

U.S. Department of Health and Human Services
Office of Inspector General

Work Plan

for Fiscal Year 2014



OIG Activities

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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 (FY) 2014 (*Work Plan*) summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the current fiscal year (FY) and beyond.

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, and the integrity of contracts and grants management processes and transactions.

How and where do we operate?

Our staff members 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).** 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).** OEI conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These
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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).** 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).** OCIG provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

The organizational entities described above are supported by the Immediate Office of the Inspector General (IO) 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 2013, we reported expected recoveries of over \$5.8 billion consisting of nearly \$850 million in audit receivables and about \$5 billion in investigative receivables, which include about \$1 billion in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution. We also identified about \$19.4 billion in savings estimated for FY 2013 on the basis of prior-period legislative, regulatory, or administrative actions that were supported by OIG recommendations.

Such estimates generally reflect third-party projections (such as those by the Congressional Budget Office or HHS actuaries) made at the time the action was taken. Actual savings may be higher or lower.

We reported FY 2013 exclusions of 3,214 individuals and entities from participation in Federal health care programs; 960 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 472 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) 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 2014, but a review designated as “new start,” meaning it is slated to begin in FY 2014, could result in an FY 2014 or FY 2015 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 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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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:

CAH—critical access hospital
CoP—conditions of participation (in Medicare)
DRG—diagnosis related group

MAC—Medicare Administrative Contractor
IPPS—inpatient prospective payment system
PPS—prospective payment system

Hospital-Related Policies and Practices

➤ Reconciliations of outlier payments

Policies and Practices. We will review Medicare outlier payments to hospitals to determine whether CMS performed necessary reconciliations in a timely manner to enable Medicare contractors to perform final settlement of the hospitals' associated cost reports. We will also determine whether the Medicare contractors referred all hospitals that meet the criteria for outlier reconciliations to CMS. **Context—**Outliers are additional payments that Medicare provides to hospitals for beneficiaries who incur unusually high costs. CMS reconciles outlier payments on the basis of the most recent cost-to-charge ratio from hospitals' associated cost reports. Outlier payments also may be adjusted to reflect the time value of money for overpayments and underpayments. Without reconciliations and final settlements, the cost reports remain open and funds may not be properly returned to the Medicare Trust Fund. (42 CFR, § 412.84(i)(4).) (OAS; W-00-13-35451; W-00-14-35451; various reviews; expected issue date: FY 2014; work in progress)

➤ **New inpatient admission criteria (new)**

Policies and Practices. We will determine the impact of new inpatient admission criteria on hospital billing, Medicare payments, and beneficiary payments. This review will also determine how billing varied among hospitals in FY 2014. Context—Previous OIG work found overpayments for short inpatient stays, inconsistent billing practices among hospitals, and financial incentives for billing Medicare inappropriately. Beginning in FY 2014, new criteria state that physicians should admit for inpatient care those beneficiaries who are expected to need at least 2 nights of hospital care. Beneficiaries whose care is expected to last less than 2 nights should be treated as outpatients. The criteria represent a substantial change in the way hospitals bill for inpatient and outpatient stays. (OEI; 00-00-00000; expected issue date: FY 2015; new start)

➤ **Medicare costs associated with defective medical devices (new)**

Policies and Practices. We will review Medicare claims to identify the costs resulting from additional utilization of medical services associated with defective medical devices and determine the impact of the cost on the Medicare Trust Fund. Context—CMS has previously expressed concerns about the impact of the cost of replacement devices, including ancillary cost, on Medicare payments for inpatient and outpatient services. (OAS; W-00-13-35516; various reviews; expected issue date: FY 2014; work in progress)

➤ **Analysis of salaries included in hospital cost reports (new)**

Policies and Practices. We will review data from Medicare cost reports and hospitals to identify salary amounts included in operating costs reported to and reimbursed by Medicare. We will determine the potential impact on the Medicare Trust Fund if the amount of employee compensation that could be submitted to Medicare for reimbursement on future cost reports had limits. Context—Employee compensation may be included in allowable provider costs only to the extent that it represents reasonable remuneration for managerial, administrative, professional, and other services related to the operation of the facility and furnished in connection with patient care. (CMS's *Provider Reimbursement Manual*, Part 1, Pub. No. 15-1, Ch. 9 § 902.2.) Medicare does not provide any specific limits on the salary amounts that can be reported on the hospital cost report. (OAS; W-00-13-35715; W-00-14-35713; expected issue date: FY 2015; work in progress)

➤ **Impact of provider-based status on Medicare billing**

Policies and Practices. We will determine the impact of subordinate facilities in hospitals billing Medicare as being hospital based (provider based) and the extent to which such facilities meet CMS's criteria. Context—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 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 2014; work in progress)

➤ **Comparison of provider-based and free-standing clinics (new)**

Policies and Practices. We will review and compare Medicare payments for physician office visits in provider-based clinics and free-standing clinics to determine the difference in payments made to the

clinics for similar procedures and assess the potential impact on the Medicare program of hospitals' claiming provider-based status for such facilities. Context—Provider-based facilities often receive higher payments for some services than do freestanding clinics. The requirements to be met for a facility to be treated as a provider-based facility are at 42 CFR § 413.65(d). (OAS; W-00-14-35724; expected issue date: FY 2014; new start)

➤ **Critical access hospitals—Payment policy for swing-bed services**

Policies and Practices. We will compare reimbursement for swing-bed services at critical access hospitals (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. Context—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; W-00-13-35101; W-00-14-35101; various reviews; expected issue date: FY 2014; work in progress)

➤ **Critical access hospitals—Beneficiary costs for outpatient services**

Policies and Practices. We will determine the costs to Medicare beneficiaries for outpatient services received at CAHs. Context—In 1997, the Balance Budget Act created the CAH certification to ensure that hospital care was accessible to beneficiaries in rural communities. Small hospitals that meet specific requirements can qualify for the CAH certification and receive favorable Medicare reimbursements. Medicare reimburses CAHs at 101 percent of their reasonable costs for services provided. However, beneficiaries who receive outpatient services at CAHs pay coinsurance amounts that are computed on the basis of CAHs' submitted charges, rather than the costs of the services. (Social Security Act, § 1820(c)(2)(B).) (OEI; 05-12-00085; expected issue date: FY 2014; work in progress)

➤ **Long-term-care hospitals—Billing patterns associated with interrupted stays**

Policies and Practices. We will identify readmission patterns in long-term-care hospitals (LTCHs) to determine the extent to which LTCHs readmit patients after a certain number of days, thereby billing Medicare for higher paying new stays and separate payments instead of for interrupted stays. We will also determine the extent to which co-located LTCHs readmit patients from the providers with which they are co-located. We will also determine the extent to which Medicare made improper payments associated with readmissions in long-term-care hospitals (LTCH) in 2011. Context—Prior OIG work identified vulnerabilities in CMS's ability to detect readmissions and appropriately pay the readmissions as interrupted stays instead of as higher paying new admissions. 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 leaves the LTCH for treatment and services that are not available at the LTCH and returns within a specific number of days. If patients return to the LTCH after a specific number of days, the stays are billed as new admissions rather than interrupted stays

and the LTCHs will receive two Medicare payments. (42 CFR § 412.531.) (OEI; 04-12-00490; expected issue date: FY 2014; work in progress)

Hospitals—Billing and Payments

➤ Inpatient claims for mechanical ventilation

Billing and Payments. We will review Medicare payments for inpatient hospital claims with certain Medicare Severity-Diagnosis Related Group (MS-DRG) assignments that require mechanical ventilation to determine whether hospitals' DRG assignments and resultant Medicare payments were appropriate. Context—Mechanical ventilation is the use of a ventilator or respirator to take over active breathing for a patient. Claims must be completed accurately to be processed correctly and promptly. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, § 80.3.2.2.) For certain DRGs to qualify for Medicare coverage, a patient must receive 96 or more hours of mechanical ventilation. Our review will include claims for beneficiaries who received over 96 hours of mechanical ventilation. Previous OIG reviews identified improper payments made because hospitals inappropriately billed for beneficiaries who did not receive 96 or more hours of mechanical ventilation. (OAS; W-00-14-35575; various reviews; expected issue date: FY 2015; work in progress)

➤ Selected inpatient and outpatient billing requirements

Billing and Payments. We will review Medicare payments to acute care hospitals to determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments. We will also survey or interview hospitals' leadership and compliance officers to provide contextual information related to hospitals' compliance programs. Context—Prior OIG audits, investigations, and inspections have identified areas at risk for noncompliance with Medicare billing requirements. Our review will focus on those hospitals with claims that may be at risk for overpayments. (OAS; W-00-12-35538; W-00-13-35538; W-00-14-35538; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ Duplicate graduate medical education payments

Billing and Payments. We will review provider data from CMS's Intern and Resident Information System (IRIS) to determine whether hospitals received duplicate or excessive graduate medical education (GME) payments. We will also assess the effectiveness of IRIS in preventing duplicate payments for GME costs. If duplicate payments were claimed, we will determine which payment was appropriate. Context—Prior OIG reviews have determined that hospitals have received duplicate reimbursement for GME costs. Medicare pays teaching hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs. In calculating 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. (OAS; W-00-13-35432; W-00-14-35432; various reviews; expected issue date: FY 2014; work in progress)

➤ Outpatient dental claims

Billing and Payments. We will review Medicare hospital outpatient payments for dental services to determine whether such payments were made in accordance with Medicare requirements. Context— Current OIG audits have indicated that hospitals received Medicare reimbursement for

noncovered dental services, resulting in significant overpayments. 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. No. 100-02, ch. 15, § 150). (OAS; W-00-13-35603; W-00-14-35432; various reviews; expected issue date: FY 2014; work in progress)

➤ **Outpatient evaluation and management services billed at the new-patient rate (new)**

Billing and Payments. We will review Medicare outpatient payments made to hospitals for evaluation and management (E/M) services for clinic visits billed at the new-patient rate to determine whether they were appropriate and recommend recovery of overpayments.

Context—Preliminary work identified overpayments that occurred because hospitals used new-patient codes when billing for services to established patients. The rate at which Medicare pays for evaluation and management services requires hospitals to identify patients as either new or established, depending on previous encounters with the hospital. According to Federal regulations, the meaning of “new” and “established” pertains to whether the patient has been seen as a registered inpatient or outpatient of the hospital within the past 3 years. (73 Fed. Reg. 68679 (November 18, 2008).) (OAS; W-00-12-35627; W-00-14-35627; expected issue date: FY 2014; work in progress)

➤ **Nationwide review of cardiac catheterization and heart biopsies (new)**

Billing and Payments. We will review Medicare payments for right heart catheterizations (RHC) and heart biopsies billed during the same operative session and determine whether hospitals complied with Medicare billing requirements. **Context—**Previous OIG reviews have identified inappropriate payments when hospitals were paid for separate RHC procedures when the services were already included in payments for heart biopsies. To be processed correctly and promptly, a bill must be completed accurately. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, §80.3.2.2.) (OAS; W-00-14-35721; various reviews; expected issue date: FY 2015; new start)

➤ **Payments for patients diagnosed with kwashiorkor (new)**

Billing and Payments. We will review Medicare payments made to hospitals for claims that include a diagnosis of Kwashiorkor to determine whether the diagnosis is adequately supported by documentation in the medical record. **Context—**To be processed correctly and promptly, a bill must be completed accurately. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, §80.3.2.2.) A diagnosis of Kwashiorkor on a claim substantially increases the hospitals' reimbursement from Medicare. Kwashiorkor is a form of severe protein malnutrition that generally affects children living in tropical and subtropical parts of the world during periods of famine or insufficient food supply. It is typically not found in the United States. Prior OIG reviews have identified inappropriate payments to hospitals for claims with a Kwashiorkor diagnosis. (OAS; W-00-13-35715; W-00-14-35715; various reviews; expected issue date: FY 2014; work in progress)

➤ **Bone marrow or stem cell transplants (new)**

Billing and Payments. We will review Medicare payments made to hospitals for bone marrow or stem cell transplants to determine whether Medicare payments were paid in accordance with

Federal rules and regulations. Context—Bone marrow or peripheral blood stem cell transplantation is a process that includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, §90.3.) Transplantations are covered under Medicare only for specific diagnoses. Procedure codes must be accompanied with by the diagnosis codes that meet specified coverage criteria. Prior OIG reviews have identified hospitals that have incorrectly billed for bone marrow or stem cell transplants. (OAS; W-00-14-35723; expected issue date: FY 2014; new start)

➤ Indirect medical education payments (new)

Billing and Payments. We will review provider data to determine whether hospitals' indirect medical education (IME) payments were made in accordance with Federal regulations and guidelines. We will determine whether the IME payments were calculated properly. Context—Prior OIG reviews have determined that hospitals have received excess reimbursement for IME costs. Teaching hospitals with residents in approved graduate medical education programs receive additional payments for each Medicare discharge to reflect the higher indirect patient care costs of teaching hospitals relative to those of nonteaching hospitals. (42 U.S.C. § 1395ww(d)(5)(B).) The additional payments, known as the IME adjustments, are calculated using the hospital's ratio of resident full-time equivalents to available beds. (OAS; W-00-14-35722; expected issue date: FY 2014; new start)

Hospitals—Quality of Care and Safety

➤ Participation in projects with quality improvement organizations

Quality of Care and Safety. We will determine the extent and nature of hospitals' participation in quality improvement projects with Quality Improvement Organizations (QIO). We will also determine the extent to which QIOs' quality improvement projects in hospitals overlap with projects offered by other entities. Context—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 will spend about \$1.3 billion in the current 3-year QIO contract period, and each contract specifies clinical areas for quality improvement projects. (OEI; 01-12-00650; expected issue date: FY 2014; work in progress)

➤ Oversight of pharmaceutical compounding (new)

Quality of Care and Safety. We will describe Medicare's oversight of pharmaceutical compounding in Medicare-participating acute care hospitals. We will also describe how State agencies and hospital accreditors assess such pharmacy services in hospitals. Context—Pharmaceutical compounding is the creation of a prescription drug tailored to meet the needs of an individual patient. Most hospitals compound at least some pharmaceuticals onsite. Medicare oversees the safety of pharmaceuticals compounded at Medicare participating hospitals through the accreditation and certification process. This work is particularly important in view of a recent meningitis outbreak resulting from contaminated injections of compounded drugs. (OEI; 01-13-00400; expected issue date: FY 2014; work in progress)

➤ **Hurricane Sandy—Case study of hospitals' emergency preparedness and response (new)**

Quality of Care and Safety. We will assess and describe hospital preparedness and response during Hurricane Sandy. Specifically, we will assess the emergency preparedness of hospitals in selected counties affected, including the hospitals' participation in the Public Health Emergency Preparedness Cooperative Agreements program funded through the Centers for Disease Control and Prevention and the Hospital Preparedness Program funded through the Office of the Assistant Secretary for Preparedness and Response. Context—CMS's Conditions of Participation (CoPs) require that hospitals develop and maintain a hospital environment that ensures the safety and well-being of patients and have adequate medical and nursing staff during disasters. (CFR § 482.41 and CFR § 482.55(b)(2).) CoPs must be met for hospitals to participate in Medicare. (OEI; 06-13-00260; expected issue date: FY 2014; work in progress)

➤ **Oversight of hospital privileging (new)**

Quality of Care and Safety. We will determine how hospitals assess medical staff candidates prior to granting initial privileges, including verification of credentials and review of the National Practitioner Databank. Context—Hospitals that participate in Medicare must have an organized medical staff that periodically appraises its members (42 CFR § 482.22). A hospital's governing body must ensure that the members of the medical staff, including physicians and other licensed independent practitioners, are accountable for the quality of care provided to patients. Robust hospital privileging programs contribute to patient safety. (OEI; 06-13-00410; expected issue date: FY 2015; work in progress)

➤ **inpatient rehabilitation facilities—Adverse events in post-acute care for Medicare beneficiaries**

Quality of Care and Safety. We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving postacute care in inpatient rehabilitation facilities (IRF). We will also identify factors contributing to these events, determine the extent to which the events were preventable, and estimate the associated costs to Medicare. Context—IRFs are inpatient facilities that provide intensive rehabilitation therapy to patients recovering from illness, injury, or surgery, typically consisting of at least 3 hours of therapy per day. Upon discharge from the hospital, IRF residents often require extensive services to improve functioning before returning home. IRFs provide 11 percent of postacute facility care and have experienced rapid growth over the last decade. IRF care accounted for \$7 billion in Medicare expenditures in 2011. (OEI; 06-14-00110; expected issue date: FY 2015; work in progress)

Nursing Homes

Acronyms and Abbreviations for Selected Terms:

IRF—inpatient rehabilitation facility

SNF—skilled nursing facility

➤ Medicare Part A billing by skilled nursing facilities (new)

Policies and Practices. We will describe SNF billing practices in selected years and will describe variation in billing among SNFs in those years. **Context—**Prior OIG work found that SNFs increasingly billed for the highest level of therapy even though beneficiary characteristics remained largely unchanged. OIG also found that SNFs billed one-quarter of all 2009 claims in error, resulting in \$1.5 billion in inappropriate Medicare payments. CMS has made substantial changes to how SNFs bill for services for Medicare Part A stays. (OEI; 02-13-00610; 00-00-0000; various reviews; expected issue date: FY 2014; work in progress)

➤ Questionable billing patterns for Part B services during nursing home stays

Billing and Payments. We will identify questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to nursing home residents during stays not paid under Part A (for example, stays during which benefits are exhausted or the 3-day prior-inpatient-stay requirement is not met). A series of studies will examine several broad categories of services, such as foot care. **Context—**Congress explicitly directed OIG to monitor Part B billing for abuse during non-Part A stays. (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 313.) (OEI; 06-14-00160; various reviews; expected issue date: FY 2014; work in progress)

➤ State agency verification of deficiency corrections

Quality of Care and Safety—We will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. **Context—**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. 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.) (OAS; W-00-13-35701; W-00-14-35101; various reviews; expected issue date: FY 2014; work in progress)

➤ Program for national background checks for long-term-care employees

Quality of Care and Safety. We will review the procedures implemented by participating States for long-term-care facilities or providers to conduct background checks on prospective employees and providers who would have direct access to patients and determine the costs of conducting background checks. We will determine the outcomes of the States' programs and determine whether the programs led to any unintended consequences. **Context—**This mandated work is ongoing and will be issued at the program's conclusion as required. (Affordable Care Act, § 6401.) (OEI; 07-10-00420; expected issue date: FY 2017; work in progress; Affordable Care Act)

➤ Hospitalizations of nursing home residents for manageable and preventable conditions

