

OFFICE OF INSPECTOR GENERAL

U.S. Department of Health and Human Services

Fiscal Year 2015

WORK PLAN

Mid-Year Update | May 2015

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 Mid-Year Update (Work Plan)* for fiscal year (FY) 2015 summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the current fiscal year 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 health care laws. Our mission encompasses more than 100 programs administered by HHS at agencies such as the Centers for Medicare & Medicaid Services, Administration for Children and Families, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health.

The amount of work conducted in each category is set by the purpose limitations in the money appropriated to OIG. OIG's funding that is directed toward oversight of the Medicare and Medicaid programs constitutes a significant portion of its total funding (approximately 76 percent in 2014). The remaining share of OIG's efforts and resources focuses on HHS's other programs and management processes, including key issues, such as the accuracy of financial assistance payments, efficient and effective operation of health insurance marketplaces, safety of the Nation's food and drug supply, security of national stockpiles of pharmaceuticals for use during emergencies, and 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 (CMPs), 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 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.
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- **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 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 coordinates with DOJ and other Federal, State, and local law enforcement authorities. OI also coordinates with OAS and OEI when audits and evaluations uncover potential fraud. OI's investigative efforts 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 CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

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

What do we accomplish?

For FY 2014, we reported expected recoveries of over \$4.9 billion, consisting of nearly \$834.7 million in audit receivables and about \$4.1 billion in investigative receivables, which include about \$1.1 billion in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution. We also identified about \$15.7 billion in savings estimated for FY 2014 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 2014 exclusions of 4,017 individuals and entities from participation in Federal health care programs; 971 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 533 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, CMP settlements, and administrative recoveries related to provider self-disclosure matters.

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;
- top management and performance challenges facing HHS;
- work performed by partner organizations;
- management's actions to implement our recommendations from previous reviews; and
- timeliness.

A Note About This Edition:

This edition of the *Work Plan*, effective as of May 2015, describes OIG audits, evaluations, and certain legal and investigative initiatives that are ongoing. In response to adjustments made to our *Work Plan*, this mid-year update removes items that have been completed, postponed, or canceled and includes new items that have been started since October 2014. The word “new” before a project title indicates that the project did not appear in the previous *Work Plan*. For each project, we include the subject, primary objective, and criteria related to the topic. At the end of each description, we provide the internal identification code for the review (if a number has been assigned) and the year in which we expect one or more reports to be issued as a result of the review.

This edition also forecasts areas for which OIG anticipates planning and/or beginning work in the upcoming fiscal year and beyond. Typically, these broader areas of focus are based on the results of OIG's risk assessments and have been identified as significant management and performance challenges facing HHS. In FY 2015 and beyond, we will continue to focus on emerging payment, eligibility, management, and information technology systems security vulnerabilities in health care reform programs, such as the health insurance marketplaces. OIG plans to add to its portfolio of work on care quality and access in Medicare and Medicaid, as well as on public health and human services programs. OIG's examination of the appropriateness of Medicare and Medicaid payments will continue, with possible additional work on the efficiency and effectiveness of payment policies and practices in inpatient and outpatient settings, for prescription drugs, and in managed care. Other areas under consideration for new work include, for example, the integrity of the food, drug, and medical device supply chains; the security of electronic data; the use and exchange of health information technology; and emergency preparedness and response efforts.

OIG will periodically update its online *Work Plan*, available at www.oig.hhs.gov.

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, and Appendix B, which describes our oversight of the funding that HHS received under the American Recovery and Reinvestment Act of 2009.

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 us at public.affairs@oig.hhs.gov.

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Medicare Part A and Part B

Medicare Part A covers certain inpatient services in hospitals and skilled nursing facilities (SNF) and some home health services. Medicare Part B covers designated practitioners' services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover. The Centers for Medicare & Medicaid Services (CMS) uses Medicare Administrative Contractors (MACs) to administer Medicare Part A and Medicare Part B and to process claims for both parts.

