected issue date: FY 2013; work in progress; Recovery Act)*

Contractor System Enhancements

We will review heatlh information technology (HIT) enhancements to systems used by Medicare and Part D contractors to ensure that adequate security controls are in place to protect sensitive EHR and personal information that is being added as a result of the Federal HIT initiatives. CMS contractor systems require modification to comply with the new requirements. *(OAS; W-00-12-27109; various reviews; expected issue date: FY 2013; new start; Recovery Act)*

OCR Oversight of the HIPAA Privacy Rule

We will review Office for Civil Rights (OCR) oversight of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The Privacy Rule establishes Federal minimum standards for safeguarding individually identifiable protected health information (PHI). The Recovery Act requires that OCR investigate all privacy complaints filed against covered entities if a preliminary investigation indicates willful neglect of the Privacy Rule. Covered entities include health plans, health care clearinghouses, and health care providers that electronically transmit health information in connection with certain HIPAA transactions and technical standards. The Recovery Act also strengthened OCR's enforcement of the HIPAA Privacy Rule by increasing the civil monetary penalties (CMP) for covered entities' noncompliance. (74 Fed. Reg. 56123.) We will review OCR's investigation policies and assess OCR's oversight to ensure that covered entities are complying with the Privacy Rule. *(OEI; 09-10-00510; expected issue date: FY 2013; work in progress; Recovery Act)*

OCR Oversight of the HITECH Breach Notification Rule

We will review OCR's oversight of the Heath Information Technology for Economic and Clinical Health Act (HITECH) Breach Notification Rule, which requires that covered entities, as defined by HIPAA, notify affected individuals; the Secretary of HHS; and when required, the media, following the discovery of a breach in unsecured PHI. A breach is the unauthorized acquisition, access, use, or disclosure of PHI that compromises the security or privacy of such information. Unsecured PHI is individually identifiable health information that is unencrypted or not destroyed in a way that renders the PHI unusable or unreadable by unauthorized individuals. HHS provided additional guidance on what is considered to be unsecured PHI in its issuances at 74 Fed. Reg. 19006 and 74 Fed. Reg. 42741. The Secretary of HHS delegated oversight responsibility to OCR. We will review OCR's policies for investigating breaches reported by covered entities and determine whether Medicare Part B-covered entities have policies or plans in place to mitigate breaches.
(OEI; 09-10-00511; expected issue date: FY 2013; work in progress; Recovery Act)

Public Health Programs

Acronyms and Abbreviations for Selected Terms Used in the Public Health Programs Section:

EHR—electronic health records

ONC—Office of the National Coordinator for Health Information Technology

Health Resources and Services Administration

HRSA—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-00-11-27105; W-00-12-27105; various reviews; expected issue date: FY 2013; work in progress, Recovery Act)*

HRSA—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. Forty-six community health centers in Florida were awarded about $88 million in Recovery Act funding. In Alabama, one community health center received about $15 million for a competitive Facility Investment Program grant, almost half of the total amount received by the other 14 Alabama grantees. On the basis of results, audits may be performed in other States.
(OAS; W-00-11-27105; W-00-12-27105; expected issue date: FY 2013; work in progress; Recovery Act)

HRSA—Community Health Centers Receiving Health Information Technology Funding

We will review general security controls in place for community health center systems funded by HRSA HIT grants to ensure that adequate HIT security controls are in place to protect sensitive EHR and personal information. HRSA will expend $120 million of $1.5 billion in Recovery Act funding for HIT 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-00-13-27109; various reviews; expected issue date: FY 2013; new start; Recovery Act)*

HRSA—Health Information Technology Grants

We will determine the extent to which HRSA Recovery Act grants supported the implementation and expansion of EHRs through health-center-controlled networks. In 2009 and 2010, HRSA awarded 99 grants totaling nearly $121 million in Recovery Act funds for EHR implementation and other HIT initiatives. We will survey HRSA grantees about how Recovery Act grants supported the adoption, use, and sustainability of EHRs through health-center-controlled networks. *(OEI; 09-11-00380; expected issue date: FY 2013; work in progress; Recovery Act)*

National Institutes of Health

NIH—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, improvements, or construction of core research facilities. The shared instrumentation spending plan proposes $300 million in 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-00-11-2710 ; W-00-12-27101; expected issue date: FY 2013; work in progress, Recovery Act)*

NIH—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. Such costs are usually treated as indirect costs.
(Office of Management and Budget (OMB) Circular A-21, *Cost Principles for Educational Institutions.)*
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-00-11-27101; W-00-12-27101; expected issue date: FY 2013; work in progress, Recovery Act)*

Human Services Programs

Acronyms and Abbreviations for Selected Terms Used in the Human Services Programs Section:

ACF—Administration for Children and Families
GATES—Grants Administration Tracking Evaluation System
TANF—Temporary Assistance for Needy Families

Administration for Children and Families

ACF—Grantees' Use of 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. (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; W-00-12-27100; expected issue date: FY 2013; work in progress, Recovery Act)*

ACF—Grant System

We will determine whether adequate general and application security controls for ACF'S Grants Administration Tracking Evaluation System (GATES) 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 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), child care and development, and community services. We will also determine whether ACF's grant awards require increased security provisions to protect sensitive EHR or personal information at the grantee level. *(OAS; W-00-11-27109; various reviews; expected issue date: FY 2013; new start; Recovery Act)*

ACF—Health Information Technology Grants

We will review general security controls for systems funded by ACF HIT grants to determine whether adequate security controls are in place to protect sensitive EHR and personal information. ACF will award HIT grants to State agencies, local governments, nonprofit organizations, and school systems administering Head Start, Early Head Start, TANF, Child Care and Community Development Block Grant, and Community Services Block Grant programs. We will also determine whether ACF grantees receiving HIT funds have sufficient processes in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. *(OAS; W-00-11-27109; various reviews; expected issue date: FY 2013; new start; Recovery Act)*

Other HHS-Related Issues

Office of the National Coordinator

ONC—State Compliance With Grant Requirements

We will review security controls implemented by States to safeguard electronic health information exchanges. 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. (Public Health Service Act of 1944, § 3013, as added by the Recovery Act, § 13301.) 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. *(OAS; W-00-13-27109; various reviews; expected issue date: FY 2013; new start; Recovery Act)*

Cross-Cutting Investigative Activities

Integrity of Recovery Act Expenditures

We will 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 the Department of Health and Human Services (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 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. The Recovery Act extends whistleblower protection to employees who reasonably believe they are being retaliated against for reporting misuse of Recovery Act funds received by their non-Federal employers. (§ 1553.) *(OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)*

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