Quality of Care and Safety—We will determine the extent to which Medicare beneficiaries residing in nursing homes are hospitalized as a result of conditions thought to be manageable or preventable in the nursing home setting. Context—A 2013 OIG review found that 25 percent of Medicare beneficiaries were hospitalized for any reason in FY 2011. Hospitalizations of nursing home residents are costly to Medicare and may indicate quality-of-care problems in the nursing homes. (OEI; 06-11-00041; expected issue date: FY 2014; work in progress)

Hospices

Acronyms and Abbreviations for Selected Terms:

CoPs—(Medicare) conditions of participation

➤ Hospice in assisted living facilities (new)

Policies and Practices. We will review the extent to which hospices serve Medicare beneficiaries who reside in assisted living facilities (ALFs). We will determine the length of stay, levels of care received, and common terminal illnesses of beneficiaries who receive hospice care in ALFs. Context—Pursuant to the Affordable Care Act, § 3132, CMS must reform the hospice payment system, collect data relevant to revising hospice payments, and develop quality measures for hospices. Our work is intended to provide HHS with information relevant to these requirements. Medicare covers hospice services for eligible beneficiaries under Medicare Part A. (Social Security Act, § 1812(a).) Hospice care may be provided to individuals and their families in various settings, including the beneficiary's place of residence, such as an ALF. ALF residents have the longest lengths of stay in hospice care. The Medicare Payment Advisory Commission has said that these long stays bear further monitoring and examination. (OEI; 02-14-00070; expected issue date: FY 2014; work in progress; Affordable Care Act)

➤ Hospice general inpatient care

Quality of Care and Safety. We will review the use of hospice general inpatient care. We will assess the appropriateness of hospices' general inpatient care claims and the content of election statements for hospice beneficiaries who receive general inpatient care. We will also review hospice medical records to address concerns that this level of hospice care is being misused. Context—Hospice care is palliative rather than curative. When a beneficiary elects hospice care, the hospice agency assumes the responsibility for medical care related to the beneficiary's terminal illness and related conditions. Federal regulations address Medicare conditions of participation for hospices. (42 CFR Part 418.) Beneficiaries may revoke their election of hospice care and return to standard Medicare coverage at any time. (42 CFR § 418.28.) (OEI; 02-10-00491; 02-10-00492; expected issue date: FY 2014; work in progress)

Home Health Services

Acronyms and Abbreviations for Selected Terms:

CoP—(Medicare) conditions of participation
HHA—home health agency

PPS—prospective payment system

➤ Home health prospective payment system requirements

Billing and Payments. We will review compliance with various aspects of the home health prospective payment system (PPS), including the documentation required in support of the claims paid by Medicare. We will determine whether home health claims were in paid in accordance with Federal laws and regulations. **Context—**A prior OIG report found that one in four HHAs had questionable billing. Further, CMS designated newly enrolling HHAs as high-risk providers, citing their record of fraud, waste, and abuse. Since 2010, nearly \$1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit. 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-00-13-35501; W-00-14-35501; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ Employment of individuals with criminal convictions

Quality of Care and Safety. We will determine the extent to which home health agencies (HHAs) are complying with State requirements for conducting criminal background checks on HHA applicants and employees. **Context—**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 should have been disqualified from working in nursing homes because OIG did not have access to detailed information on the nature of the employees' crimes. 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).) Nearly all States have laws prohibiting certain health-care-related entities from employing individuals with prohibited criminal convictions. (OEI; 07-14-00130; expected issued date: FY 2015; work in progress)

Medical Equipment and Supplies

Acronyms and Abbreviations for Selected Terms:

CBA—Competitive Bidding Areas
E/M—evaluation and management (services)

LCD—local coverage determination
PMD—power mobility device

Equipment and Supplies—Policies and Practices

➤ Reasonableness of Medicare's fee schedule amounts for selected medical equipment items compared to amounts paid by other payers (new)

Policies and Practices. The review will determine the reasonableness of the Medicare fee schedule amount for various medical equipment items, including commode chairs, folding walkers, and transcutaneous electrical nerve stimulators. We will compare Medicare payments made for various medical equipment items 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 the various Items with those of non-Medicare payers. Context—Prior OIG work found that Medicare overpays for various types of medical equipment. Federal statutes and regulations authorize CMS to determine whether the standard methods of determining the fee schedule amounts have resulted in unreasonably high or low payment amounts for particular items or services. If CMS determines that the standard methods of determining fee schedule amounts for certain categories of items or services will result in "grossly deficient or excess amounts," CMS may replace the current fee schedule amounts with special payment limits that are reasonable and equitable. (42 CFR § 405.502(g)(1)(ii) - (iii).) (OAS; W-00-14-35462; expected issue date: FY 2015; new start)

➤ Power mobility devices—Lump-sum purchase versus rental (new)

Policies and Practices. We will determine whether potential savings can be achieved by Medicare if certain power mobility devices (PMDs) are rented over a 13-month period rather than acquired through a lump-sum purchase. (OAS; W-14-35461; expected issue date: FY 2015; new start)

➤ Parenteral nutrition—Reasonableness of Medicare payments compared to payments by other payers

Policies and Practices. We will determine the reasonableness of Medicare reimbursement rates for Parenteral Nutrition compared to amounts paid by other payers. Context—Previous OIG work found that Medicare allowances for parenteral nutrition 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. 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. (OEI; 04-12-00640; expected issue date: FY 2015; work in progress)

➤ Competitive bidding for medical equipment items and services—Mandatory postaward audit

Policies and Practices. 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. Context—Federal law requires OIG to conduct postaward audits to assess this process. (Medicare Improvements for Patients and Providers Act of 2008 (MIA), § 154(a)(1)(E).) (OAS; W-00-12-35241; W-00-13-35241; various reviews; expected issued date: FY 2014; work in progress)

➤ **Competitive bidding for diabetes testing supplies—Mandatory market share review (new)**

Policies and Practices. We will determine the market share of different types of diabetic testing strips immediately following implementation of Round 2 of the Competitive Bidding Program. **Context—**The Medicare Improvements for Patients and Providers Act (MIA) requires OIG to complete a review to determine the market share of diabetic testing strip types and to submit it to the Secretary of HHS before each subsequent round of the Competitive Bidding Program. MIA requires that in rounds subsequent to the Round 1 Rebid of the Competitive Bidding program, contracts for mail order diabetic testing strips be awarded to suppliers that provide at least 50 percent, by volume, of all types of diabetic testing strips. (OEI; 04-13-00680; 04-13-00681; 04-13-00682; expected issue date: FY 2014; work in progress)

Equipment and Supplies—Billing and Payments

➤ **Power mobility devices—Supplier compliance with payment requirements**

Billing and Payments. We will review Medicare Part B payments for suppliers of power mobility devices (PMD) to determine whether such payments were in accordance with Medicare requirements. We will focus particularly on whether Medicare payments for PMD claims submitted by medical equipment suppliers are medically necessary and are supported in accordance with requirements at 42 CFR § 410.38. (OAS; W-00-13-35706; various reviews; expected issue date: FY 2014; work in progress)

➤ **Power mobility devices—Add-on payment for face-to-face examination (new)**

Billing and Payments. We will review Medicare Part B payments for PMD to determine whether the Medicare requirements for a face-to-face examination were met. **Context—**Medicare requires that the treating physician, when prescribing a PMD, conduct a face-to-face examination to determine the medical necessity of the PMD and write a prescription for the PMD. (42 CFR § 410.38(c)(2).) To receive compensation for conducting the face-to-face examination, the prescribing physician can bill for an evaluation and management (E/M) service and has the option of billing Medicare for an add-on payment for the sole purpose of documenting the need for the PMD. Prior OIG work found that when the prescribing physician did not bill the code for the add-on payment in addition to the evaluation and management (E/M) code, the resulting PMD claim was likely to be unallowable. (OAS; W-00-14-35460; expected issue date: FY 2014; work in progress)

➤ **Lower limb prosthetics—Supplier compliance with payment requirements**

Billing and Payments. 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. No. 100-02, ch. 15, § 120, were met. **Context—**A national OIG review of suppliers of lower limb prosthetics identified 267 suppliers that had questionable billing. Earlier 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 for lower limb prostheses for a high percentage of beneficiaries with no history of amputations or missing limbs). Such claims are questionable and, if determined to be improper, should not be paid by Medicare. 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).) (OAS; W-00-13-35702; various reviews; expected issue date: FY 2014; work in progress)

➤ **Nebulizer machines and related drugs—Supplier compliance with payment requirements (new)**

Billing and Payments. We will review Medicare Part B payments for nebulizer machines and related drugs to determine whether medical equipment suppliers’ claims are for nebulizers and related drugs that are medically necessary and are supported in accordance with Medicare requirements. Context—Prior OIG work found that suppliers were overpaid approximately \$46 million for inhalation drugs used with nebulizer machines. Medicare requires that such items be “reasonable and necessary.” (Social Security Act § 1862(a)(1)(A).) Further, the local coverage determinations (LCD) issued by the four Medicare contractors that process medical equipment and supply claims contain utilization guidelines and documentation requirements. (OAS; W-00-14-35465; expected issue date: FY 2015; new start)

➤ **Frequently replaced supplies—Supplier compliance with medical necessity, frequency, and other requirements**

Billing and Payments. We will review claims for frequently replaced medical equipment supplies to determine whether medical necessity, frequency, and other Medicare requirements are met. Context—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. 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).) (OAS; W-00-13-35240; various reviews; expected issue date: FY 2015; new start)

➤ **Diabetes testing supplies—Supplier compliance with payment requirements for blood glucose test strips and lancets**

Billing and Payments. We will review Medicare Part B payments for home blood glucose test strips and lancet supplies to determine their appropriateness. Context—Prior OIG reviews determined that suppliers of diabetic related supplies did not always comply with Federal requirements. As reflected in the local coverage determinations (LCD) issued by the Medicare contractors that process medical equipment and supply claims, physicians’ orders for items billed to Medicare must include certain elements and be retained by the suppliers to support billing for the services. Suppliers of diabetes testing supplies are required to add a modifier code on claims 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 2014; work in progress)

➤ **Diabetes testing supplies—Effectiveness of system edits to prevent inappropriate payments for blood-glucose test strips and lancets to multiple suppliers**

Billing and Payments. 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.

Context—Prior OIG work found that inappropriate payments were made to multiple medical equipment suppliers for test strips and lancets dispensed to the same beneficiaries with overlapping service dates. 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 specifically request the refills before the suppliers dispense them. 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 2015; work in progress)

Other Providers and Suppliers

Acronyms and Abbreviations for Selected Terms:

CERT—Comprehensive Error Rate Testing (program)
E/M—evaluation and management (services)
ESRD—end-stage renal disease

PHP—partial hospitalization program
PPS—prospective payment system
RHC—rural health clinic

Other Providers—Policies and Practices

➤ **Ambulance services—Portfolio report on Medicare Part B payments (new)**

Policies and Practices. We will analyze and synthesize OIG evaluations, audits, investigations, and compliance guidance related to ground ambulance transport services paid by Medicare Part B to identify vulnerabilities, inefficiencies, and fraud trends and offer recommendations to improve detected vulnerabilities and minimize inappropriate payments for ambulance services. **Context—**Prior OIG work identified fraud schemes and trends indicating overutilization and medically unnecessary payments. The planned portfolio will offer recommendations to address the vulnerabilities that we have identified and improve efficiency. Medicare does not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness of injury...” (Social Security Act, § 1862(a)(1)(A).) Specifically, ambulance services are covered “where the use of other methods of transportation is contraindicated by the individual’s condition...” (§ 1861(s)(7).) The *Medicare Benefit Policy Manual*, § 10.2.1, more specifically states that Medicare covers ambulance transports when a beneficiary’s medical condition at the time of the transport is such that using other means of transportation would endanger the beneficiary’s health. Coverage requirements and requirements for ambulance suppliers are in 42 CFR §§ 410.40 and 41. (OIG; OIG-12-14-02; expected issue date: FY 2014; work in progress)

➤ Ambulatory surgical centers—Payment system

Policies and Practices. We will review the appropriateness of Medicare's methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. We will also determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. Context—A change in Federal law required the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs beginning January 1, 2008. Accordingly, CMS implemented a revised ASC payment system modeled on the Outpatient Prospective Payment System. (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 2014; work in progress)

➤ End-stage renal disease facilities—Payment system for renal dialysis services and drugs

Policies and Practices. We will review Medicare payments for and utilization of renal dialysis services and related drugs pursuant to the new bundled end-stage renal disease (ESRD) prospective payment system (PPS). We will compare facilities' acquisition costs for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed. Context—Previous OIG work found that data from the Bureau of Labor Statistics (BLS) did not accurately measure changes in facilities' acquisition costs for high-dollar ESRD drugs. However, CMS has based the ESRD PPS price updates on wage and price proxy data from the BLS. 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. (75 Fed. Reg. 49030 at page 49151 (Aug. 12, 2010).) (OAS; W-00-12-35608; W-00-13-35608; various reviews; and OEI; 03-12-00550; expected issue date: FY 2014; work in progress)

➤ Rural health clinics—Compliance with location requirements

Policies and Practices. We will determine the extent to which Rural Health Clinics (RHCs) do not meet basic location requirements and the extent to which Medicare reimbursements to such clinics are occurring. Context—The Balanced Budget Act of 1997 (BBA) authorized CMS to remove from the RHC program clinics that do not meet location requirements. In 2005, OIG recommended that CMS promulgate regulations to implement the BBA. However, CMS has yet to promulgate the final regulations. As a result, RHCs that no longer meet eligibility requirements continue to receive enhanced Medicare reimbursement. (OEI; 05-13-00290; expected issue date: FY 2014)

Other Providers—Billing and Payments

➤ Ambulance services—Questionable billing, medical necessity, and level-of-transport

Billing and Payments. We will examine Medicare claims data to assess the extent of questionable billing for ambulance services, such as transports that potentially never occurred or potentially medically unnecessary transports to dialysis facilities. We will also determine whether Medicare payments for ambulance services were made in accordance with Medicare requirements. Context—

Prior OIG work found that Medicare made inappropriate payments for advanced life support emergency transports. 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 2014; work in progress; and OAS; W-00-11-35574; W-00-12-35574; various reviews; expected issue date: FY 2014; work in progress)

➤ Anesthesia services—Payments for personally performed services

Billing and Payments. 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. **Context—**Physicians report the appropriate anesthesia modifier code to denote whether the service was personally performed or medically directed. (CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch.12, § 50) Reporting an incorrect modifier on the claim as if services were personally performed when they were not will result in Medicare's paying a higher amount. The service code "AA" modifier is used for anesthesia services personally performed by an anesthesiologist, whereas the QK modifier limits payment to 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 2014; new start)

➤ Chiropractic services—Portfolio report on Medicare Part B payments (new)

Billing and Payments. We will compile the results of prior OIG audits, evaluations, and investigations of chiropractic services paid by Medicare to identify trends in payment, compliance, and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities. **Context—**Prior OIG work identified inappropriate payments for chiropractic services that were medically unnecessary, were not documented in accordance with Medicare requirements, or were fraudulent. Medicare does not pay for items or services that are "not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." (Social Security Act, § 1862(a)(1)(A).) Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if there is a neuro-musculoskeletal condition for which such manipulation is appropriate treatment. (42 CFR § 410.21(b).) CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 30.5, states that chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. Further, § 240.1.2 of the Manual establishes Medicare requirements for documenting chiropractic services. This planned portfolio document will offer new recommendations to improve Medicare chiropractic vulnerabilities detected in prior OIG work. (OAS; OIG-12-14-03; expected issue date: FY 2014; work in progress)

➤ Chiropractic services—Part B payments for noncovered services

Billing and Payments. We will review Medicare Part B payments for chiropractic services to determine whether such payments were claimed in accordance with Medicare requirements. **Context—**Prior OIG work identified inappropriate payments for chiropractic services furnished during calendar year (CY) 2006. Subsequent OIG work (CY 2013) also identified unallowable

Medicare payments for chiropractic services. Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if there is a neuro-musculoskeletal condition for which such manipulation is appropriate treatment. (42 CFR § 410.21(b).) Chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. (CMS's *Medicare Benefit Policy Manual*, Pub. No. 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 2014; work in progress)

➤ **Chiropractic services—Questionable billing and maintenance therapy (new)**

Billing and Payments. We will determine the extent of questionable billing for chiropractic services. We will also identify trends suggestive of maintenance therapy billing. Context—Previous OIG work has demonstrated a history of vulnerabilities relative to inappropriate payments for chiropractic services, including recent work that identified a chiropractor with a 93-percent claim error rate and inappropriate Medicare payments of about \$700,000. Although chiropractors may submit claims for any number of services, Medicare reimburses claims only for manual manipulations or treatment of subluxations of the spine that provides "a reasonable expectation of recovery or improvement of function." Moreover, Medicare does not reimburse for chiropractic maintenance therapy. (CMS's *Medicare Benefit Policy Manual*, Pub. No. 100 02, ch. 15, § 30.5B.) (OEI; 01-14-00200; expected issue date: FY 2015, work in progress)

➤ **Diagnostic radiology—Medical necessity of high-cost tests**

Billing and Payments. We will review Medicare payments for high-cost diagnostic radiology tests to determine whether they were medically necessary and the extent to which utilization has increased for these tests. 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 2015; work in progress)

➤ **Electrodiagnostic testing—Questionable billing**

Billing and Payments. We will review Medicare claims data to identify questionable billing for electrodiagnostic testing and determine the extent to which Medicare utilization rates differ by provider specialty, diagnosis, and geographic area for these services. Context—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 could pose a growing vulnerability to Medicare. (OEI; 04-12-00420; expected issue date: FY 2013; work in progress)

➤ **Evaluation and management services—Inappropriate payments**

Billing and Payments. We will determine the extent to which selected payments for evaluation and management (E/M) services were inappropriate. We will also review multiple E/M services associated with the same providers and beneficiaries to determine the extent to which electronic or paper medical records had documentation vulnerabilities. Context—Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the billing code for the service on the basis of the content of the service and to 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 2014; work in progress)

➤ **Imaging services—Payments for practice expenses**

Billing and Payments. We will review Medicare Part B payments for 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. **Context—**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 2014; work in progress)

➤ **Laboratory tests—Billing characteristics and questionable billing**

Billing and Payments. We will review billing characteristics for Part B clinical laboratory (lab) tests and identify questionable billing. **Context—**Medicare is the largest payer of clinical lab services in the Nation. Medicare's payments for lab services in 2008 represented an increase of 92 percent over payments in 1998. In 2010, Medicare paid about \$8.2 billion for lab tests, accounting for 3 percent of all Medicare Part B payments. Much of the growth in lab spending has resulted from the increased volume of ordered services. Part B covers most lab tests and pays 100 percent of allowable charges; Medicare beneficiaries do not pay copayments or deductibles for lab tests. Medicare should pay only for those lab 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)