The Office of Inspector General (OIG) has identified reducing waste in Medicare Parts A and B and ensuring quality, including quality in nursing home, hospice care, and home- and community-based care, as top management challenges facing the Department of Health and Human Services (HHS or the Department). OIG has focused its efforts on reducing improper payments, improving quality and access, and fostering economical payment policies. Work planning for fiscal year (FY) 2015 and beyond will consider the following:

Quality of Care: Planned work will examine settings in which OIG has identified gaps in program safeguards intended to ensure medical necessity, patient safety, and quality of care. We will also continue our focus on access to care, including beneficiary access to durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) in the context of new programs involving competitive bidding.

Appropriate Payments: Planning is ongoing to expand OIG's portfolio examining inefficient payment policies or practices, including comparison among Government programs to identify instances when Medicare paid significantly different amounts for the same or similar services or when less efficient payment methodologies were used. Planning is ongoing for work addressing Medicare costs incurred because of deficiencies in services or defective medical devices, as well as noncompliance or other vulnerabilities in care settings with high payment error rates.

Oversight of Payment and Delivery Reform: Planning is underway to expand OIG's work addressing changes to Medicare programs designed to improve efficiency and quality of care and to promote program integrity and transparency. OIG will consider work examining the transition from volume- to value-based payments and the soundness and effectiveness of the payment structures, care coordination, and administration of these new payment models. Work expected to begin in 2015 and beyond includes examinations of data and metrics to document and measure quality and performance.

Hospitals

Acronyms and Abbreviations for Selected Terms:

ASPR—Assistant Secretary for Preparedness and Response
CDC—Centers for Disease Control and Prevention
CMS—Centers for Medicare & Medicaid Services
CoP—conditions of participation (in Medicare)
MS-DRG—Medicare severity-diagnosis related group
FTE—full-time-equivalent
GME—graduate medical education

IME—indirect medical education
IMRT—intensity-modulated radiation therapy
IRF—inpatient rehabilitation facility
LTCH—long-term care hospital
PPS—prospective payment system
RHC—right heart catheterization
SNF—skilled nursing facility

Hospital-Related Policies and Practices

➤ Reconciliations of outlier payments

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. 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 timely 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 2015)

➤ Hospitals' use of outpatient and inpatient stays under Medicare's 2-midnight rule

We will determine how hospitals' use of outpatient and inpatient stays changed under Medicare's 2-midnight rule, as well as how Medicare and beneficiary payments for these stays changed. We will also determine the extent to which the use of outpatient and inpatient stays varied among hospitals. CMS implemented the 2-midnight rule on October 1, 2013. This rule represents a substantial change to the criteria hospital physicians are expected to use when deciding whether to admit beneficiaries as inpatients or treat them as outpatients. (OEI; 02-15-00020; expected issue date: FY 2016).

➤ Medicare costs associated with defective medical devices

We will review Medicare claims to identify the costs resulting from additional use of medical services associated with defective medical devices and determine the impact of the cost on the Medicare Trust Fund. 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 2015)

➤ **Analysis of salaries included in hospital cost reports**

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. 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-00-14-35713; expected issue date: FY 2015)

➤ **Medicare oversight of provider-based status**

We will determine the extent to which provider-based facilities meet CMS's criteria. Provider-based status allows facilities owned and operated by hospitals to bill as hospital outpatient departments. Provider-based status can result in higher 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; expected issue date: FY 2015)

➤ **Comparison of provider-based and free-standing clinics**

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. 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 provider based are at 42 CFR § 413.65(d). (OAS; W-00-14-35724; W-00-15-35724; expected issue date: FY 2015)

Hospitals—Billing and Payments

➤ **Inpatient claims for mechanical ventilation**

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. 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)

➤ **Selected inpatient and outpatient billing requirements**

We will review Medicare payments to acute care hospitals to determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments. 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; W-00-15-35538; various reviews; expected issue date: FY 2015)

➤ **Duplicate graduate medical education 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. 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. When payments for DGME and IME costs are being calculated, 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; various reviews; expected issue date: FY 2015)

➤ **Indirect medical education payments**

We will review provider data to determine whether hospitals' IME payments were made in accordance with Federal regulations and guidelines. We will determine whether the IME payments were calculated properly. Prior OIG reviews have determined that hospitals have received excess reimbursement for IME costs. Teaching hospitals with residents in approved GME 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 FTEs to available beds. (OAS; W-00-14-35722; W-00-15-35722; expected issue date: FY 2015)