➤ **Ophthalmologists—Questionable billing**

Billing and Payments. We will review Medicare claims data to identify inappropriate payments and/or questionable billing for ophthalmological services during 2012. We will also determine the geographic locations of providers exhibiting questionable billing for ophthalmological services in 2012. **Context—**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)

➤ **Partial hospitalization programs—Services in hospital outpatient departments and community mental health centers**

Billing and Payments. We will review Medicare payments for partial hospitalization program (PHP) psychiatric services in hospital outpatient departments and freestanding community mental health centers (CMHC) to determine whether Medicare requirements were met, with a focus on supporting documentation, including patient plans of care and physician supervision and certification. **Context—**Prior OIG reviews have identified inappropriate payments made for PHP services provided by CMHCs. PHPs are intensive outpatient programs of psychiatric services provided to individuals in lieu of inpatient psychiatric care. The programs include individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. Medicare coverage of PHP services is provided by the Social

Security Act, § 1832(a)(2)(J), and requirements 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; W-00-14-35453; various reviews; expected issue date: FY 2014; work in progress)

➤ **Physicians and suppliers—Noncompliance with assignment rules and excessive billing of beneficiaries**

Billing and Payments. We will review the extent to which physicians and suppliers participated in Medicare and accepted claim assignment during 2012. We will also assess the effects of their participation and claim assignments on the Medicare program (such as noncompliance with assignment rules) and on beneficiaries (such as excessive billing of beneficiaries' share of charges). **Context—**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 other 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—Place-of-service coding errors**

Billing and Payments. 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. **Context—** Prior OIG reviews determined that physicians did not always correctly code nonfacility places of service on Part B claims submitted to and paid by Medicare contractors. 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 2014; work in progress)

➤ **Physical therapists—High utilization of outpatient physical therapy services**

Billing and Payments. We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. **Context—** Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable or medically necessary or were not 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. No. 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 2014; work in progress and new start)

➤ **Portable x-ray equipment—Supplier compliance with transportation and setup fee requirements (new)**

Billing and Payments. We will review Medicare payments for the transportation and setup of portable x-ray equipment to determine whether payments were correct and were supported by documentation. We will also assess the qualifications of the technologists who performed the services and determine whether the services were ordered by a physician (e.g., doctor of medicine or doctor of osteopathy). **Context—**Prior OIG work found that Medicare improperly paid portable x-ray suppliers for return trips to nursing facilities (i.e., multiple trips to a facility in 1 day) and for services ordered by nonphysicians that are not covered by Medicare. Medicare generally reimburses for transportation and setup of portable x-ray equipment if the conditions for coverage are met. (42 CFR § 486, §§ 486.100 – 486.110.) (OAS; W-00-14-35464; various reviews; expected issue date: FY 2015; new start)

➤ **Sleep disorder clinics—High utilization of sleep-testing procedures**

Billing and Payments. We will examine Medicare payments to physicians, hospital outpatient departments, and independent diagnostic testing facilities for sleep-testing procedures to assess the appropriateness of Medicare payments for high utilization sleep-testing procedures and determine whether they were in accordance with Medicare requirements. **Context—**An OIG 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-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. No. 100-02, ch. 15, § 70. (OAS; W-00-10-35521; W-00-12-35521; various reviews; expected issue date: FY 2014; work in progress)

Other Providers—Quality of Care and Safety

➤ **End-stage renal disease—Dialysis facility survey cycle (new)**

Quality of Care and Safety. We will determine the extent, nature, and outcomes of Medicare’s survey and certification process of dialysis facilities. **Context—**State Agencies (SAs) conduct onsite surveys of dialysis facilities on behalf of CMS. (Social Security Act, § 1864.) When performing onsite surveys, the SAs use CMS’s guidelines to ensure facilities’ compliance with Medicare’s Conditions for Coverage. SAs cite a deficiency when they determine that facilities are not meeting statutory or regulatory requirements. Researchers have raised concerns that the SA survey process falls short in identifying poorly performing facilities. (OEI; 01-11-00551; expected issue date: FY 2015; work in progress)

➤ **Mental health providers—Medicare enrollment and credentialing (new)**

Quality of Care and Safety. We will review and describe Medicare’s mental health provider enrollment and credentialing requirements and assess CMS’s oversight efforts to verify the qualifications of mental health service providers. We will determine whether selected providers have the required Federal and State qualifications to bill Medicare for mental health services. **Context—**Medicare-covered mental health services are provided by several types of health

professionals, including psychiatrists or other physicians; clinical psychologists; clinical social workers, and clinical nurse specialists. To participate in Medicare, these providers must meet general Medicare provider enrollment standards as well as specific standards for licensure or certification within their States of practice. (OEI; 06-13-00560; expected issue date: FY 2014; 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

Prescription Drugs—Policies and Practices

➤ **Manufacturer reporting of average sales prices for Part B drugs (new)**

Policies and Practices. We will determine the potential effect on average sales price reporting if all manufacturers of Part B-covered drugs were required to submit ASPs to CMS. We will also determine whether CMS has improved its process for collecting ASP data, as we previously recommended. Context—Previous OIG work found that a number of manufacturers did not provide ASP data for their Part B drugs to CMS. When setting payment amounts for drugs covered under Medicare Part B, CMS relies on ASP data reported by manufacturers. With some exceptions, manufacturers that have Medicaid drug rebate agreements in effect are required to provide CMS with pricing information, including the ASPs, for their Part B drugs. (Social Security Act, §1927.) We found that not all manufacturers subject to the requirement complied while nearly one-fifth of the manufacturers that submitted ASP data to CMS were not required to do so because they did not have Medicaid rebate agreements in effect. We recommended that CMS seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. (OEI; 12-13-00040; expected issue date: FY 2014; work in progress)

➤ **Comparison of average sales prices to average manufacturer prices**

Policies and Practices. We will review Medicare Part B drug prices by comparing average sales prices (ASPs) to average manufacturer prices (AMPs) and identify drug prices that exceed a designated threshold. Context—In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The enabling law mandated that OIG compare ASPs with AMPs. (Social Security Act, § 1847A(d)(2)(B).) Pursuant to the requirement, OIG conducts such reviews and issues quarterly and annual reports of its findings. When OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent), OIG notifies the Secretary of HHS, who may disregard the ASP for the drug when setting reimbursement amounts (e.g., apply a price substitution policy). (OEI; 00-00-00000; various studies; expected issue date: FY 2015; new start)

➤ **Part B payments for drugs purchased under the 340B Program (new)**

Policies and Practices. We will determine how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs. We will calculate the amount

by which ASP-based payments exceed 340B prices and estimate potential savings on the basis of various shared-benefit methodologies. Context—Previous OIG work revealed that some Medicaid State agencies have developed strategies to take advantage of the discounts on 340B drugs. The 340B Program requires drug manufacturers to provide discounted outpatient drugs to approximately 10,000 covered entities. Medicare Part B reimburses for almost all covered outpatient drugs (including those purchased by 340B entities) on the basis of the average sales price (ASP), regardless of the amount paid for the drug. Medicare Part B providers that purchase drugs under the 340B program can fully retain the difference between the ASP-based payment amount and the 340B purchase price. (OEI; 12-14-00030; expected issue date: FY2014; work in progress)

Prescription Drugs—Billing and Payments

➤ Payments for immunosuppressive drug claims with KX modifiers

Billing and Payments. We will determine whether Part B payments for immunosuppressive drugs that were billed with a service code modifier “KX” met Medicare documentation requirements. Context— Medicare claims for immunosuppressive drugs reported with the KX modifier may not always meet the documentation requirements for payment under Part B. 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).) Since July 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary annotate the Medicare 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. (CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 17, § 80.3.) (OAS; W-00-13-35707; various reviews; expected issue date: FY 2014; new start)

➤ Payments for outpatient drugs and administration of the drugs

Billing and Payments. We will review Medicare outpatient payments to providers for certain drugs (e.g., chemotherapy drugs) and the administration of the drugs to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. Context—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 *Claims Processing Manual*, Pub. No. 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. (Chapter 5, § 20.2, and ch. 26, § 10.4.) (OAS; W-00-12-35576; various reviews; expected issue date: FY 2014; work in progress)

Prescription Drugs—Quality of Care and Safety

➤ Covered uses for Medicare Part B drugs (new)

Quality of Care and Safety. We will review the oversight actions CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria. We will also identify challenges contractors face when making coverage decisions for drugs. Context—If Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drugs with little clinical evidence of the drugs’ safety and effectiveness. Medicare Part B

generally covers drugs when they are used to treat conditions approved by the Food and Drug Administration, referred to as “on-label” uses. Part B may also cover drugs when an “off-label” use of the drug is supported in major drug compendia or when an off-label use is supported by clinical evidence in authoritative medical literature. (Social Security Act, § 1861(t).) (OEI; 03-13-00450; expected issue date: FY 2014; work in progress)

➤ Payment for compounded drugs under Medicare Part B (new)

Quality of Care and Safety. We will examine MACs’ policies and procedures for reviewing and processing Part B claims for compounded drugs and assess the appropriateness of such claims. Context—Pharmacy compounding is a practice in which pharmacists combine, mix, or alter ingredients to create unique medications that meet specific needs of individual patients. Compounded drugs may be eligible for coverage under Medicare Part B. However, for Medicare to pay for these drugs, they must be produced in accordance with the Federal Food, Drug, and Cosmetic Act. (Social Security Act, § 1862(a)(1)(A) and CMS’s *Benefits Policy Manual*, ch. 15, Sec. 50.4.7.) CMS notifies the MACs when FDA has determined that compounded drugs are being produced in violation of the Act. (OEI; 03-13-00270; expected issue date: FY 2014; work in progress)

➤ Ethics—Conflicts of interest involving prescription drug compendia

Quality of Care and Safety. We will determine the extent to which publishers of authoritative prescription drug compendia recognized by CMS have publicly transparent processes for evaluating anticancer drug therapies and identifying conflicts of interest related to the therapies included in the compendia. We will also determine the extent to which the publishers have processes for evaluating non-anticancer drug therapies and for identifying related conflicts and determine whether CMS ensures that the publishers identify and address conflicts. Context—Generally, Medicare covers drugs that are approved by FDA and supported by one or more drug compendia recognized by CMS. (CMS’s *Medicare Benefits Policy Manual*, Pub. No. 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 generally require the compendia to 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. Since 2010, publishers must have publicly transparent processes for evaluating anticancer drug therapies and for identifying potential conflicts related to inclusion of those therapies in the compendia (Social Security Act, § 1861); there are no such requirements for non-anticancer drugs. (OEI; 07-13-00220; expected issue date: FY 2014; work in progress)

Part A and Part B Contractors

Acronyms and Abbreviations for Selected Terms:

FAR—Federal Acquisition Regulation
LCD—local coverage determination

MAC—Medicare Administrative Contractor
ZPIC—Zone Program Integrity Contractor

Oversight of Contracts

➤ Contract management at the Centers for Medicare & Medicaid Services

Oversight of Contracts. We will determine how CMS manages and maintains contracts. We will determine the number and types of contracts active at CMS, the way in which CMS manages these contracts, the extent to which CMS performed all required contract closeouts, and the way in which CMS ensures that all required closeouts are completed. We will also determine how CMS ensures that contract file documentation is maintained as required by regulation. Context—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 2012, CMS obligated \$4.8 billion under contracts for a variety of goods and services. Previous Government Accountability Office (GAO) reports highlighted the vulnerabilities and weaknesses within the contracting environment at CMS, including problems with the contract closeout process. Given the number of contracts and the obligated dollars, oversight and monitoring are vital for ensuring effective programs and safeguarding taxpayer dollars. In addition, timely and effective contract closeouts protect the Government's financial interests and allow for recovery of excess funds. (OEI; 03-12-00680; 00-00-0000; various expected issue date: FY 2014; work in progress)

➤ Administrative costs claimed by Medicare contractors

Oversight of Contracts. We will review administrative costs claimed by various contractors for their Medicare activities, focusing on costs claimed by terminated contractors. We will also determine whether the costs claimed were reasonable, allocable, and allowable. Context—We will coordinate with CMS regarding 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 Part 31. (OAS; W-00-10-35005; W-00-11-35005; W-00-12-35005; W-00-13-35005; various reviews; expected issue date: FY 2014; work in progress)

➤ Executive compensation benchmark (new)

Oversight of Contracts. We will review contractor employee salaries charged to Medicare to determine whether the selected contractors applied a required senior executive compensation benchmark required by regulation and determine the potential cost savings if contractors were required to apply the same benchmark to all employee compensation. (48 CFR § 31.205-6(p).) We will determine the potential effect of expanding the executive compensation benchmark to all employees. Context—The term "senior executive" is defined as the top five compensated employees of each organizational segment. (48 CFR § 31.205-6(p)(2)(B)(ii).) Several articles have been written addressing the exorbitant salaries for contractors. (OAS; W-00-13-35710; various reviews; expected issue date: FY 2015; work in progress)

➤ Contractor pension cost requirements

Oversight of Contracts. 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, assess Medicare's share of future pension costs, and determine the amount of excess

pension assets as of the closing dates. Context—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 2014; work in progress)

➤ **Contractor postretirement benefits and supplemental employee retirement plan costs**

Oversight of Contracts. We will review the postretirement health benefit costs and the supplemental employee retirement plans of Medicare fiscal intermediaries and carriers to determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts. Context—Criteria are in the FAR at 48 CFR §§ 31.201 through 31.205. (OAS; W-00-12-35095; various reviews; expected issue date: FY 2014; work in progress)

Contractor Functions and Performance

➤ **Medicare administrative contractors—Use and evaluation of local edits**

Contractor Functions and Performance. We will determine the extent to which MACs used and evaluated their local claims processing system edits in 2011. We will also describe how the change in MAC error rates from 2010 to 2011 compared to MACs' use and evaluation of local edits in 2011. Context—Local claims processing edits are a key safeguard for identifying improper payments before Medicare payment is made and for ensuring that Part A and Part B claims are paid correctly. MACs are responsible for developing, inputting, and turning on local edits within their jurisdictions, as well as evaluating the effectiveness of medical review edits. (OEI; 04-12-00140; expected issue date: FY 2015; work in progress)

➤ **Medicare benefit integrity contractors' activities (new)**

Contractor Functions and Performance. We will review and report the level of benefit integrity activity performed by Medicare benefit integrity contractors in calendar years 2012 and 2013. Context—The Centers for Medicare & Medicaid Services (CMS) contracts with entities to carry out benefit integrity activities to safeguard the Medicare program against fraud, waste, and abuse. Activities that these contractors perform include analyzing data to identify aberrant billing patterns, conducting fraud investigations, responding to requests for information from law enforcement, and referring suspected cases of fraud to law enforcement for prosecution. Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs) carry out benefit integrity activities for Medicare Parts A and B, and a Medicare Drug Integrity Contractor (MEDIC) carries out benefit integrity activities for Medicare Parts C and D. (OEI-03-13-00620 ; expected issue date: FY 2015; work in progress)

➤ **ZPICs and PSCs—Identification and collection status of Medicare overpayments (new)**

Contractor Functions and Performance. We will determine the total amount of overpayments that ZPICs and PSCs identified and referred to claims processors in 2013 and the amount of these overpayments that claims processors collected. We will also review the procedures for tracking collections on overpayments identified by ZPICs and PSCs. Context—OIG has issued several reports regarding the tracking and collection of the overpayments that Medicare's contractors have made to

providers. In response, CMS has added reporting requirements that would improve overpayment tracking among the claims processors and ZPICs and PSCs. ZPICs and PSCs are required to detect and deter fraud and abuse in Medicare Part A and/or Part B in their jurisdictions. They conduct investigations; refer cases to law enforcement; and take administrative actions, such as referring overpayments to claims processors for collection and return to the Medicare program. (OEI; 03-13-00630; expected issue date: FY 2014; work in progress)

Information Technology Security, Protected Health Information, and Data Accuracy

➤ Medicare contractor information systems security programs—Annual report to congress

Information Technology Security. We will review independent evaluations of information systems security programs of Medicare fiscal intermediaries, carriers, and MACs. We will report to Congress on our assessment of the scope and sufficiency of the independent evaluations and summarize their results. Context—Federal law requires independent evaluations of the security programs of fiscal intermediaries, 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-00-14-41010; expected issue date: FY 2014; new start)

➤ Security of portable devices containing personal health information

Protected Health Information. We will review security controls implemented by Medicare and Medicaid contractors and at 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. Context—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-00-13-41014; various reviews; expected issue date: FY 2014; work in progress)

➤ Controls over networked medical devices at hospitals (new)

Protected Health Information. We will determine whether hospitals' security controls over networked medical devices are sufficient to effectively protect associated electronically protected health information (ePHI) and ensure beneficiary safety. Context—Computerized medical devices, such as dialysis machines, radiology systems, and medication dispensing systems that are integrated with EMRs and the larger health network, pose a growing threat to the security and privacy of personal health information. Such medical devices use hardware, software, and networks to monitor a patient's medical status and transmit and receive related data using wired or wireless communications. To participate in the Medicare program, providers such as hospitals are required to

secure medical records and patient information, including ePHI. (42 CFR § 482.24(b).) Medical device manufacturers provide Manufacturer Disclosure Statement for Medical Device Security (MDS2) forms to assist health care providers in assessing the vulnerability and risks associated with ePHI that is transmitted or maintained by a medical device. (OAS; W-00-14-42020; various reviews; expected issue date: FY 2014; new start)

➤ Accuracy of the Physician Compare Web site (new)

Data Accuracy. We will review CMS's efforts to ensure that the Physician Compare Web site contains accurate information on health care providers. Context—CMS was required by law to create the Physician Compare Web site, which is intended to help Medicare beneficiaries make informed choices about their health care by providing them with information about health care providers. (Affordable Care Act, § 10331.) CMS repurposed its Provider Enrollment, Chain, and Ownership System (PECOS) as its data source for provider information on Physician Compare. However, prior OIG work found that the provider information in PECOS was often inaccurate and, at times, incomplete. (OEI; 01-14-00210; expected issue date: FY 2015, new start; Affordable Care Act)

Other Part A and Part B Program Management Issues

Acronyms and Abbreviations for Selected Terms:

NPI—national provider identifier

PSC—Program Safeguard Contractor

Beneficiary Eligibility

➤ Payments for incarcerated beneficiaries

Beneficiary Eligibility. We will review Medicare payments for incarcerated beneficiaries to determine whether the payments were made for beneficiaries who did not meet the criteria for exception identified in Medicare regulations. Context—Prior OIG reviews have identified improper Medicare payments for incarcerated beneficiaries. 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.) CMS provides instructions for providers who render services to incarcerated beneficiaries who meet the criteria for exception. (CMS's *Medicare Claims Processing Manual*, ch 1, § 10.4.) (OAS; W-00-13-35624; W-00-14-35624; expected issue date: FY 2014; work in progress)

Provider Eligibility

➤ Enhanced enrollment screening process for Medicare providers

Provider Eligibility. We will determine the extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for Medicare providers pursuant to the Affordable Care Act, § 6401. We will also collect data on and report the number of initial enrollments and enrollment revalidations approved and denied by CMS before and after the implementation of the enhanced screening procedures. Context—As part of an effort to prevent fraud, waste, and abuse resulting from vulnerabilities in the Medicare enrollment process, CMS is

implementing new authorities that include a site visit process, an automated provider screening process, fingerprinting, and background checks. (OEI; 03-13-00050; expected issue date: FY 2014; work in progress. Affordable Care Act.)