➤ **Outpatient dental claims**

We will review Medicare hospital outpatient payments for dental services to determine whether such payments were made in accordance with Medicare requirements. 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-00-14-35603; various reviews; expected issue date: FY 2015)

➤ **Nationwide review of cardiac catheterizations and endomyocardial biopsies**

We will review Medicare payments for right heart catheterizations (RHCs) and endomyocardial biopsies billed during the same operative session and determine whether hospitals complied with

Medicare billing requirements. Previous OIG reviews have identified inappropriate payments when hospitals were paid for separate RHC procedures when the services were already included in payments for endomyocardial 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)

➤ **Payments for patients diagnosed with kwashiorkor**

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. 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 2015)

➤ **Bone marrow or stem cell transplants**

We will review Medicare payments to hospitals for bone marrow or stem cell transplants to determine whether the payments were made in accordance with Federal rules and regulations. Bone marrow or peripheral blood stem cell transplantation includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high-dose chemotherapy or radiotherapy before 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.) Bone marrow or stem cell transplants are covered under Medicare only for specific diagnoses. Procedure codes must be accompanied 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 2015)

➤ **Review of hospital wage data used to calculate Medicare payments**

We will review hospital controls over the reporting of wage data used to calculate wage indexes for Medicare payments. Prior OIG wage index work identified hundreds of millions of dollars in incorrectly reported wage data and resulted in policy changes by CMS with regard to how hospitals reported deferred compensation costs. Hospitals must accurately report wage data to CMS annually to develop wage index rates. (Social Security Act, §1886(d)(3) and 1886(d)(3)(E).) (OAS; W-00-14-35725; W-00-15-35725; various reviews; expected issue date: FY 2015)

➤ **NEW Intensity-modulated radiation therapy**

We will review Medicare outpatient payments for intensity-modulated radiation therapy (IMRT) to determine whether the payments were made in accordance with Federal rules and regulations. IMRT is an advanced mode of high-precision radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. Prior OIG reviews have identified hospitals that have incorrectly billed for IMRT services. 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.) In addition, certain services should not be billed when they are performed as part of developing an IMRT plan. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 4, § 200.3.2) (OAS; W-00-15-35740; various reviews; expected issue date: FY 2016)

Hospitals—Quality of Care and Safety

➤ Inpatient rehabilitation facilities—Adverse events in postacute care for Medicare beneficiaries

We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving postacute care in inpatient rehabilitation facilities (IRFs). 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. 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)

➤ Long-term-care hospitals—Adverse events in postacute care for Medicare beneficiaries

We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving care in long-term-care hospitals (LTCHs). 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. LTCHs are inpatient hospitals that provide long-term care to clinically complex patients, such as those with multiple acute or chronic conditions. Medicare beneficiaries typically enter LTCHs following an acute-care hospital stay to receive intensive rehabilitation and medical care. LTCHs are the third most common type of postacute care facility after SNFs and IRFs, accounting for nearly 11 percent of Medicare costs for post-acute care (\$5.4 billion in FY 2011). (OEI; 06-14-00530; expected issue date: FY 2016)

➤ **NEW** Hospital preparedness and response to high-risk infectious diseases

We will describe hospitals' efforts to prepare for the possibility of public health emergencies resulting from infectious diseases. Several HHS agencies, including the Centers for Disease Control and Prevention (CDC), the Office of the Assistant Secretary for Preparedness and Response (ASPR), and CMS provide resources, i.e., guidance and support, for hospitals as they prepare. Additionally, we will determine hospital use of HHS resources and identify lessons learned through recent experiences with pandemic or highly-contagious diseases, such as Ebola. Prior OIG work identified shortcomings in such areas as community preparedness for a pandemic (2009) and hospital preparedness for a natural disaster (i.e., Superstorm Sandy, 2013). (OEI; 06-15-00230; expected issue date: FY 2016)

Nursing Homes

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act

SNF—skilled nursing facility

CMS—Centers for Medicare & Medicaid Services

➤ Medicare Part A billing by skilled nursing facilities

We will describe changes in SNF billing practices from FYs 2011 to 2013. 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; this erroneous billing resulted 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; various reviews; expected issue date: FY 2015)