➤ Idle Medicare provider records (new)

Provider Eligibility. We will identify active Medicare providers who have not billed Medicare for more than 1 year. Context—Previous OIG work suggested that many providers have active Medicare records but have not submitted any claims for more than 1 year. Federal regulations permit CMS to deactivate the billing privileges of Medicare providers who do not submit any claims for 12 consecutive months. Deactivation helps deter fraudulent use of inactive records. Providers enrolled in Medicare solely to refer items and services for beneficiaries (ordering and referring providers) and certain provider specialty types are excluded from this deactivation process. (OEI; 07-13-00590; expected issue date: FY 2014; work in progress)

➤ Payments to providers subject to debt collection

Provider Eligibility. 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. Context—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 2014; work in progress)

Medicare as Secondary Payer

➤ Improper Medicare payments for beneficiaries with other insurance coverage

Medicare as Secondary Payer. We will identify 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. We will determine whether selected non-Medicare health plans properly reported insurance coverage information to Medicare as required. Context—The provisions underlying the objectives are in the Social Security Act, § 1862(b), and the Medicare, Medicaid and SCHIP Extension Act of 2007, §111. (OAS; W-00-14-35317; various reviews; expected issue date: FY 2014; work in progress)

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:

MA—Medicare Advantage

PDE—prescription drug event

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.

MA Organization's Compliance With Part C Requirements

➤ Encounter data—CMS oversight of data integrity

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

➤ Risk adjustment data—Sufficiency of documentation supporting diagnoses

Compliance With Requirements. We will review the medical record documentation to ensure that it supports the diagnoses MA organizations submitted to CMS for use in CMS's risk-score calculations and determine whether the diagnoses submitted complied with Federal requirements. Context—Prior OIG reviews have shown that medical record documentation does not always support the diagnoses submitted to CMS by the MA organizations. MA organizations are required to submit risk adjustment data to CMS in accordance with CMS instructions. (42 CFR § 422.310(b).) Payments to MA organizations are adjusted on the basis of the health status of each beneficiary, so inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. (Social Security Act,

§§ 1853(a)(1)(C) and (a)(3).) (OAS;W-00-14-35078; various reviews; expected issue date: FY 2014; new start)

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 made on the basis of bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit.

Medicare, Sponsor, and Manufacturer Policies and Practices

➤ Savings potential of adjusting risk corridors

Policies and Practices. We will analyze risk-sharing payments between Medicare 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. Context—CMS has the authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. Risk corridors determine the amount of unexpected profits or losses that Medicare and sponsors share. (Social Security Act § 1860D-15.) (OEI; 00-00-00000; expected issue date: FY 2015; new start)

➤ Savings potential of retail pharmacy discount generic drug programs

Policies and Practices. We will determine whether Part D sponsors receive the discount drug prices available to the general public at certain retail pharmacies. We will determine the number and percentage of Part D claims for which the amounts paid were equal to the discount prices. Context—Several retail chain pharmacies offer certain generic drugs at discounted prices (e.g., \$4 for a 30-day supply). However, some of the pharmacies have restrictions in their discount generic programs that prevent Part D from sharing in the discounted prices. Part D prescription drug plan sponsors may include “usual and customary” price provisions in their contracts with pharmacies, which generally require that the sponsor pay the lesser of the pharmacy’s negotiated price or the discount price for the drugs. (OEI; 03-11-00460; expected issue date: FY 2014; work in progress)

➤ Comparison of Medicare Part D and Medicaid pharmacy reimbursement and rebates (new)

Policies and Practices. This review, which is a followup to previous work, will compare pharmacy reimbursement and rebate amounts for a sample of brand-name drugs paid by Medicare Part D and by Medicaid. Context— Spending on drugs is partially recouped through manufacturers' rebates. A previous OIG review revealed that Part D sponsors and State Medicaid agencies paid pharmacies roughly the same amounts for brand-name drugs. However, statutorily defined Medicaid unit rebate amounts for brand-name drugs exceeded Part D unit rebate amounts by a substantial margin, resulting in lower drug program costs for Medicaid. (OEI; 03-13-00650; expected issue date: FY 2014; Work in Progress;)

➤ **Program integrity—Manufacturer safeguards to prevent the use of copayment coupons for drugs paid for by Part D**

Policies and Practices. We will identify the safeguards that pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D. **Context—**Copayment 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. The use of copayment coupons in Federal health care programs implicates the anti-kickback statute. (OEI; 05-12-00540; expected issue date: FY 2014; work in progress)

Sponsor Compliance With Part D Requirements

➤ **Documentation of administrative costs in sponsors' bid proposals**

Compliance With Requirements. We will review the sufficiency of Part D sponsors' documentation supporting the administrative costs they included in their annual bid proposals to CMS. **Context—**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).) Medicare's subsidy payments to Part D plans and beneficiary premiums are calculated on the basis of the sponsors' bids. (OAS; W-00-14-35506; various reviews; expected issue date: FY 2015; new start)

➤ **Reconciliation of payments—Sponsor reporting of direct and indirect remuneration**

Compliance With Requirements. We will determine whether Part D sponsors complied with Medicare requirements for reporting direct and indirect remunerations (DIR). **Context—**Medicare calculates certain payments to sponsors on the basis of amounts actually paid by the Part D sponsors, net of 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-00-13-35508; W-00-14-35508; various reviews; expected issue date: FY 2014; work in progress)

➤ **Reconciliation of payments—Reopening final payment determinations**

Compliance With Requirements. We will review CMS's policies, procedures, instructions, and processes for reopening final payment determinations and determine the adequacy of sponsor compliance and sponsor-submitted data. **Context—**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).) In April 2013, CMS announced that it planned to reopen 2007 and 2008 reconciliations during the 2013 calendar year and would assess at a later time whether it is necessary to reopen 2009, 2010, and 2011 reconciliations. CMS allowed sponsors to request reopening and to submit additional prescription drug event (PDE) data and DIR data. (OAS; W-00-14-35621; various reviews; expected issue date: FY 2014; new start)

➤ Ensuring dual eligibles' access to drugs under Part D

Compliance With Requirements. We will review the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries as required.

Context—Dual-eligible beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as Part D plans meet certain limitations outlined in 42 CFR § 423.120, they have discretion to include different Part D drugs and drug utilization tools in their formularies. The Affordable Care Act, § 3313, requires OIG to conduct this review annually. (OEI; 05-14-00170; expected issue date: FY 2014; work in progress; Affordable Care Act)

Part D Billing and Payments

➤ Documentation of pharmacies' prescription drug event data (new)

Billing and Payments. We will conduct additional reviews of selected retail pharmacies identified in a prior OIG report as having questionable Part D Billing. We will determine whether Medicare Part D PDE records submitted by the selected pharmacies were adequately supported and complied with applicable Federal requirements. Context—Drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans. (Social Security Act, § 1860D-15(f)(1).) (OAS; W-00-13-35411; various reviews; expected issue date: FY 2014; work in progress)

➤ Duplicated and/or unsupported claims

Billing and Payments. 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. Context—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. Medicare Part A and Part B do not cover most of the outpatient prescription drugs that may be covered under Part D. Drugs covered under Part B include injectable drugs administered by a physician, drugs used in conjunction with medical equipment, and some vaccines. (OAS; W-00-14-35409; various reviews; expected issue date: FY 2014; work in progress)

➤ Questionable utilization patterns for HIV drugs

Billing and Payments. We will describe human immunodeficiency virus (HIV) drugs covered under Medicare Part D and determine the extent to which beneficiaries had questionable utilization patterns. We will describe the characteristics of beneficiaries associated with questionable utilization patterns and the associated pharmacies and prescribers. Part D covers drugs that are prescribed and used for medically accepted indications. (OEI; 02-11-00170; expected issue date: FY 2014; work in progress)

➤ Quality of sponsor data used in calculating coverage-gap discounts

Billing and Payments. We will review data submitted by Part D sponsors for use in calculating the coverage gap discount to assess the accuracy of the data and determine whether beneficiary payments are correct and amounts paid to sponsors are supported. Context—The Affordable Care Act required the Secretary to establish a Medicare coverage gap discount program to provide relief to beneficiaries who are responsible for paying all drug costs during their coverage gaps. (Social

Security Act, § 1860D-14A, as amended by the Affordable Care Act, § 3301.) Sponsors track beneficiary payment information and the drug cost data necessary to calculate eligibility for the program. (OAS; W-00-14-35611; various reviews; expected issue date: FY 2015; new start; Affordable Care Act)

Medicaid Program

The Federal Government and States 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. Many States contract with managed care organizations (MCOs) to provide or coordinate comprehensive health services.

Medicaid Prescription Drug Reviews

Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price

DRA - Deficit Reduction Act of 2005

State and Manufacturer Compliance With Medicaid Requirements

➤ **States' use of Medicaid drug utilization review to reduce the inappropriate dispensing of opioids**

Compliance With Requirements. We will review the education and enforcement actions States have taken on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription opiates. Context—States are required to establish DUR programs to receive the Federal share of Medicaid payments. (42 CFR § 456.703.) DUR involves, among other functions, ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implementing corrective action when needed. (OEI; 05-13-00550; expected issue date: FY 2014; work in progress)

➤ **States' methods for resolving rebate disputes with manufacturers**

Compliance With Requirements—We will review the causes of and resolutions to Medicaid rebate disputes with manufacturers and the methods States use to resolve them. Context—Previous OIG reports have found large amounts in uncollected rebates. In 2008, Medicaid spent about \$24 billion on prescription drugs and received about \$8 billion in 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 2014; work in progress)

➤ **Manufacturer compliance with AMP reporting requirements**

Compliance With Requirements. We will review manufacturer compliance with AMP reporting requirements and determine what percentage of manufacturers complied with the requirements.

We will also determine whether stepped-up enforcement actions by CMS and OIG are reflected in increased compliance by manufacturers. Context—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. Rebate amounts are determined on the basis of AMPs. 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; 03-14-00150; expected issue date: FY 2015; work in progress)

➤ States' collection and reporting of rebates

Compliance With Requirements. We will determine whether the increased amount of manufacturer rebates for brand-name and generic drugs were collected by States and reported to the Federal government, as required. We will also determine the amount of supplemental drug rebates that States collected during a selected period. Context—The Affordable Care Act, § 2501, increased the basic Federal minimum rebate amount that helps States and the Federal Government lower the costs of Medicaid prescription drug programs. To further reduce such costs, States negotiate supplemental rebate agreements (SRAs) with drug manufacturers that agree to pay amounts in addition to their basic Federal rebates. We previously estimated that between 2006 and 2011, SRAs saved Medicaid an additional \$1 billion per year, on average. (OEI; 03-12-00520; expected issue date: FY 2014; work in progress; Affordable Care Act)

➤ Rebates for new formulations of existing drugs

Compliance With Requirements. 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 of their drugs that are subject to a recent change in law. Context—The Affordable Care Act increased 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.) (OAS; W-00-14-31451; various reviews; expected issue date: FY 2015; new start; Affordable Care Act)

➤ States collection of rebates on physician-administered drugs

Compliance With Requirements. 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. Context—Prior OIG work identified concerns with States' collection and submission of data to CMS, including national drug codes that identify drug manufacturers, thus allowing States to invoice the manufacturers responsible for paying rebates. (Deficit Reduction Act of 2005 (DRA).) To be eligible for Federal matching funds, States are required to collect rebates on covered outpatient drugs administered by physicians. (Social Security Act, § 1927(a).) (OAS; W-00-12-31400; W-00-13-31400; W-00-14-31400; various reviews; expected issue date: FY 2014; work in progress)

State Claims for Federal Reimbursement

➤ Medicaid payments for multiuse vials of Herceptin (new)

State Claims—We will review States’ claims for the Federal share of Medicaid payments for the drug Herceptin, which is used to treat breast cancer, to determine whether providers properly billed the States for the drug. We will determine whether providers’ claims to States were complete and accurate and were billed in accordance with the regulations of the selected States. **Context**—Prior OIG audits of Herceptin have shown provider noncompliance with Medicare billing requirements. Similar issues may occur in Medicaid. (OAS; W-00-14-31476; various reviews; expected issue date: FY 2014; new start)

Quality of Care and Safety of Beneficiaries

➤ Atypical antipsychotic drugs prescribed for children in Medicaid

Quality of Care and Safety. We will determine the extent to which Medicaid claims for atypical antipsychotic drugs were for treatment of children aged 18 years and younger. We will determine, on the basis of medical record reviews, the extent to which the atypical antipsychotic drug claims were for uses and indications not listed in one or more of the approved drug compendia. We will also determine the extent to which the medical reviews identified concerns about the treatment of the children with the prescribed drugs related to dosage, duration of treatment, indications for use, monitoring, side effects, reactions to combinations of drugs (polypharmacy), and patient age. **Context**—State Medicaid programs must pay for covered outpatient drugs for medically accepted indications (i.e., those approved for the drug by the Food and Drug Administration (FDA) and/or uses supported by one or more approved compendia). States may choose to also pay for covered outpatient drugs for indications not listed in approved compendia. (OEI; 07-12-00320; expected issue date: FY 2014; work in progress)

Home Health Services and Other Community–Based Care

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

Billing and Payments

➤ Home health services—provider and beneficiary eligibility

Billing and Payments. We will review HHA claims to State Medicaid programs to determine whether the billing providers met applicable criteria to provide home health services to Medicaid beneficiaries. We will also determine whether the beneficiaries met the criteria to receive such services. **Context**—Medicaid home health services providers must meet standards and conditions of participation, many of which relate to quality of care and safety of beneficiaries, such as a minimum

number of professional staff, proper licensing and certification, review of service plans of care, and proper authorization and documentation of provided services. Services are provided to a beneficiary at the beneficiary's place of residence and on a physician's orders as part of a written care plan that the physician reviews every 60 days. The care must include intermittent (not full-time) skilled nursing care and may include physical therapy or speech-language pathology services. The related Federal standards and conditions for HHAs' participation in Medicaid are at 42 CFR § 440.70 and 42 CFR Part 484. (OAS; W-00-12-31304; various reviews; expected issue date: FY 2015; work in progress)

➤ Adult day health care services

Billing and Payments. We will review Medicaid payments by States for adult day care services to determine whether the providers complied with Federal and State requirements. Context—Adult day health care programs provide health, therapeutic, and social services and activities to program enrollees. Beneficiaries enrolled 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 home and community-based services (HCBS) waivers. (Social Security Act, § 1915, and 42 CFR § 440.180.) (OAS; W-00-12-31386; W-00-13-31386; various reviews; expected issue date: FY 2014; work in progress)

➤ Continuing day treatment mental health services

Billing and Payments. We will review Medicaid payments to continuing day treatment (CDT) mental health services providers to determine whether their claims were adequately supported. Our review will follow up on a State Commission's findings of unsubstantiated claims. Context—CDT providers render an array of services to people with mental illnesses. CDT providers bill Medicaid on the basis of the number of service hours rendered to beneficiaries. 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 in that State could not be substantiated. 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-00-12-31128; W-00-13-31128; various reviews; expected issue date: FY 2014; work in progress)

State Claims for Federal Reimbursement

➤ Room and board costs associated with HCBS waiver program payments

State Claims—We will determine whether selected States claimed Federal reimbursement for unallowable room and board costs associated with services provided under HCBS waiver programs. We will determine whether HCBS payments included the costs of room and board and identify the methods the States used to determine the amounts paid. Context—Medicaid covers the cost of HCBS provided under a written plan of care to individuals in need of such services but does not allow for payment of room and board costs. (42 CFR §§ 441.301(b) and 441.310(a).) HCBS are provided pursuant to the Social Security Act, § 1915(c). States may use various methods to pay for such 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; work in progress)

Quality of Care and Safety of Beneficiaries

➤ Home health services—Screenings of health care workers

Quality of Care and Safety—We will review health-screening records of Medicaid home health agency (HHA) health care workers to determine whether they were screened in accordance with Federal and State requirements. Context—Health screenings for home health care workers include vaccinations such as those for hepatitis and influenza. HHAs provide health care services to Medicaid beneficiaries while the home health care workers are 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 Part 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 2014; 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

Policies and Practices

➤ Medical equipment and supplies—Opportunities to reduce Medicaid payment rates for selected items

Policies and Practices. 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 rebates, competitive bidding, or other means. Context—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-00-13-31390; various reviews; expected issue date: FY 2014; new start)

Billing and Payments

➤ Transportation services—Compliance with Federal and State requirements

Billing and Payments. We will review Medicaid payments by States to providers for transportation services to determine the appropriateness of the payments for such services. Context—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-00-12-31121; W-00-13-31121; various reviews; expected issue date: FY 2015; work in progress)

➤ **Questionable billing for outpatient mental health services by Medicaid providers**

Billing and Payments. We will review State payments for Medicaid outpatient mental health services to identify questionable billing patterns. We will also review combined Medicaid and Medicare claims data to identify additional questionable billing patterns. **Context—**Medicaid can cover outpatient mental health services through a variety of benefits authorized by various parts of Title XIX of the Social Security Act. States are required to ensure that Medicaid payments are consistent with efficiency, economy, and quality of care standards. (Social Security Act, § 1902(a)(30)(A), and 42 CFR 447.200.) Providers whose claims exhibit questionable patterns may be receiving payments that are not consistent with those standards. Combining claims data from Medicaid and Medicare may reveal additional questionable billing patterns that are not evident when data from each program is examined in isolation. (OEI; 07-13-00320; expected issue date: FY 2014; work in progress)

➤ **Health-care-acquired conditions—Prohibition on Federal reimbursements**

Billing and Payments. 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. **Context—**As of July 1, 2011, Federal payments to States, are prohibited for any amounts expended for providing medical assistance for health-care-acquired conditions. (Social Security Act, § 1903, and Affordable Care Act, § 2702.) Federal regulations prohibit Medicaid payments by States for services related to health-care-acquired conditions and for provider-preventable conditions. (42 CFR § 447.26.) (OAS; W-00-14-31452; various reviews; expected issue date: FY 2015; new start; Affordable Care Act)

State Claims for Federal Reimbursement

➤ **Dental services for children—Inappropriate billing**

State Claims. We will review Medicaid payments by States for dental services to determine whether States have properly claimed Federal reimbursement. **Context—**Prior OIG work indicated that some dental providers may be inappropriately billing for services. 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. (OAS; W-00-11-31135; W-00-12-31135; various reviews; expected issue date: FY 2014; work in progress)

➤ **Family planning services—Claims for enhanced Federal funding**

State Claims. 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. **Context—**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-00-11-31078; W-00-12-31078; W-00-13-31078; various reviews; expected issue date: FY 2014; work in progress)

Quality of Care and Safety of Beneficiaries

➤ Access to pediatric dental care for children enrolled in Medicaid

Quality of Care and Safety. We will review billing patterns of pediatric dentists and their associated clinics in selected States and describe the extent to which children enrolled in Medicaid received services from them. Context—Previous OIG investigations identified numerous vulnerabilities with pediatric dental care, particularly with the care provided by certain for-profit dental chains. OIG investigations have also identified significant problems with access to pediatric dental services. 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. (OEI; 02-12-00330; 02-14-00120; various reviews; expected issue date: FY 2014; work in progress)

➤ Utilization of preventive screening services for children enrolled in Medicaid (new)

Quality of Care and Safety. We will determine what steps CMS has taken to address OIG's recommendations to improve the provision of Medicaid EPSDT services and what obstacles it faces in implementing these recommendations. We will also determine whether the underutilization of EPSDT services continues to be a challenge for children enrolled in Medicaid. Context—Previous OIG work found that, in nine States, three out of four children did not receive all required medical, vision, and hearing screenings. OIG made several recommendations to CMS to increase participation in EPSDT screenings and to increase the completeness of medical screenings. (OEI, 05-13-00690; expected issue date: FY 2014; work in progress)

State Management of Medicaid

Acronyms and Abbreviations for Selected Terms Used in This Section:

CPE—certified public expenditures
Form CMS-64—Quarterly Medicaid Statement of Expenditures

MIP—Medicaid Integrity Program

State Mechanisms to Fund Their Medicaid Programs

➤ State use of provider taxes to generate Federal funding

Funding Mechanisms. 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. Context—Previous OIG work 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. Federal regulations define and set forth the standard for

permissible health-care-related taxes. (42 CFR §§ 433.55 and 433.68.) (OAS; W-00-13-31455; various reviews; expected issue date: FY 2014; work in progress)

➤ State compliance with Federal Certified Public Expenditures regulations

Funding Mechanisms. We will determine whether States are complying with Federal regulations for claiming Certified Public Expenditures (CPEs), 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-00-13-31110; various reviews; expected issue date: FY 2014; work in progress)

State Claims for Federal Reimbursement

➤ State allocation of Medicaid administrative costs

State Claims—We will review administrative costs claimed by several States to determine whether they were properly allocated and claimed or directly charged to Medicaid. Context—Prior reviews in a 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-00-13-31123; various reviews; expected issue date: FY 2014; work in progress)

➤ State-operated facilities—Reasonableness of payment rates

State Claims—We will determine whether Medicaid payment rates to State-operated facilities are reasonable and the Federal share is claimed in accordance with Federal and State requirements. We will determine in selected States the extent to which payments to such providers may be excessive. Context—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; W-00-13-31398; various reviews; expected issue date: FY 2014; work in progress)

➤ State cost allocations that deviate from acceptable practices

State Claims—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. Context—Prior OIG reviews of school-based and community-based administrative claims found significant unallowable payments when payments were based on RMSS. Such systems 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).) (OAS; W-00-13-31467; various reviews; expected issue date: FY 2015; work in progress)

➤ **Enhanced Federal Medical Assistance Percentage (new)**

State Claims. We will review States' Medicaid claims to determine whether the States correctly applied enhanced Federal Medical Assistance Percentage (FMAP) payment provisions of the Affordable Care Act. Context—The Affordable Care Act, § 2001, authorized the use of an FMAP of 100 percent for individuals who are newly eligible because of Medicaid expansion. In addition, the Affordable Care Act, § 2012, required that Medicaid payments to primary care providers be at least that of the Medicare rates in effect for calendar years 2013 and 2014. (OAS; W-00-14-31480; various reviews; expected issue date: FY 2015; new start; Affordable Care Act)

➤ **Medicaid eligibility enrollment—National error rates**

State Claims. We will determine the extent to which States improperly enrolled individuals in Medicaid programs who did not meet eligibility criteria and estimate national enrollment error rates. For FY 2014, the national enrollment error rates will be estimated for newly enrolled Medicaid beneficiaries in States that expanded their Medicaid programs pursuant to the Affordable Care Act and in States that did not. We will also identify issues that contributed to enrollment errors. Context—The Affordable Care Act, § 2001, allowed States to expand Medicaid eligibility coverage to individuals between ages 19 and 64 with incomes up to 133 percent of the Federal poverty level and made other changes affecting State processes for Medicaid enrollment. (OEI; 00-00-0000; expected issue date: FY2015; new start; Affordable Care Act).

➤ **Medicaid eligibility determinations in selected States (new)**

State Claims. We will review Medicaid eligibility determinations in selected States. For each State selected, we will calculate a Medicaid eligibility error rate. We will focus on eligibility determinations for beneficiaries who are newly eligible for Medicaid pursuant to the Affordable Care Act and beneficiaries who were eligible for Medicaid prior to the eligibility expansion. We will also determine the amount of payments associated with beneficiaries who received incorrect eligibility determinations. Context—The Affordable Care Act, § 2001, authorized States to raise the Medicaid minimum eligibility level to 133 percent of the Federal poverty level for nearly all Americans under age 65 and authorized the use of an enhanced Federal medical assistance percentage of 100 percent for newly eligible individuals. Eligibility errors could result in improper Medicaid payments and improper State claims for Federal reimbursement. (OAS; W-00-14-31140; various reviews; expected issue date: FY 2015; new start; Affordable Care Act)

State Adjustments of Federal Reimbursement

➤ **State Medicaid monetary drawdowns—Reconciliation with Form CMS-64**

State Adjustments—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. Context—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; W-00-13-31456; various reviews; expected issue date: FY 2014; work in progress)

➤ State reporting of Medicaid collections on Form CMS-64

State Adjustments. We will determine whether States accurately captured Medicaid collections on their Form CMS-64 and returned the correct Federal share related to those collections.

Context—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. Collections decrease the total expenditures reported for the period. (42 CFR §§ 433.154 and 433.320.) States should compute the Federal share of collections at the rate at which the Federal Government matched the original expenditures. (CMS's *State Medicaid Manual*, § 2500.1(B).) (OAS; W-00-12-31457; W-00-13-31457; various reviews; expected issue date: FY 2014; work in progress)

➤ Estate recoveries—Compliance and reporting of recovered costs

State Adjustments—We will determine whether States complied with requirements to recover Medicaid costs from deceased Medicaid beneficiaries' estates. We will also determine whether States properly reported any such recoveries to CMS. Context—CMS requires that States report the amounts States collected from deceased Medicaid beneficiaries' estates on Form CMS-64 as reductions to total Medicaid expenditures. 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 the medical assistance costs of inpatient stays at nursing facilities, intermediate care facilities for persons with intellectual disabilities, or other medical institutions. States may also 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'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 2014; work in progress)

➤ State use of incorrect FMAP for Federal share adjustments (new)

State Adjustments. 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 Form CMS-64. Context—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-00-14-31460; various reviews; expected issue date: FY 2015; work in progress)

State Program Integrity Activities and Compliance With Federal Requirements

➤ State actions to address vulnerabilities identified during CMS reviews

Program Integrity. 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. Context—As part of its Medicaid Integrity Program (MIP) activities, 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 2015; new start)

➤ **State terminations of providers terminated by Medicare or by other States**

Program Integrity. We will review States' compliance with a new requirement that they terminate their Medicaid program providers that have been terminated under Medicare or by another State Medicaid program. We will determine whether such providers are terminated by all State Medicaid programs in which they are enrolled, 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. Context—The new requirement became effective January 1, 2011. (Social Security Act, § 1902(a)(39), as amended by the Affordable Care Act, § 6501.) (OEI; 06-12-00030; expected issue date: FY 2014; work in progress; Affordable Care Act)

➤ **Recovering Medicaid overpayments—Credit balances in Medicaid patient accounts**

Overpayment Recovery. We will review providers' patient accounts to determine whether there are Medicaid overpayments in accounts with credit balances. Context—Previous OIG work found Medicaid overpayments in patients' accounts with credit balances. Credit balances generally occur when the reimbursement that a provider receives for services provided to a Medicaid beneficiary exceeds the charges billed, such as when a provider receives a duplicate payment for the same service from the Medicaid program or another third party payer. In such cases, the provider should return the existing overpayment to the Medicaid program. When there is more than one payer, Medicaid is the payer of last resort. (Social Security Act, § 1902(a)(25); 42 CFR Part 433, Subpart D; various State laws; and CMS's *State Medicaid Manual*, Pub. No. 45, Part 3, § 3900.1.) (OAS; W-00-12-31311; W-00-13-31311; various reviews; expected issue date: FY 2014; work in progress)

➤ **State collection and verification of provider ownership information**

Program Integrity—We will determine the extent to which States and CMS collect and verify required ownership information for provider entities enrolled in Medicare and Medicaid. We will also review States' and CMS's 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. Context—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 entity. (42 CFR § 455.104.) (OEI; 04-11-00590, 04-11-00591, 04-11-00592; expected issue date: FY 2015; work in progress)

➤ **States' experiences with enhanced provider screening**

Program Integrity. We will review States' progress toward rescreening or revalidating all Medicaid providers by 2016. We will assess how States are complying with the mandate to conduct enhanced screening; determine how many providers are enrolled in both Medicare and Medicaid; and determine whether States can use screenings from Medicare, other State Medicaid programs, and CHIP. Context—The Affordable Care Act, § 6402, requires enhanced screening for providers and suppliers seeking initial enrollment, re-enrollment, or revalidation in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). States are responsible for employing screening and revalidation procedures for their Medicaid and CHIP providers. (OEI; 05-13-00520; expected issue date FY 2015; work in progress; Affordable Care Act)

➤ **Provider payment suspensions during pending investigations of credible fraud allegations (new)**

Program Integrity. We will review payments to providers with allegations of fraud deemed credible by States. We will also review States' suspension of payments processes. Context—Federal financial participation in the Medicaid program is not available for items or services furnished by an individual or entity when the State has failed to suspend payments during a period when there is a credible allegation of fraud. (Social Security Act, 1903(i)(2), as amended by the Affordable Care Act, § 6402(h)(2).) Upon determinations that allegations of fraud are credible, States must suspend all Medicaid payments to the providers, unless the States have good cause to not suspend payments or to suspend payment only in part. (42 CFR § 455.23(a).) States are required to make fraud referrals to MFCUs or to appropriate law enforcement agencies in States with no certified MFCUs. (42 CFR § 455.23(d).) We will determine if select Medicaid State agencies are in compliance with these provisions. (OAS; W-00-14-31473; various reviews; expected issue date: FY 2015; new start; and OEI; 09-14-00020; expected issue date: FY 2015; work in progress; Affordable Care Act)

OIG Oversight of State Medicaid Fraud Control Units

➤ **Reviews of State Medicaid Fraud Control Units**

Program Integrity. We will review the overall management, operations, and performance of a sample of Medicaid Fraud Control Units (MFCU). We will identify effective practices and areas for improvement in MFCU management and operations. Context—As part of its responsibility for administering Federal grants to the MFCUs, OIG provides oversight and guidance to the MFCUs, assesses MFCU compliance with Federal regulations and policy, and evaluates MFCU performance under established performance standards. State MFCU reviews are part of periodic, indepth onsite reviews of each MFCU. (OEI; 00-00-00000; various reviews; expected issue date: FY 2014; work in progress).

➤ **States and Territories without Medicaid Fraud Control Units (new)**

Program Integrity. We will determine whether each of the U.S. territories, none of which currently operate a MFCU, have sought an exemption as part of their State Medicaid plan as required by section 1902(a)(61) of the Social Security Act. We will also determine whether North Dakota, the only State without a MFCU and which received an exemption in 1994, continues to operate under the conditions that supported the State's exemption. Context—Each State and territory must maintain a certified MFCU as part of a State Medicaid program, unless the HHS Secretary determines

that operation of a MFCU would not be cost effective and that other safeguards are in place. (Social Security Act, §§ 1902(a)(61) and 1101(a)(1).) The District of Columbia and 49 States have established MFCUs. North Dakota was granted a waiver in 1994 and has not established a MFCU. The United States territories of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands have also not established MFCUs but are required to operate a MFCU as part of their Medicaid programs or receive an exemption. (OEI; 00-00-00000; expected issue date: FY 2015; new start)

Medicaid Information System Controls and Security

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

Controls to Prevent Improper Medicaid Payments

➤ Inactive or invalid provider identifier numbers

Payment Controls. 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 NPIs, including claims for services alleged to have been provided after the dates of the referring physicians' deaths.

Context—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, a U.S. Senate oversight committee reported that a substantial volume of Medicare-paid medical claims contained NPIs of deceased physicians. (OAS; W-00-13-31338; various reviews; expected issue date: FY 2015; work in progress)

➤ Duplicate payments for beneficiaries with multiple Medicaid identification numbers

Payment Controls. We will review duplicate payments made by States on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and identify States' procedures or other controls for preventing such payments. Context—A preliminary data match 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. (OAS; W-00-12-31374; W-00-13-31374; various reviews; expected issue date: FY 2014; work in progress)

➤ States' use of PARIS data matching to reduce improper payments

Payment Controls. We will review Public Assistance Reporting Information System (PARIS) enrollment data and determine the extent to which States use PARIS to prevent improper Medicaid payments made on behalf of beneficiaries who are simultaneously enrolled in more than one State. Context—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.) PARIS is a computer matching and information exchange system administered by the Administration for Children and Families. Using States'

enrollment data, PARIS identifies beneficiaries that may be concurrently enrolled in multiple State Medicaid programs, as well as other means-tested programs, such as food stamps. (OEI; 09-11-00780; expected issue date: FY 2014; work in progress)

➤ National Correct Coding Initiative edits and CMS oversight (new)

Payment Controls. We will review selected States' implementation of National Correct Coding initiative (NCCI) edits for Medicaid claims and describe CMS's oversight of NCCI edits.

Context—The NCCI is a program consisting of coding policies and automatic computer edits. The NCCI's original purpose was to promote correct coding of health care services provided to Medicare beneficiaries and to prevent payment for improperly coded services. Federal law required States to incorporate compatible methodologies of the NCCI for Medicaid claims filed on or after October 1, 2010. (Social Security Act, § 1903(r), as amended by the Affordable Care Act, § 6507.) States were permitted to deactivate some or all NCCI edits because of conflicts with State laws, regulations, administrative rules, payment policies, and/or the States' levels of operational readiness. (State Medicaid Director Letter #10-017.) As of April 1, 2011, lack of operational readiness was no longer a permissible basis for deactivation of the edits. (State Medicaid Director Letter #11-003.) After April 1, 2011, the only basis for deactivation is conflicts with State laws, regulations, administrative rules, and/or payments policies. (OAS; W-00-13-31459; various reviews; expected issue date: FY 2014; work in progress; and OEI; 00-00-00000; expected issue date: FY 2015; work in progress, Affordable Care Act)

Controls to Ensure the Security of Medicaid Systems and Information

➤ CMS oversight of States' Medicaid information systems security controls (new)

System Security Controls. We will determine the adequacy of CMS's oversight of States' Medicaid system and information security controls, including the policies, technical assistance, and security and operational guidance provided to the States. For selected States, we will use OIG's automated assessment tools to assess controls for their information system networks, databases, Web-facing applications, logical access, and wireless access. We will also review general controls, such as disaster recovery plans and physical security. **Context—**Prior OIG audits reported that States lack sufficient security features, potentially exposing Medicaid beneficiary health information to unauthorized access. State system controls for Medicaid data and transactions have not been consistently applied and have not been adequately monitored by CMS pursuant to Federal requirements for Automated Data Processing System Security and Review (45 CFR § 95.621(f).) CMS is responsible for ensuring that appropriate security controls have been implemented. (OAS, W-00-13-40019; W-00-14-40019; various reviews; expected issue date: FY 2014; work in progress and new start)

Medicaid Managed Care

Managed care is a health delivery system that aims to maximize efficiency by negotiating rates, coordinating care, and managing the use of services. State Medicaid agencies contract with managed care organizations (MCOs) to provide comprehensive health services in return for a fixed, prospective payment (capitated payment) for each enrolled beneficiary.