➤ State agency verification of deficiency corrections

We will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. 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-00-14-35701; various reviews; expected issue date: FY 2015)

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

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. Section 6201 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary of Health and Human Services to carry out a nationwide program for States to conduct national and State background checks for prospective direct patient access employees of nursing facilities and other long-term-care providers. The program is administered by CMS. To carry out the nationwide program, CMS has issued solicitations for grant awards. All States, the District of Columbia, and U.S. territories are eligible to be considered for a grant award. OIG is required under the ACA to submit a report to Congress evaluating this program upon its conclusion. This mandated work is ongoing and an interim report will be issued prior to the program's conclusion (ACA, § 6401.) (OEI; 07-10-00420; expected issue date: FY 2015; ACA)

Hospices

Acronyms and Abbreviations for Selected Terms:

CoP—conditions of participation

➤ Hospice general inpatient care

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. 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 (CoP) 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 2015)

Home Health Services

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
HHA—home health agency

PPS—prospective payment system

➤ Home health prospective payment system requirements

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 paid in accordance with Federal laws and regulations. A prior OIG report found that one in four home health agencies (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. Home health 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 2015)

➤ Employment of individuals with criminal convictions

We will determine the extent to which HHAs employed individuals with criminal convictions. We will also examine the criminal convictions of selected employees with potentially disqualifying convictions. 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 certain types of criminal convictions. (OEI; 07-14-00130; expected issue date: FY 2015)

Medical Equipment and Supplies

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
LCD—local coverage determination

MIPPA—Medicare Improvements for Patients and Providers Act
PMD—power mobility device

Equipment and Supplies—Policies and Practices

➤ Power mobility devices—Lump-sum purchase versus rental

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-00-14-35461; expected issue date: FY 2015)

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

We will review the process CMS used to conduct competitive bidding and to make subsequent pricing determinations for certain medical equipment items and services in selected competitive bidding areas under rounds 1 and 2 of the competitive bidding program. Federal law requires OIG to conduct postaward audits to assess this process. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(1)(E).) (OAS; W-00-13-35241; various reviews; expected issued date: FY 2015)

Equipment and Supplies—Billing and Payments

➤ Power mobility devices—Supplier compliance with payment requirements

We will review Medicare Part B payments for suppliers of PMDs to determine whether such payments were in accordance with Medicare requirements. We will focus particularly on whether PMDs are medically necessary and whether Medicare payments for PMD claims submitted by medical equipment suppliers are supported in accordance with requirements at 42 CFR § 410.38. (OAS; W-00-14-35703; various reviews; expected issue date: FY 2015)

➤ Nebulizer machines and related drugs—Supplier compliance with payment requirements

We will review Medicare Part B payments for nebulizer machines and related drugs to determine whether medical equipment suppliers' claims for nebulizers and related drugs are medically necessary and are supported in accordance with Medicare requirements. 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 (LCDs) issued by the four Medicare

contractors that process medical equipment and supply claims contain utilization guidelines and documentation requirements. (OAS; W-00-14-35465; W-00-15-35465; expected issue date: FY 2015)

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

We will review claims for frequently replaced medical equipment supplies to determine whether medical necessity, frequency, and other Medicare requirements are met. 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-00-15-35420; various reviews; expected issue date: FY 2015)

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

We will review Medicare Part B payments for home blood glucose test strips and lancet supplies to determine their appropriateness. Prior OIG reviews determined that suppliers of diabetic-related supplies did not always comply with Federal requirements. As reflected in the LCDs 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 the claim 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-00-12-35407; W-00-14-35407; various reviews; expected issue date: FY 2015)

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

We will review Medicare's claims processing edits (special system controls) designed to prevent payments to multiple suppliers of home blood glucose test strips and lancets and determine whether they are effective in preventing inappropriate payments. 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; W-00-14-35604; various reviews; expected issue date: FY 2015)

Equipment and Supplies—Quality of Care and Safety

➤ **NEW** Access to durable medical equipment in competitive bidding areas

We will determine the effects of the competitive bidding program on Medicare beneficiaries' access to certain types of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) subject to competitive bidding. In an effort to reduce waste, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) updated Medicare's payment system for certain DMEPOS from a fee schedule to a competitive bidding program. Under this program, DMEPOS suppliers compete on price to supply to particular geographic areas. Anecdotal reports allege that competitive bidding has led to reduced access to DME and, in turn, compromised the quality of care beneficiaries receive. (OEI; 01-15-00040; expected issue date: FY 2016)