Acronyms and Abbreviations for Selected Terms Used in This Section:

MCO—managed care organizations

MSIS—Medicaid Statistical Information System

OMB—Office of Management and Budget

State Payments to Managed Care Entities

➤ Medicaid managed care reimbursement (new)

State Payments to MCOs. We will review States' managed care plan reimbursements to determine whether managed care organizations (MCOs) are appropriately and correctly reimbursed for services provided. We will ensure that the data used to set rates are reliable and include only costs for services covered under the State plan as required by or costs of services authorized by CMS. (42 CFR §438.6(e).) Also, we will verify that payments made under a risk-sharing mechanism and incentive payments made to MCOs are within the limits set forth in Federal regulations. (42 CFR § 438.6(c)(5)(ii) and 42 CFR § 438.6(c)(5)(iii)&(iv).) Context—Previous GAO work found that CMS's oversight of States' rate setting required improvement and that States may not audit or independently verify the MCO reported data used to set rates. (GAO-10-810.) (OAS; W-00-14-31471; various reviews; expected issue date: FY 2015; new start)

➤ Medical loss ratio—Managed care plans' refunds to States

Adjustments to State Payments. We will review managed care plans with contract provisions that require a minimum percentage of total costs to be expended for medical services (medical loss ratio) to determine whether a refund was made to the State agency when the minimum medical loss ratio threshold was not met. We will also determine whether plan expenses were properly classified as medical or administrative. Context—Prior OIG work found that although the minimum medical loss ratios were not met, the managed care plans did not make the required refunds to the State. States must properly report expenditures and apply any applicable credits (such as refunds). (OMB Circular A-87.) (OAS; W-00-13-31372; various reviews; expected issue date: FY 2015; work in progress)

Data Collection and Reporting

➤ Completeness and accuracy of managed care encounter data

Data Collection and Reporting. We will determine the extent to which complete Medicaid managed care encounter data are included in Medicaid Statistical Management Systems (MSIS). We will also identify factors that enable States' and Medicaid managed care entities to collect and report MSIS encounter data or prevent them from performing these functions. Finally, we will assess CMS's oversight of the reporting of MSIS encounter data. Context—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 MCOs 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; 07-13-00120; expected issue date: FY 2015; work in progress; Affordable Care Act)

Program Integrity in Managed Care

➤ Medicaid managed care entities' identification of fraud and abuse

Program Integrity—We will determine whether Medicaid MCOs identified and addressed potential fraud and abuse incidents. We will also describe how States oversee MCOs' efforts to identify and address fraud and abuse. **Context**—A prior OIG report revealed 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 MCOs and States are taking steps to address fraud and abuse in managed care and they remain concerned about their prevalence. 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. (OEI; 02-13-00640; expected issue date: FY 2015; new start)

Beneficiary Protections in Managed Care

➤ Beneficiary access to services under Medicaid managed care

Beneficiary Protections. We will review Medicaid managed care provider networks and describe the extent to which managed care beneficiaries have access to services. We will also describe State standards for ensuring access to primary and specialty care and will determine the extent to which States identify and address problems with access to care in their managed care plans. **Context**—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. (42 CFR §§ 438.202-210.) 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 locations of providers and beneficiaries. (OEI; 02-11-00320; 02-13-00670; expected issue date: FY 2014; work in progress; Affordable Care Act)

➤ Medicaid managed care beneficiary grievances and appeals process

Beneficiary Protections. We will review the extent to which States monitor Medicaid MCOs' grievances and appeals systems for compliance with Federal requirements. **Context**—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 managed care entities 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).) (OEI; 00-00-00000; expected issue date: FY 2014; new start)

➤ **Oversight of managed care entities' marketing practices**

Beneficiary Protections. We will review State Medicaid agencies' oversight policies, procedures, and activities to determine the extent to which States monitor Medicaid MCOs' marketing practices and compliance with Federal and State contractual marketing requirements. We will also determine the extent to which CMS ensures that States' comply with Federal requirements involving Medicaid MCO marketing practices. Context—No marketing materials may be distributed by Medicaid MCOs without first obtaining States' approval. (Social Security Act, § 1932(d)(2).) States are permitted to impose additional requirements in contracts with MCOs about marketing activities. (42 CFR § 438.104.) (OEI; 00-00-00000; expected issue date: FY 2015; new start)

CMS-Related Legal and Investigative Activities

Acronyms and Abbreviations for Selected Terms Used in Part IV:

CIA—corporate integrity agreement
CMP—civil monetary penalty
CPG—compliance program guidance

DOJ—Department of Justice
FBI—Federal Bureau of Investigation
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 penalties (CMP) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIA) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the 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) 2013, OIG excluded 3,214 individuals and entities from participation in Federal health care programs. 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 Medical Treatment and Labor Act of 1986 (EMTALA); items and services furnished to patients of a quality that fails to meet professionally recognized standards of health care; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

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. Current CIAs and other integrity agreements are listed on OIG's Web site at:

- http://oig.hhs.gov/fraud/cia/cia_list.asp

Advisory Opinions and Other Industry Guidance

To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the 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: <http://oig.hhs.gov/fraud/advisoryopinions.asp>
- Fraud Alerts: <http://oig.hhs.gov/compliance/alerts/index.asp>
- Compliance Guidance: <http://oig.hhs.gov/fraud/complianceguidance.asp>
- Open Letters: <http://oig.hhs.gov/fraud/openletters.asp>
- Other Guidance: <http://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, DC. 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. A [complete video](#) of the training is 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). 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:

- <http://oig.hhs.gov/fraud/selfdisclosure.asp>.

On April 17, 2013, OIG updated its Provider Self-Disclosure Protocol, which is available at:

- <http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>

Investigative Activities

OIG 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 criminal, civil, and administrative proceedings; and corrective management actions, regulations, or legislation. Each year, thousands of complaints from various sources are brought to OIG's attention for review, investigation, and resolution. The nature and volume of complaints and priority of issues vary from year to year. We describe some of the more significant investigative outcomes in OIG's *Semiannual Report(s) to Congress*, which are available on our Web site at:

- <http://oig.hhs.gov/publications.asp>.

See also OIG's Consumer Alerts at:

- <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Medicare Fraud 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.

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. In support of strike force operations, 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;
- investigates business arrangements that allegedly violate the Federal health care antikickback statute and the statutory limitation on self-referrals by physicians; and
- examines quality-of-care and failure-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which Federal programs may have been billed for services that were medically unnecessary, not rendered or not rendered as prescribed, or the care was so deficient that it constituted "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, but charging the full amount).

Working with law enforcement partners at the Federal, State, and local levels, we investigate schemes that 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 Medicaid Fraud Control Units 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 <http://oig.hhs.gov/fraud/enforcement/criminal/>.

Public Health Reviews

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:

AIDS—acquired immunodeficiency syndrome
FAR—Federal Acquisition Regulation

HIV—human immunodeficiency virus
OMB—Office of Management and Budget

Agency for Healthcare Research and Quality

➤ AHRQ—Early implementation of patient safety organizations

Quality of Care and Safety. We will review the policies and activities of Patient Safety Organizations (PSOs) to determine the extent of hospitals' participation in such activities, identify PSOs' practices for receiving and analyzing adverse event reports, and determine 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. Context—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. 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, such as infections or injury, caused to patients during medical care. (OEI; 06-14-00080; expected issue date: FY 2015; work in progress)

Centers for Disease Control and Prevention

➤ CDC—World Trade Center Health program: review of medical claims (new)

Funds Management. We will review World Trade Center Health Program (WTCHP) expenditures to assess the reasonableness of billing, payments, and administrative costs. Context—Prior Federal audits found that that CDC did not reliably estimate costs for monitoring and treating program beneficiaries. Pursuant to the enabling law, medical services are provided to eligible responders and survivors with health conditions related to the September 11, 2001, terrorist attacks on the World Trade Center through contracted facilities known as "Clinical Centers of Excellence." The WTCHP was established in January 2011 and is administered by CDC. (James Zadroga 9/11 Health and Compensation Act of 2010 and Public Health Service Act, § 3301(d).) (OAS; W-00-14-59040; expected issue date: FY 2014; new start).

➤ CDC—Oversight of HIV/AIDS prevention and research grants

Grants Management. We will assess whether CDC's oversight of HIV/AIDS prevention and research grants was conducted in accordance with Federal regulations and HHS policies. Context—During FYs 2007 through 2011, CDC awarded more than \$3.6 billion in grants for HIV/AIDS prevention and research. The grants are important tools in carrying out CDC's responsibility for meeting the goals of the National HIV/AIDS Strategy for the United States. (OEI; 00-00-00000; expected issue date: FY 2015; new start)

➤ CDC—Award process for the President's Emergency Plan for AIDS Relief cooperative agreements

Cooperative Agreements. We will review CDC's award process for the cooperative agreements that it 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. Context—During previous reviews of CDC’s award monitoring process, we noted possible deficiencies, such as conflicting, missing or inaccurate information in the Funding Opportunity Announcement and the Notice of Award. The *Grants Policy Directive*, Part 2, § 04, specifies the process for competitive review, ranking applications, approval of applications, and award policy. (OAS; W-00-13-58311; expected issue date: FY 2014; new start)

➤ **CDC—Accountability for property (new)**

Property Management. We will determine whether CDC implemented recommendations that OIG previously made on the basis of an audit of CDC’s property system. Context—CDC maintains various types of accountable property in the United States and overseas. In a previous report, we recommended that CDC improve its controls over property. Specifically, we recommended that CDC adjust the property system to reflect the results of the annual physical inventory; remove from the property system any lost or missing property; ensure that all newly acquired property items are barcoded and correctly added to the property system; and reconcile the general ledger to the property system to identify and resolve discrepancies. As of January 2013, CDC had 60,820 items of accountable property in its inventory, representing an original purchase cost of about \$455 million. (OAS; W 00-14-59025; expected issue date: FY 2014; new start)

➤ **CDC—Oversight of security of the strategic national stockpiles of pharmaceuticals**

Quality of Care and Safety—We will review CDC’s efforts 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 (DHS’s) *Physical Security Manual* to assess security risks at selected stockpiles. Context—The Strategic National Stockpile program, for which CDC and 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. The stockpiles are stored at strategic locations for the most rapid distribution possible. 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 2014; new start)

Food and Drug Administration

➤ **FDA—Inspection of generic drug manufacturers (new)**

Drug Inspections and Approvals. We will describe the extent to which FDA conducts inspections of generic drug manufacturers. We will also describe the results of such inspections and the enforcement actions taken by FDA in response to shortcomings or deficiencies found. Context—FDA typically inspects drug manufacturing facilities prior to generic drug approval and also conducts routine inspections of both foreign and domestic manufacturers to monitor compliance with current good manufacturing practices. Generic drugs are copies of FDA-approved brand name drugs that must be equivalent to the original drug with respect to conditions of use, active ingredient(s), route of administration, dosage form, strength, labeling, and performance characteristics. Pharmaceutical companies must receive FDA approval prior to marketing and manufacturing a new generic drug. (OEI; 01-13-00600; expected issue date: FY 2014; work in progress)

Health Resources and Services Administration

➤ HRSA—Contract pharmacy arrangements in the 340B Program

Program Integrity. We will assess the extent to which selected 340B-covered entities and HRSA oversee contract pharmacies' compliance with 340B Program requirements. Context—The 340B Drug Pricing Program (Public Health Service Act, § 340B) requires that manufacturers who sell covered outpatient drugs to covered entities listed in the statute must charge a price that will not exceed the amount determined under a statutory formula. 340B-covered entities may contract with pharmacies to provide services to the covered entities' patients. Covered entities are required to ensure that the contracted pharmacies comply with certain 340B Program requirements. (75 Fed. Reg. 10272, 10278.) For example, contract pharmacies are required to have tracking systems in place to prevent diversion of 340B-purchased drugs to people who are not patients of the 340B-covered entities that paid for the drugs. (42 U.S.C. 256b(a)(5)(B).) Contract pharmacies must also have systems in place to prevent subjecting drug manufacturers to paying Medicaid rebates on drugs already sold to 340B-covered entities at the discounted 340B price, a situation referred to as duplicate discounts. (U.S.C. 256b(a)(5)(A)(i).) HRSA administers the 340B Program and oversees covered entities' contract pharmacy arrangements. (OEI; 05-13-00430; 05-13-00431; expected issue date: FY 2014; work in progress)

➤ HRSA—340B-covered entities access to 340B ceiling prices (new)

Program Integrity. We will determine what steps HRSA has taken to address the OIG's previous recommendation to provide 340B covered entities with access to 340B ceiling prices and what obstacles HRSA faces in implementing this recommendation. We will also determine whether drug manufacturers are overcharging 340B covered entities. Context—In 2005 and 2006, OIG made several recommendations to HRSA to strengthen its oversight of the 340B Program, including a recommendation that HRSA provide covered entities with 340B ceiling prices to detect overcharges. The Affordable Care Act, §7102, codified this recommendation by requiring HRSA to share 340B ceiling prices with covered entities. (OEI; 05-13-00510; expected issue date: FY 2014; work in progress; Affordable Care Act)

Indian Health Service

➤ IHS—Hospital oversight (new)

Quality of Care and Safety. We will examine Indian Health Service (IHS) hospitals' efforts to ensure its hospitals provide quality inpatient care. We will examine IHS's efforts to monitor each hospital's ability to provide quality care and maintain compliance with Medicare conditions of participation and will identify which quality or compliance problems are most common. Context—IHS operates 28 acute care hospitals that provide inpatient care to eligible American Indians and Alaska Natives. IHS hospitals are monitored through periodic on-site surveys by State Agencies or CMS-approved accrediting organizations that assess compliance with Medicare conditions of participation. (OEI; 09-13-00280; 06-14-00010; expected issue date: FY 2014; work in progress)

National Institutes of Health

➤ NIH—Superfund financial activities for fiscal year 2013

Funds Management. We will review payments, obligations, reimbursements, and other uses of Superfund money by NIH's National Institute of Environmental Health Sciences. Context—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 2014; new start)

➤ NIH—Extramural construction grants

Grantee Compliance. We will perform reviews at facilities that received extramural construction grants to determine whether funds were spent in accordance with Federal requirements. We will determine whether appropriate bidding procedures were followed and whether expenditures were allowable under the terms of the grants and applicable Federal requirements. Context—Extramural construction grants are awarded to build, renovate, or repair non-Federal biomedical and behavioral research facilities. The intended recipients of these awards are institutions of higher education as well as nonprofit and regional organizations across the country. (42 CFR Part 52b, 45 CFR Part 74, 2 CFR Part 215, 2 CFR Part 220, and 2 CFR Part 225.) (OAS; W-00-13-50042; various reviews; expected issue date: FY 2015; new start)

➤ NIH—Colleges' and universities' compliance with cost principles

Grantee Compliance. We will assess colleges' and universities' compliance with selected cost principles issued by OMB in Circular A-21, *Cost Principles for Educational Institutions*. Context—We will conduct reviews at selected colleges and universities 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 2014; new start)

➤ NIH—Oversight of grants management policy implementation

Grants Management. We will examine the NIH's oversight of the grants administration processes implemented by the 24 institutes and centers (IC) that award extramural grants. We will also examine NIH's oversight of each IC's compliance with regulations, department directives, and agency policies. Context—NIH issues grants administration policy to the ICs and oversees ICs' compliance with Federal regulations and departmental guidance. Each IC maintains a Grants Administration Office that implements its own procedures. Federal regulations establish uniform administrative requirements governing HHS grants. (45 CFR Parts 74 and 92.) The HHS Grants Policy Directives and the NIH Grants Policy Statement provide guidance on implementing the regulations. (OEI; 07-11-00190; various reviews; expected issue date: FY 2014; work in progress)

➤ NIH—Use of appropriated funds for contracting (new)

Use of Funds. We will review the appropriateness of NIH's obligation of appropriated funds for the services it obtains through contracts to ensure that appropriated funds were used only during their period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and were used only for a bona fide need arising in the fiscal year for which the appropriation was made.

We will review contracts and contract modifications in order to quantify any errors. Context—Prior reviews identified problems in the use of appropriated funds for various NIH contracts. Key provisions of the Anti-Deficiency Act prohibit the Government from obligating or expending funds in advance of an appropriation unless authorized by law. (31 U.S.C § 1341(a)(1).) Also, appropriations may be used only for bona fide needs arising in the fiscal year for which the appropriation was made. (31 U.S.C. § 1502.) We will issue a summary report of corrective actions taken to address weaknesses identified in our reports. (OAS, W-00-10-52314; various reviews; expected issue date FY 2014; work in progress)

Substance Abuse and Mental Health Services Administration

➤ SAMHSA—Reporting and oversight of the Substance Abuse Treatment Block Grant program performance

Grantee Performance. We will determine the extent to which SAMHSA and States are overseeing and reporting performance for the Substance Abuse Prevention and Treatment Block Grant program. Context—The program’s goals are to prevent substance abuse and 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 and to report the extent to which the goals are met. (Government Performance and Results Act of 1993.) (OEI; 04-12-00160; various reviews; expected issue date: FY 2014; work in progress)

Other Public-Health-Related Reviews

➤ Hurricane Sandy—HHS use of volunteer medical personnel to respond (new)

Disaster Response. We will describe the use of Medical Reserve Corps (MRC) volunteers in New Jersey and New York during the Hurricane Sandy response. We will assess the availability of volunteers across specialties, determine how quickly volunteers were deployed, determine how States ensured that volunteers were appropriately qualified to render medical assistance, and describe any challenges and successes encountered while using MRC volunteers. Context—MRC is a national network of volunteers that are organized and managed at the local level. These volunteers provide various services, such as supporting local public health activities and assisting in emergency preparedness response and recovery. More than 600 volunteers were deployed within New York and New Jersey during the Hurricane Sandy response. (OEI; 04-13-00350; expected issue date: FY 2014; work in progress)

➤ Hurricane Sandy—Social Services Block Grant guidance, disbursement, and reporting summary (new)

Disaster Response. We will assess guidance, disbursement, and reporting related to the \$500 million in Hurricane Sandy disaster funding transferred to the Social Services Block Grant (SSBG). We will

determine when HHS and States provided guidance to grantees regarding the expenditure of the funds, the timeliness with which HHS and States disbursed awards, and what reporting requirements were put in place. We will also describe challenges that States and their subgrantees encountered in accessing and using disaster funding. Context—The Disaster Relief Appropriations Act of 2013 provided additional funds to the SSBG program to address necessary expenses resulting from Hurricane Sandy, including social, health, and mental health services for individuals, and for repair, renovation, and rebuilding of health care facilities, child care facilities, and other social services facilities. (OEI; 07-13-00390; expected issue date: FY 2015; work in progress)

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.

➤ Violations of select agent requirements

Compliance With 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 against individuals or entities for violations of these requirements. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

Human Services Reviews

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

- Administration for Children and Families (ACF). ACF 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.
- Administration for Community Living (ACL). ACL includes the Administration on Aging (AoA), which 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.

Acronyms and Abbreviations for Selected Terms:

CCDF—Child Care and Development Fund
CSE—child support enforcement

CSGB—Community Services Block Grant [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 Children and Families

➤ CSGB—Compliance with monitoring and reporting requirements (new)

Grants Management. We will determine whether ACF complied with certain Federal monitoring and reporting requirements identified in the Community Opportunities, Accountability, and Training and Education Services Act of 1998 and the Omnibus Reconciliation Act of 1981. Context—In 2006, the Government Accountability Office (GAO) reported that ACF lacked effective internal controls in the Community Services Block Grant (CSGB) program. OIG conducted a subsequent review to determine whether ACF had taken corrective actions to address GAO’s recommendations. OIG reported that ACF had developed written policies and procedures and that another followup review would be performed to evaluate the effectiveness of the newly implemented policies and procedures. ACF oversees several programs that provide a range of human and economic development services and activities that address the causes and characteristics of poverty and otherwise assist persons in need. ACF monitors grantees’ use of funds and reports annually to Congress on the use of the funds. (OAS;

W-00-13-59026; A-01-13-02505; W-00-14-59026; expected issue date FY 2014; work in progress)

➤ **TANF—Compliance and oversight of work participation verification and reporting requirements**

Grants Management. We will review the extent to which States comply with TANF work verification plan requirements. We will review ACF's oversight of States' compliance with work verification plan and reporting requirements. We will also assess ACF's oversight of tribes' compliance with Tribal Family Assistance Plan requirements under TANF. Context—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 Parts 261-265.) (OEI; 09-11-00490; 09-11-00491; expected issue date: FY 2014; work in progress)

➤ **CCDF—Child Care Development Fund direct services**

Compliance With Requirements. We will review States' Child Care and Development Fund (CCDF) programs, which are developed on the basis of 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 child care providers, and ensuring proper payment for services. We will also review the extent to which States complied with Federal regulations when developing their CCDF programs. Context—The CCDF assists low-income families, families receiving temporary public assistance, and families transitioning from public assistance in obtaining child care so that family members can work or attend training or education. (Child Care and Development Block Grant Act of 1990, Social Security Act, § 418, and 45 CFR Part 98.) (OAS; W-00-12-25053; W-00-13-25053; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ **CCDF—Child Care Development Fund targeted funds**

Compliance With Requirements. We will review CCDF targeted funds to determine the extent to which States comply with Federal regulations in the expenditure of the funds. Context—Some CCDF funds are designated for targeted purposes, such as improving quality of child care, and are authorized in annual appropriations. (Child Care and Development Block Grant Act, § 658B.) Targeted activities are 100 percent federally funded. (45 CFR 98.60(d).) (OAS; W-00-12-25054; W-00-13-25054; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ **CCDF—Licensing and oversight of health and safety standards at Federally funded facilities**

Compliance With Requirements. We will review licensing, health, and safety standards at child care facilities that received Federal funding from the 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 child care facilities. Context—Federal regulations for the CCDF require States to certify that they have licensing and health and safety requirements applicable to child care 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 2014; work in progress and new start)

➤ **Foster care and adoption assistance maintenance payments (new)**

Compliance With Requirements. We will determine whether State agencies claimed foster care maintenance payments and adoption assistance payments in accordance with Federal requirements. Context—Prior OIG audits found that States claimed costs for services that did not meet the requirements for the foster care and the adoption assistance programs. (Social Security Act, Title IV-E.) (OAS; W-00-12-24100; W-00-13-24100; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ **Foster care—State oversight and coordination of health services for children**

Compliance With Requirements. We will determine the extent to which States provide oversight and coordination of health services for children in foster care, as required. For selected States, we will determine the extent to which children in foster care receive health care services as outlined in States' health oversight and coordination plans. Context—Each State is required to develop a plan for ongoing oversight and coordination of health care services for children in foster care. (The Fostering Connections to Success and Increasing Adoptions Act of 2008.) States' plans must include certain elements, such as a schedule for initial and followup health screening and oversight of prescription medicines. (OEI; 07-13-00460; expected issue date: FY 2014; work in progress)

➤ **Child support enforcement—State and local protection of child support information**

Compliance With Requirements. 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 impose penalties for 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 imposing penalties for unauthorized access to or disclosure of child support information. (OEI; 04-12-00050; expected issue date: FY 2015; work in progress)

➤ **Child support enforcement—Investigations under the child-support enforcement task force model**

Coordinated Enforcement. We will continue to encourage and coordinate enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases. Context—Project Save Our Children seeks to identify, investigate, and prosecute individuals who fail to meet their court-ordered support obligations. The project brings together OIG, the U.S. Marshals Service, 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.

Administration for Community Living

➤ ACL—Senior Medicare Patrol projects' performance data

Grantee Performance. We will review performance measures for the Senior Medicare Patrol projects, including documentation supporting expected recoveries for the Medicare and Medicaid programs. Context—In 1997, SMP projects were established to recruit and train retired professionals and other senior citizens to recognize and report instances or patterns of health care fraud. The initiative stemmed from recommendations in a Congressional committee report accompanying the Omnibus Consolidated Appropriations Act of 1997. OIG reports this performance data annually. The information was requested by the Administration on Aging (AoA), which is part of ACL, and will support ACL's efforts to evaluate and improve the performance of the projects. (OEI; 00-00-00000; expected issue date: FY 2014; new start)

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

FAR—Federal Acquisition Regulation

OMB—Office of Management and Budget

PEPFAR—President's Emergency Plan for AIDS Relief

Financial Statement Audits and Related Reviews

➤ Audit of fiscal year 2014 consolidated HHS financial statements and financial-related reviews

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 Federal requirements. **Context—**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. (Chief Financial Officers Act of 1990, as amended by the Government Management Reform Act of 1994; Government Auditing Standards; and OMB Bulletin 14-02, "Audit Requirements for Federal Financial Statements.") The audited consolidated FY 2014 financial statements for the Department of Health and Human Services (HHS) are due to the Office of Management and Budget (OMB) by November 17, 2014. The Audit Report on the HHS Special Purpose Financial Statements entered into the Governmentwide Financial Report System is intended to support the preparation of Governmentwide financial statements and reports. The report is

prepared by the Independent Auditor who audits the HHS Consolidated Financial Statements. We plan to perform a number of ancillary financial-related reviews related to the audit of the FY 2014 financial statements. The purpose of the financial-related reviews is to fulfill requirements in Office of Management and Budget (OMB) Bulletin No. 14-02, §§ 6.1 through 13. (OAS; W-00-14-40009; A 17-14-00001; A-17-14-00006; expected issue date: FY 2015; new start)

➤ Fiscal year 2014 Centers for Medicare & Medicaid Services' financial statements

Financial Statements. We will review the independent auditor's workpapers to determine whether the financial statement audit of the Centers for Medicare and Medicaid Services (CMS) was conducted in accordance with Federal requirements. 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. (Chief Financial Officers Act of 1990, as amended by the Government Management Reform Act of 1994; Government Auditing Standards; and OMB Bulletin 14-02, "Audit Requirements for Federal Financial Statements.") (OAS; W-00-14-40008; A-17-14-02014; expected issue date: FY 2015; new start)

Financial Reviews

➤ Compliance with improper payment reporting requirements

Payment Errors and Reporting. We will review certain aspects of HHS's compliance with the Improper Payments Information Act of 2002 (IPIA), as amended, regarding reporting improper payments. We will also assess HHS's compliance with the Improper Payment Elimination and Recovery Act (IPERA) and the data presented in HHS's Annual Financial Report (AFR) and provide recommendations for modifying the reporting and addressing the goals of the reporting requirements as needed. Context—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. 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. (OAS; W-00-12-40047; expected issue date: FY 2014; work in progress)

➤ Evaluation of predictive analytics for reducing improper payments

Payment Errors and Reporting. HHS to implement over a 4-year period predictive analytics technologies for reducing improper payments in Medicare fee-for-service. We will evaluate the Department's implementation of predictive analytics technologies and will assess HHS's reporting of actual and projected savings for improper payments avoided and recovered and the relative return on investment and provide HHS any recommendations for modifying its methodology. We will also assess the Department's use of the technologies and determine whether improvements could be made to increase Medicare savings. Context—HHS is required to report annually on the progress of the programs and to certify certain amounts reported by the Department. (Small Business Jobs Act of 2010.) (OAS; W-00-14-40060; various reviews; expected issue date: FY 2014; new start)

➤ HHS contract management review

Contract Administration. We will review the controls the HHS Program Support Center has in place to ensure compliance with requirements specified in appropriations statutes when awarding contracts. We will review HHS's quality assurance procedures to determine the accuracy and completeness of the internal control reviews to ensure full compliance with appropriations laws. Context—HHS, 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 that there would be no future violations of the Anti-Deficiency Act. (31 U.S.C. § 1341(a)(1)) and Bona Fide Needs Rule. (31 U.S.C. § 1502.) (OAS; W-00-13-52313; expected issue date: FY 2014; new start)

➤ HHS agencies' annual accounting of drug-control funds

Compliance With Requirements. 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 such 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 2013 annual accounting. (OAS; W-00-13-52312; various reviews; expected issue date: FY 2014; new start)

➤ The President's Emergency Plan for AIDS Relief funds

Use of Funds. We will review the effectiveness of HHS's accounting for and control of funds received under The President's Emergency Plan for AIDS Relief (PEPFAR) program. Context—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 2014; work in progress)

➤ OIG reviews of non-Federal audits

Compliance With Requirements. 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 also ensure that the auditors have audited and reported in compliance with the American Recovery and Reinvestment Act of 2009 (Recovery Act). Context—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 inform 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. (OAS; W-00-00-0000; various reviews; expected issue date: FY 2014; work in progress)

➤ **OIG reimbursable audits of non-HHS funds**

Audits of Non-HHS Funds. 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*. Context—HHS OIG has audit cognizance over all State governments and most major research colleges and universities that receive Federal funds. We enter into agreements with other Federal audit organizations or other Federal agencies to reimburse us as the cognizant audit organization for audits that we perform of non-HHS funds. 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. (OAS; W-00-13-50012; various reviews; expected issue date: FY 2013; new start)

➤ **Requests for audit services**

Throughout the year, Congress, HHS, and other Federal organizations request that we perform a variety of financial-related 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. (OAS; W-00-00-0000; various reviews; expected issue date: FY 2014; work in progress)

Automated Information Systems

➤ **HHS compliance with the Federal Information Security Management Act of 2002**

Information Security. We will review various HHS operating divisions' compliance with the Federal Information Security Management Act of 2002 (FISMA). Context—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-00-14-40016; W-00-13-42001; W-00-14-42001; various reviews; expected issue date: FY 2014; new start)

➤ **Information systems security audits**

Information Security. We will determine the adequacy of information technology security general controls of selected HHS systems to determine whether they are in compliance with FISMA and directives issued by OMB and the National Institute of Standards and Technology. (OAS; W-00-13-42002; W-00-14-42002; various reviews; expected issue date: FY 2014; work in progress and new start)

➤ **Penetration testing of hhs and opdiv networks (new)**

Information Security. We will conduct network and Web application penetration testing to determine HHS's and its OPDIVS' network security posture and determine whether these networks and applications are susceptible to hackers. Context—Penetration tests are used to identify

methods of gaining access to a system by using tools and techniques known to be employed by hackers. There has been an increase in activity from computer hacker groups compromising government systems and releasing sensitive data to the public or using such data to commit fraud. (OAS; W-00-13-42020; W-00-14-42020; various reviews; expected issue date: FY 2014; work in progress and new start)

Other HHS-Related Issues

➤ HHS efforts to address grantee risks

Grants Management. We will determine how HHS awarding agencies mitigate grantee risks and whether HHS awarding agencies receive and/or share information on grantees for which they have concerns regarding performance expectations and/or accountability requirements. Context—HHS is the largest grant-making agency in the Federal Government. In FY 2012, HHS awarded nearly \$347 billion in grants. Oversight of these funds is crucial to HHS's mission and to the health and well-being of the public. 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. (OEI; 07-12-00110; expected issue date: FY 2014; work in progress)

➤ HHS efforts to prevent the use of HHS grant funds for lobbying activities

Grants Management. We will determine the extent to which HHS agencies notify grantees of lobbying prohibitions. We will also examine the extent to which HHS grantees are aware of lobbying prohibitions. The review will also explore the extent to which HHS agencies have mechanisms in place to identify and address lobbying violations. Context—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." (OEI; 07-12-00620; expected issue date: FY 2014; work in progress)

➤ Hurricane Sandy—HHS internal controls for oversight of funds (new)

Use of Funds. We will assess the internal controls HHS has developed to provide stewardship over Hurricane Sandy funds and determine whether those controls were suitably designed. We will review the internal controls in place at the Department level and the top four Operating Divisions (OPDIVs) that received Hurricane Sandy funding. Context—The Disaster Relief Appropriations Act of 2013 provided nearly \$800 million to HHS in aid for Hurricane Sandy disaster victims and their communities. OMB memorandum M-13-07, "Accountability for Funds Provided by the Disaster Relief Appropriations Act," provides that Federal agencies supporting recovery and other disaster-related activities implement additional internal controls to prevent waste, fraud, and abuse. (OAS; W-00-13-27130; W-02-13-02010; W-00-14-27130; expected issue date: FY 2014; work in progress)

➤ **Review of fiscal year 2012 conference expenditures (new)**

Use of Funds. We will review the expenditures for conferences in a selected fiscal year to ensure they were appropriate and reasonable and complied with Federal requirements. We will review the conference planning and approval process, the process for awarding contracts and grants, and the submission and approval of conference-related expenditures. **Context—**Audits performed by other Federal departments have highlighted significant problems with the planning, approval, funding, and holding of various Government conferences. Conference planning and spending guidance are found in various Federal and HHS authorities (e.g., 41 CFR § 301–74, appropriations laws, acquisition policies and procedures, OMB Memorandums M-12-12 and M-11-35, and travel regulations). (OAS; W-00-13-52350; A-03-13-03003; W-00-14-52350; expected issue date: FY 2014; work in progress)

➤ **HHS’s Government purchase, travel, and integrated charge card programs (new)**

Use of Funds. We will review HHS’s charge card programs (e.g., purchase, travel, or integrated cards) to assess the risks of illegal, improper, or erroneous purchases. We will also determine the status of HHS’s progress to implement previous travel and purchase card recommendations.

Context—OMB has instructed IGs to submit annual status reports on purchase and travel card audit recommendations beginning January 31, 2014, for compilation and transmission to Congress and GAO. Further, IGs are required to conduct periodic risk assessments of their agencies’ charge card programs to analyze the risks of illegal, improper, or erroneous purchases. (Government Charge Card Abuse Prevention Act of 2012 (Charge Card Act).) The Charge Card Act requires IGs to use the risk assessments to determine the necessary scope, frequency, and number of IG audits or reviews of the charge card programs. It requires Federal agencies, including HHS, to establish and maintain safeguards and internal controls for purchase cards (including convenience checks), travel cards, and integrated cards. HHS’s charge cards programs enable cardholders to pay for commercial goods, services, and travel expenses. This risk assessment will determine the extent and focus of our subsequent audit efforts. (OAS; W-00-14-59041; expected issue date: FY 2014; new start)

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Appendix A

Affordable Care Act Reviews

This appendix identifies work-in-progress and planned reviews for fiscal year (FY) 2014 related to the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act). The Affordable Care Act enacted a range of new programs affecting the Department of Health and Human Services (HHS) and made changes to existing HHS programs. Provisions included, for example, establishing the new Health Insurance Marketplaces; expansion of and changes to the Medicaid program; changes to several Parts of the Medicare program; and new grant funding for other HHS programs and agencies such as the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC).

These programs and requirements are being implemented and operated in a rapidly changing and fluid environment.¹ The Office of Inspector General (OIG) engages in a dynamic work planning process that incorporates continuous risk assessment and prioritization of resources. OIG's Affordable Care Act work planning is informed by our assessment of potential vulnerabilities, input from stakeholders, and our strategic goals to prevent fraud, waste, and abuse; promote value, safety, and quality; and secure the future. We coordinate, as appropriate, with the Government Accountability Office (GAO) and other Federal and State oversight agencies to foster economy, efficiency, and effectiveness of oversight efforts.

For FY 2014, our Affordable Care Act oversight focuses on operation of the new Health Insurance Marketplaces and the expanding Medicaid program. This work will be supplemented in FY 2014 by reviews examining the implementation of other Affordable Care Act programs and requirements, including changes to the Medicare program.

Health Insurance Marketplaces

The Health Insurance Marketplaces (also known as the Affordable Insurance Exchanges or Health Insurance Exchanges) include the Federally-Facilitated Marketplace (FFM or "Federal Marketplace") and State-Based Marketplaces (SBMs). Individuals use the Marketplaces to get information about their health insurance options, be assessed for eligibility (for, among other things, qualified health plans, premium tax credits, and cost sharing reductions), and enroll in the health plan of their choice.

OIG's reviews will focus on ensuring that taxpayer funds are spent for their intended purposes and that Marketplaces operate efficiently and effectively. OIG has prioritized four key areas for FY 2014:

- Payment Accuracy
- Eligibility Systems
- Contracts—Planning, Acquisition, Contracting, Management, and Performance
- Security of Data and Consumer Information

¹ For OIG's summary of challenges facing HHS in implementing the Affordable Care Act, please see "Top Management Challenges" at <https://oig.hhs.gov/reports-and-publications/top-challenges/2013/>.

Payment Accuracy

HHS must implement financial management and payment systems to ensure accurate and timely payments to insurers of advance premium tax credits, cost-sharing reduction payments, and premium stabilization payments. Insurers will begin receiving some types of payments in January 2014; other types of payments begin later. Ongoing and planned FY 2014 work that is looking at payment accuracy includes:

➤ **Effectiveness of Internal Controls Over, and Validity of Payments For, Advanced Premium Tax Credits and Cost Sharing Reductions (New)**

Affordable Care Act, §§ 1401, 1402, 1411, 1412. We will determine the validity of payment amounts and assess the effectiveness of HHS internal controls to pay Advanced Premium Tax Credit (APTC) and Cost Sharing Reduction (CSR) subsidy amounts in accordance with federal requirements. Payment amounts vary according to income, marital status, household composition, and eligibility for government sponsored or employer sponsored health care coverage. This work will focus on the temporary systems managed by HHS to make these payments. In a subsequent review, we plan to examine the permanent processes and controls when they are established. (OAS; W-00-14-59018; various reviews; expected issue date: FY 2014; work in progress)

➤ **Oversight of Risk Corridor Program (New)**

Affordable Care Act, § 1342. Under the temporary risk corridors program, qualified health plans (QHPs) will establish target amounts based on premiums earned minus allowable costs. QHPs that have lower than expected allowable costs must pay HHS if costs fall below 3 percent of their target amount. Conversely, QHPs that have higher than expected allowable costs will receive payment if costs exceed 3 percent of their target amount. The risk corridor program will use funds collected from QHPs that have lower than expected costs and may use HHS funds to pay QHPs that have higher than expected costs. OIG work previously identified problems with risk corridors established during the transition to Medicare Part D (the program upon which § 1342 was based), raising concerns that this new program could have similar vulnerabilities. We will assess CMS's efforts to ensure accurate reporting and payments in the risk corridors program. We will also examine amounts paid under the program. (OEI; 00-00-00000; various reviews; expected issue date: FY2015; new start)

In FY 2014, we plan to develop additional work examining CMS's administration of payment systems, which might include, for example, HHS' role in the risk adjustment and reinsurance programs (§§ 1341 and 1343); the calculation of subsidy payments for consumers whose circumstances change; payments associated with individuals who move between Medicaid and insurance purchased through a Marketplace; the treatment of subsidy payments when consumers terminate from or drop coverage; and/or the accuracy of information received from State exchanges upon which Federal payments are based.