Other Providers and Suppliers

Acronyms and Abbreviations for Selected Terms:

ASC—ambulatory surgical center

BLS—Bureau of Labor Statistics

CMS—Centers for Medicare & Medicaid Services

ESRD—end-stage renal disease

IRF—inpatient rehabilitation facility

PPS—prospective payment system

Other Providers—Policies and Practices

➤ Ambulatory surgical centers—Payment system

We will review the appropriateness of Medicare's methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. 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. 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. (MMA, § 626.) (See also 42 CFR § 416.171.) (OAS; W-00-13-35423; W-00-14-35423; various reviews; expected issue date: FY 2015)

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

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) PPS. We will compare facilities' acquisition costs for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed. 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 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-00-14-35608; various reviews; expected issue date: FY 2015)

Other Providers—Billing and Payments

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

We will examine Medicare claims data to assess the extent of questionable billing for ambulance services, such as transports to dialysis facilities that potentially never occurred or potentially were medically unnecessary. We will also determine whether Medicare payments for ambulance services were made in accordance with Medicare requirements. 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 2015; and OAS; W-00-11-35574; W-00-12-35574; W-00-13-35574; W-00-14-35574; various reviews; expected issue date: FY 2015)

➤ Anesthesia services—Payments for personally performed services

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 anesthesia services reported on a claim with the "AA" service code modifier met Medicare requirements. 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 service code modifier on the claim as if services were personally performed by an anesthesiologist 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; W-00-14-35706; W-00-15-35706; various reviews; expected issue date: FY 2015)

➤ Chiropractic services—Part B payments for noncovered services

We will review Medicare Part B payments for chiropractic services to determine whether such payments were claimed in accordance with Medicare requirements. 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; W-00-14-35606; various reviews; expected issue date: FY 2015)

➤ Chiropractic services—Questionable billing

We will determine and describe the extent of questionable billing for chiropractic services. 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." (CMS's *Medicare Benefit Policy Manual*, Pub. No. 100 02, ch. 15, § 240.1.3.) (OEI; 01-14-00200; expected issue date: FY 2015)

➤ Chiropractic services—Portfolio report on Medicare Part B 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. 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." (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 work will offer recommendations to reduce Medicare chiropractic vulnerabilities detected in prior OIG work. (OAS; OIG-12-14-03; expected issue date: FY 2015)

➤ Diagnostic radiology—Medical necessity of high-cost tests

We will review Medicare payments for high-cost diagnostic radiology tests to determine whether the tests were medically necessary and to determine the extent to which use 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-00-13-35454; W-00-14-35454; various reviews; expected issue date: FY 2015)

➤ Imaging services—Payments for practice expenses

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. Practice expenses may include 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 insurance costs, and practice expenses. (Social Security Act, § 1848(c)(1)(B).) (OAS; W-00-13-35219; W-00-14-35219; various reviews; expected issue date: FY 2015)

➤ **Selected independent clinical laboratory billing requirements**

We will review Medicare payments to independent clinical laboratories to determine laboratories' compliance with selected billing requirements. We will use the results of these reviews to identify clinical laboratories that routinely submit improper claims and recommend recovery of overpayments. Prior OIG audits, investigations, and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements. 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).) We will focus on independent clinical laboratories with claims that may be at risk for overpayments. (OAS; W-00-14-35726; W-00-15-35726; various reviews; expected issue date: FY 2015)

➤ **Ophthalmologists—Inappropriate and questionable billing**

We will review Medicare claims data to identify potentially inappropriate and questionable billing for ophthalmology services during 2012. We will also determine the locations and specialties of providers with questionable billing. Medicare payments for Part B physician services, which include ophthalmologists, are authorized by the Social Security Act, § 1832(a)(1), and 42 CFR § 410.20. In 2010, Medicare allowed more than \$6.8 billion for services provided by ophthalmologists. (OEI; 04-12-00280; expected issue date: FY 2015)