Eligibility Systems

The FFM and SBMs must verify consumers' personal information; accurately determine eligibility for qualified health plans, tax credits, and cost-sharing reduction subsidies; and transmit complete, accurate, and timely eligibility information to insurers and consumers. The Marketplaces must also

facilitate Medicaid enrollment for those who qualify. (Reviews addressing Medicaid eligibility are identified below in the "Medicaid Expansion and Other Medicaid Issues" section of this Appendix.) OIG's on-going and planned work to ensure the effectiveness and efficiency of eligibility systems includes:

➤ **Review of Affordable Care Act Enrollment Safeguards (New)**

Affordable Care Act, §1411. We will assess the effectiveness of internal controls in place to ensure that accurate information is used by a marketplace to determine consumer eligibility for enrollment and subsidy payments. The Continuing Appropriations Act (CAA) of 2014, Section 1001(c), requires OIG to submit to the Congress by July 1, 2014, a report regarding the effectiveness of the procedures and safeguards preventing the submission of inaccurate or fraudulent information by applicants for enrollment in a qualified health plan (QHP). Initially, we plan to select the FFM and two SBMs for internal control review. Using a statistically valid sample of applicants, we will review whether each Marketplace has performed all the required verifications to determine eligibility for enrollment in a QHP and for tax credits and cost sharing reductions, and has resolved any inconsistencies through manual verification in accordance with regulations. We plan to expand our reviews to additional SBMs in subsequent work. (OAS; W-00-14-42024; various reviews; expected issue date: FY 2014; work in progress)

➤ **Health Insurance Marketplaces' Manual Verification Procedures (New)**

Affordable Care Act, § 1411. We will determine how and to what extent health insurance Marketplaces manually verify applicants' eligibility to enroll in qualified health plans and their eligibility for tax credits and cost sharing reductions. In some circumstances, information on a consumer's application cannot be verified electronically because data are unavailable or do not exist or because the information on the application is inconsistent with data received. In most of these cases, the Marketplace is required to request additional information or documentation. This inspection of manual verification procedures will supplement OIG work mandated by Congress under the CAA, § 201(c). (OEI; W-01-14-00180; expected issue date: FY 2014; work in progress)

Contracts—Planning, Acquisition, Contracting, Management, and Performance

Contractors played, and will continue to play, a vital role in building, fixing, and maintaining the systems that underpin the FFM authorized under the Affordable Care Act, § 1321. These systems are critical to the operation of the FFM through HealthCare.gov and to allowing consumers to shop for and purchase affordable health plans. HealthCare.gov is a CMS-managed Web site that hosts the FFM. For FY 2014, OIG plans a comprehensive look at the Department's efforts to implement and operate the FFM. This body of work will include reviews of the planning, acquisition, contracting, contract management, and contractor performance for the FFM. We anticipate covering timeframes both before and after October 1, 2013, including existing and new contracts and contractors. On-going and planned work presently includes:

➤ **Implementation of the Federal Marketplace (New)**

We will review the Department's overall efforts in planning, coordinating, and implementing the FFM. The difficulties encountered during the launch of the FFM on October 1, 2013, raised serious concerns about the planning, management, and oversight of the FFM project. We will also review

changes made after October 1, 2013. (OEI; 03-14-00280; various reviews; expected issue date: FY 2015; work in progress)

➤ **Procurement of the Federal Marketplace (New)**

We will review HHS's acquisition plans for the implementation of the FFM, including selection of contractors and contract types and the rationale for these selections. (OEI; 03-14-00230; expected issue date: FY 2014; work in progress)

➤ **Reporting and Resolution of Problems During the Federal Marketplace Development (New)**

The review will determine the extent to which HHS and its contractors had mechanisms to communicate problems or concerns about the FFM and whether they used those mechanisms effectively. (OAS; W-00-14-59030; A-03-14-03001; expected issue date: FY 2014; work in progress).

➤ **Payments to Federal Marketplace Contractors (New)**

This review will examine HHS payments to contractors for work on the FFM. We plan to address key questions, including whether performance-based contracting was used to determine payments to contractors; whether contractors received incentive payments; whether contractor invoices met requirements; and whether contractors were paid appropriately. (OAS; W-00-14-59030; A-03-14-03001; expected issue date: FY 2014; work in progress).

➤ **Oversight of Federal Marketplace Contractors (New)**

This review will examine whether HHS exercised appropriate and adequate oversight and direction over the contracts related to the FFM, whether HHS complied with oversight and monitoring requirements required by Federal and HHS regulations, and whether contractors individually and as a whole met requirements of their contracts, the acquisition plan, and the Affordable Care Act. (OAS; W-00-14-59032; A-03-14-03003; expected issue date: FY 2015; work in progress)

Security of Data and Consumer Information

Effective operation of the Marketplaces requires rapid, accurate, and secure integration of data from numerous Federal and State sources and individuals who use the Marketplaces. Because these systems handle consumers' sensitive personal information, security of data and systems is paramount. Reviews currently underway and planned to address security in the Marketplaces include:

➤ **CMS's Implementation of Security Controls for the Federally Facilitated Exchange HealthCare.gov (New)**

We will determine whether information security controls for CMS's Web infrastructure, which hosts the FFM, have been implemented in accordance with CMS information security standards, recognized industry best practices, and Federal information security standards. We will conduct a vulnerability scan of the HealthCare.gov Web site using an automated tool that seeks to identify known security vulnerabilities and discover possible methods of attack that can lead to unauthorized access or the exfiltration of data. We will also review any reports related to prior vulnerability assessments of HealthCare.gov, and assess whether the vulnerabilities identified were remediated timely. (OAS, A-06-14-00023, various reviews, expected issue date: FY 2014; work in progress)

➤ **State-Based Marketplaces Information System Security Controls (New)**

We will determine whether information security controls for SBMs have been implemented in accordance with CMS guidelines, recognized industry best practices, and/or Federal information security standards. We will conduct vulnerability scans of Web-based systems using automated tools that seek to identify known security vulnerabilities and discover possible methods of attack that can lead to unauthorized access or the exfiltration of data. We will also review any reports related to prior vulnerability assessments of SBM systems, and assess whether the vulnerabilities identified were remediated timely. (OAS, A-06-14-00000; various reviews; expected issue date: FY 2014; work in progress)

Also, in coordination with other law enforcement partners, OIG is monitoring for reports of cybersecurity threats and consumer fraud. OIG has promoted, and will continue to promote, consumer awareness and prevention of fraud in the Marketplaces, including, for example, identity theft, imposter marketers, and fake websites. Additional information about consumer protection can be found at: <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Medicaid Expansion and Other Medicaid Issues

The Affordable Care Act is driving a significant expansion of the Medicaid program. Twenty-five states and the District of Columbia are currently expanding coverage to include qualifying adults earning up to 133 percent of the Federal poverty level, pursuant to Affordable Care Act, § 2001. Enrollment in Medicaid is increasing even in states that have not expanded eligibility, as previously eligible people enroll through a Marketplace.

The Medicaid section of the Work Plan describes the range of FY 2014 reviews planned and in progress to promote the effectiveness and efficiency of the growing Medicaid program. Focus areas include prescription drugs; billing, payment, reimbursement, quality, and safety of home health services, community-based care, and other services, equipment, and supplies; state management of Medicaid, information system controls and security, and Medicaid managed care.

Medicaid Reviews

Reviews related directly to specific Affordable Care Act provisions include the following (these reviews are described more fully in the Medicaid section of the *Work Plan*):

➤ **Enhanced Federal Medical Assistance Percentage (New)**

Affordable Care Act, § 2001. (OAS; W-00-14-31480; various reviews; expected issue date: FY 2015; new start) *Work Plan* p. 42.

➤ **Medicaid Eligibility Enrollment—National Error Rates (New)**

Affordable Care Act, § 2001. (OEI; 00-00-0000; expected issue FY2015; new start; Affordable Care Act) *Work Plan* p. 42.

- **Medicaid Eligibility Determinations in Selected States (New)**
Affordable Care Act, § 2001. (OAS; W-00-14-31140; various reviews; expected issue date: FY 2015; new start; Affordable Care Act) *Work Plan* p. 42.
- **Rebates for New Formulations of Existing Drugs**
Affordable Care Act, § 2501. (OAS; W-00-14-31451; various reviews; expected issue date: FY 2014; new start) *Work Plan* p. 35.
- **States' Collection and Reporting of Rebates**
Affordable Care Act, § 2501. (OEI; 03-12-00520; expected issue date: FY 2014; work in progress) *Work Plan* p. 35.
- **Health-Care-Acquired Conditions—Prohibition on Federal Reimbursements**
Affordable Care Act, § 2702. (OAS; W-00-14-31452; various reviews; expected issue date: FY 2015; new start) *Work Plan* p. 39.
- **States' Experiences with Enhanced Provider Screening**
Affordable Care Act § 6402. (OEI; 05-13-00520; expected issue date: FY 2015; work in progress) *Work Plan* p. 45.
- **Provider Payment Suspensions during Pending Investigations of Credible Fraud Allegations (New)**
Affordable Care Act, § 6402(h)(2). (OAS; W-00-14-31473; various reviews; expected issue date: FY 2015; new start; OEI; 09-14-00020; expected issue date: FY 2015; work in progress) *Work Plan* p. 45.
- **State Terminations of Providers Terminated by Medicare or by Other States**
Affordable Care Act, § 6501. (OEI; 06-12-00030; expected issue date: FY 2014; work in progress) *Work Plan* p. 44.
- **Completeness and Accuracy of Managed Care Encounter Data**
Affordable Care Act, § 6504. (OEI; 07-13-00120; expected issue date: FY 2015; work in progress) *Work Plan* p. 48.
- **National Correct Coding Initiative Edits and CMS Oversight (New)**
Affordable Care Act, § 6507. (OAS; W-00-12-31459; various reviews; expected issue date: FY 2014; work in progress; OEI; 00-00-0000; expected issue date: FY 2015; work in progress) *Work Plan* p. 47.

Other Affordable Care Act Requirements and Programs

OIG's portfolio of work related to the Affordable Care Act also includes reviews of changes to the Medicare program and other new or changed programs.

Medicare Reviews

The Affordable Care Act introduced changes to the Medicare program designed to improve efficiency and quality of care and promote program integrity and transparency. The Medicare sections of the FY 2014 *Work Plan* describe OIG's extensive body of on-going and planned reviews of all Parts of the Medicare program. Much of this work will provide data and information on cost, quality, and delivery of Medicare services that can aid the Department as it develops new, value-driven payment and delivery models for the Medicare program, including those being implemented pursuant to the Affordable Care Act.

The following reviews address specific Affordable Care Act provisions related to the Medicare program and are described in more detail in the Medicare sections of the *Work Plan*:

➤ **Hospice in Assisted Living Facilities (New)**

Affordable Care Act, § 3132. (OEI; 02-14-00070; expected issue date: FY 2014; work in progress)
Work Plan p. 9.

➤ **Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts**

Affordable Care Act, § 3301. (OAS; W-00-14-35611; various reviews; expected issue date: FY 2015; new start) *Work Plan* p. 32.

➤ **Ensuring Dual Eligibles' Access to Drugs Under Medicare Part D**

Affordable Care Act, § 3313. (OEI; 05-14-00170; expected issue date: FY 2014; work in progress)
Work Plan p. 32.

➤ **Program for National Background Checks for Long-Term-Care Employees**

Affordable Care Act, § 6201. (OEI; 07-10-00420; expected issue date: FY 2017; work in progress)
Work Plan p. 8.

➤ **Enhanced Enrollment Screening Process for Medicare Providers**

Affordable Care Act, § 6401. (OEI; 03-13-00050; expected issue date: FY 2014; work in progress)
Work Plan p. 27.

Other Programs

Planned work and work underway addressing other Affordable Care Act provisions include the following reviews:

➤ **Controls Over Pre-Existing Condition Insurance Plans**

Affordable Care Act, § 1101. We will review the Federal and State controls designed to prevent, detect, report, and recover fraud, waste, and abuse in the Pre-Existing Condition Insurance Plans (PCIPs). We will also determine the extent to which CMS oversees such controls. The anticipated high beneficiary care costs may have made PCIPs both attractive targets for fraudulent providers and difficult programs for fraud detection. Lessons learned from the PCIP experience may inform efforts to reduce fraud risks associated with coverage of high risk, high cost individuals. (OEI; 07-12-00300; expected issue date: FY 2014; work in progress)

➤ **Consumer Operated and Oriented Plan Loan Program—Eligibility Status and Use of Startup and Solvency Loans (New)**

Affordable Care Act, § 1322. We will follow up on prior OIG work that examined the selection process for Consumer Operated and Oriented Plan (CO-OP) loans and identified factors that could affect the CO-OP loan program, including startup funding levels. In this new work, we will verify CO-OP eligibility status and the use of startup and solvency loans. (OAS; W-00-14-59019; various reviews, expected issue date: FY 2015; new start)

➤ **Prevention and Public Health Fund Grants—CDC Oversight (New)**

Affordable Care Act, § 4002. We will assess the effectiveness of CDC's management of the Prevention and Public Health Fund (PPHF) program. We will also determine selected grantees' compliance with grant requirements. Context—The Affordable Care Act established the PPHF program to provide expanded and sustained national investments in prevention and public health, to improve health outcomes, and to enhance health care quality. CDC received appropriations totaling \$1.26 billion during FY 2012 – 2013, representing 64 percent of total PPHF dollars. Recent legislation may change CDC's PPHF allotment. (OAS; W-00-14-59027; expected issue date: FY 2015; new start)

➤ **HRSA—340B Covered Entity Access to 340B Ceiling Prices (New)**

Affordable Care Act, § 7102. (OEI; 05-13-00510; expected issue date: FY 2014; work in progress) *Work Plan* p. 59.

➤ **Accuracy of the Physician Compare Web Site (New)**

Affordable Care Act, § 10331. We will review CMS's efforts to ensure that Physician Compare Web site contains accurate information on healthcare providers. Context—The Affordable Care Act required HHS to create the Physician Compare Web site, which is intended to help Medicare beneficiaries make informed choices about their healthcare by providing them with information about healthcare providers. (Affordable Care Act, § 10331.) To implement the provision, CMS repurposed its Provider Enrollment, Chain, and Ownership System (PECOS) as its data source for provider information on Physician Compare. However, prior OIG work identified that the provider information in PECOS was often inaccurate and, at times, incomplete. (OEI; 01-14-00210; expected issue date: FY 2015; new start)

Appendix B

Recovery Act Reviews

Pursuant to the American Recovery and Reinvestment Act of 2009 (Recovery Act), OIG received funding for discretionary oversight of programs and operations of the Department of Health and Human Services (HHS) that received supplemental funding through the Recovery Act. The funds have been used primarily to conduct financial oversight activities to ensure that HHS agencies and grantees used the funds they received for the intended purposes and in accordance with established requirements. Recovery Act funding resulted in a significant increase in the number of grants and contracts awarded by HHS. The reviews that follow represent OIG's continuing oversight of HHS agencies' use of Recovery Act funds.

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

HIT—health information technology

PHI—protected health information

Medicare and Medicaid

Adoption of Electronic Health Records

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.

➤ **Medicare Incentive Payments for Adopting Electronic Health Records**

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. 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. Context—Medicare incentive payments are authorized over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology. (Recovery Act, §§ 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. (OAS; W-00-13-31352; expected issue date: FY 2014; work in progress; Recovery Act)

➤ **Medicaid Incentive Payments for Adopting Electronic Health Records**

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. We will determine whether incentive payments to Medicaid providers to purchase, implement, and operate EHR technology were claimed in accordance with Medicaid requirements; assess CMS's actions to remedy erroneous incentive payments and its plans for securing the payments for the duration of the incentive program; and determine whether payments to States for related administrative expenses were appropriate. Context—The law authorizes 100 percent Federal financial participation for allowable expenses for eligible Medicaid providers to purchase, implement, and operate certified EHR technology. (Recovery Act § 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 EHR incentives will total about \$12 billion between 2011 and 2019. (OAS; W-00-12-31351; W-00-13-31351; various reviews; expected issue date: FY 2014; work in progress; Recovery Act)

Systems and Information Security

➤ **Security of Certified Electronic Health Record Technology under Meaningful Use (New)**

Electronic Health Records. We will perform audits of various covered entities receiving EHR incentive payments from CMS and their business associates, such as EHR cloud service providers, to determine whether they adequately protect electronic health information created or maintained by certified EHR technology. Context—A core meaningful-use objective for eligible providers and hospitals is to protect electronic health information created or maintained by certified EHR technology through the implementation of appropriate technical capabilities. To meet and measure this objective, eligible hospitals, including critical access hospitals, must conduct a security risk analysis of certified EHR technology as defined in Federal regulations and use the capabilities and standards of Certified Electronic Health Record Technology (CEHRT). (45 CFR § 164.308(a)(1) and 45 CFR §§ 170.314(d)(1) – (d)(9).) Furthermore, business associates that transmit, process, and store EHRs for Medicare/Medicaid providers are playing a larger role in the protection of electronic health information. Therefore, audits of cloud service providers and other downstream service providers are necessary to assure compliance with regulatory requirements and contractual agreements. (OAS; W-04-14-42002; new start; various reviews; expected issue date: FY 2014; Recovery Act)

➤ **OCR Oversight of Covered Entities' Compliance with the HIPAA Privacy Rule**

Protected Health Information. We will review Office for Civil Rights (OCR) oversight of covered entities' compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. We will assess OCR's oversight of covered entities' compliance with the Privacy Rule and determine the extent to which Medicare Part B covered entities are complying with selected privacy standards. Context—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 Privacy Rule by increasing the civil monetary penalties for

covered entities' noncompliance. (74 Fed. Reg. 56123.) (OEI; 09-10-00510; expected issue date: FY 2014; work in progress; Recovery Act)

➤ **OCR Oversight of Covered Entities' Compliance with the HITECH Breach Notification Rule**

Protected Health Information. We will review OCR's oversight of covered entities' compliance with a rule that 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. We will determine the extent to which OCR investigated breaches reported by covered entities and determine the extent to which Medicare Part B covered entities complied with selected breach standards. Context—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. (Health Information Technology for Economic and Clinical Health Act Breach Notification Rule.) (OEI; 09-10-00511; expected issue date: FY 2014; work in progress; Recovery Act)

Cross-Cutting Enforcement Activities

OIG conducts criminal investigations of referrals of grant and contract fraud in the misuse of Recovery Act funds and with regard to reprisals against whistleblowers.

Fraud and Whistleblower Reprisals

➤ **Integrity of Recovery Act Expenditures**

Criminal Investigations. 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. Context—Recovery Act funding resulted 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**

Criminal Investigations. 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. Context—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. (Recovery Act, § 1553.) (OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)