➤ **Physicians—Place-of-service coding errors**

We will review physicians' coding on Medicare Part B claims for services performed in ASCs and hospital outpatient departments to determine whether they properly coded the places of service. 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 ASC. (OAS; W-00-13-35113; W-00-14-35113; various reviews; expected issue date: FY 2015)

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

We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable or were not properly documented or that the therapy services were not medically necessary. 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; W-00-14-35220; W-00-15-35220; various reviews; expected issue date: FY 2015)

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

We will review Medicare payments for portable x-ray equipment services to determine whether payments were correct and were supported by documentation. We will also assess the qualifications of the technologists who performed the services. Prior OIG work found that Medicare may have improperly paid portable x-ray suppliers for return trips to nursing facilities (i.e., multiple trips to a facility in 1 day). Medicare generally reimburses for portable x-ray services if the conditions for coverage are met. (42 CFR §§ 486.100–486.110.) (OAS; W-00-14-35464; various reviews; expected issue date: FY 2015)

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

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-use sleep-testing procedures and determine whether they were in accordance with Medicare requirements. An OIG analysis of CY 2010 Medicare payments for Current Procedural Terminology¹ 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).) To the extent that repeated diagnostic testing is performed on the same beneficiary and the prior test results are still pertinent, repeated tests may not be reasonable and necessary. 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; W-00-13-35521; W-00-14-35521; various reviews; expected issue date: FY 2015)

➤ **NEW Annual analysis of Medicare clinical laboratory payments**

We will analyze Medicare payments for clinical diagnostic laboratory tests, including the top 25 clinical diagnostic laboratory tests by Medicare expenditures in 2014. Previous OIG work has found that Medicare pays more than other insurers for certain high-volume and high-expenditure laboratory tests. Section 216 of the Protecting Access to Medicare Act of 2014 requires new Medicare payment rates for laboratory tests beginning in 2017 based on private payer rates and establishes processes for determining initial payments for new laboratory tests. Pursuant to a requirement of the Protecting Access to Medicare Act, OIG will conduct an annual analysis and monitor Medicare expenditures and the new payment system for laboratory tests. (OEI; 09-15-00210; expected issue date: FY 2016)

➤ **NEW Inpatient rehabilitation facility payment system requirements**

We will review compliance with various aspects of the IRF PPS, including the documentation required in support of the claims paid by Medicare. We will determine whether IRF claims were paid in accordance with Federal laws and regulations. IRFs provide rehabilitation for patients recovering

¹ The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright [2011] by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

from illness and surgery who require an inpatient hospital-based interdisciplinary rehabilitation program, supervised by a rehabilitation physician. Effective for discharges on or after January 1, 2010, all documentation and coverage requirements specified in 42 CFR § 412.622(a)(3) (4) and (5) must be met to ensure that IRF care is reasonable and necessary under the Social Security Act (the Act), § 1862(a)(1)(A). (74 Fed. Reg. 39762, 39788). (OAS; W-00-15-35730; various reviews; expected issue date: FY 2016)

Prescription Drugs

Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price

ASP—average sales price

CMS—Centers for Medicare & Medicaid Services

FDA—Food and Drug Administration

MAC—Medicare Administrative Contractor

Prescription Drugs—Policies and Practices

➤ Comparison of average sales prices to average manufacturer prices

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. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The enabling law required 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, who may disregard the ASP for the drug when setting reimbursement amounts (e.g., apply a price substitution policy). (OEI; various studies; expected issue date: FY 2015)

➤ Part B payments for drugs purchased under the 340B Program

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. 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, including tribal health centers, children's hospitals, and tuberculosis clinics. Medicare Part B reimburses for almost all covered outpatient drugs (including those purchased by 340B entities) on the basis of the 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: FY 2015)

Prescription Drugs—Billing and Payments

➤ Payments for immunosuppressive drug claims with KX modifiers

We will determine whether Part B payments for immunosuppressive drugs that were billed with a service code modifier “KX” met Medicare documentation requirements. Medicare claims for immunosuppressive drugs reported with the KX modifier may not always meet documentation requirements for payment under Part B. Medicare Part B covers Food and Drug Administration (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-00-14-35707; W-00-15-35707; various reviews; expected issue date: FY 2015)

Prescription Drugs—Quality of Care and Safety

➤ Covered uses for Medicare Part B drugs

We will review the oversight actions that 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. 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 FDA, 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. (*Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 50.4.2.) (OEI; 03-13-00450; expected issue date: FY 2015)

Part A and Part B Contractors

Acronyms and Abbreviations for Selected Terms:

CAS—Cost Accounting Standards
CMS—Centers for Medicare & Medicaid Services
FAR—Federal Acquisition Regulation
FI—Fiscal Intermediary
GAO—Government Accountability Office

MEDIC—Medicare Drug Integrity Contractor
OFPP—Office of Federal Procurement Policy
PSC—Program Safeguard Contractor
ZPIC—Zone Program Integrity Contractor

Oversight of Contracts

➤ Contract management at the Centers for Medicare & Medicaid Services

We will determine the number, types, and contract value of currently active contracts administered under the Federal Acquisition Regulation (FAR) by CMS. We also will determine the number and total value of FAR contracts that CMS has not closed out as required under FAR and will identify

CMS's barriers to managing and closing of FAR contracts. CMS relies extensively on contractors to help it carry out its basic mission, including administration, management, and oversight of its health programs. In FY 2013, CMS obligated \$5.4 billion under contracts for a variety of goods and services. Previous Government Accountability Office (GAO) reports highlighted the vulnerabilities and weaknesses in 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; various reviews; expected issue date: FY 2016)

➤ **Administrative costs claimed by Medicare contractors**

We will review administrative costs claimed by various contractors for their Medicare activities, focusing on costs claimed by terminated contractors. We will also determine whether the costs claimed were reasonable, allocable, and allowable. 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 FAR at 48 CFR Part 31. (OAS; W-00-13-35005; W-00-14-35005; various reviews; expected issue date: FY 2015)

➤ **Executive compensation benchmark**

We will review contractor employee salaries charged to Medicare to determine whether the selected contractors applied a senior executive compensation benchmark required by regulation, and we will determine the potential cost savings if contractors were required to apply the same benchmark to all employee compensation. Costs incurred after January 1, 1998, for compensation of a senior executive in excess of the benchmark compensation amount determined applicable for the contractor fiscal year by the Administrator, Office of Federal Procurement Policy (OFPP), under section 39 of the OFPP Act (41 U.S.C. 435) are unallowable. (48 CFR § 31.205-6(p).) We will determine the potential effect of expanding the executive compensation benchmark to all employees. The term "senior executive" is defined as the top five compensated employees of each organizational segment. (48 CFR § 31.205-6(p)(4)(B)(ii).) The issue of high salaries for executives of Government contractors has been examined in the news media. (OAS; W-00-13-35710; various reviews; expected issue date: FY 2015)

➤ **Contractor pension cost requirements**

We will determine whether Medicare contractors have calculated and claimed reimbursement for Medicare's share of various employee pension costs in accordance with their Medicare contracts and applicable Federal requirements. We will determine whether contractors have fully implemented contract clauses requiring them to determine and separately account for the employee pension assets and liabilities allocable to their contracts with Medicare. We will also review Medicare carriers and fiscal intermediaries (FIs) 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. 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-00-14-35067; W-00-14-35094; various reviews; expected issue date: FY 2015)

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

We will review the postretirement health benefit costs and the supplemental employee retirement plans of Medicare FIs and carriers to determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts. Criteria are in the FAR at 48 CFR §§ 31.201 through 31.205. (OAS; W-00-13-35095; W-00-14-35095; various reviews; expected issue date: FY 2015)

Contractor Functions and Performance

➤ **Medicare benefit integrity contractors' activities**

We will review and report the level of benefit integrity activity performed by Medicare benefit integrity contractors in CYs 2012 and 2013. 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 2016)

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

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. OIG has issued several reports regarding the tracking and collection of the overpayments that Medicare's contractors have made to providers. In response, CMS stated that it 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 2016)

Information Technology Security, Protected Health Information, and Data Accuracy

➤ **Medicare contractor information systems security programs—Annual report to Congress**

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and MACs. We will report to Congress on our assessment of the scope and sufficiency of the independent evaluations and summarize their results. Federal law requires independent evaluations of the security programs of FIs, carriers, and MACs and requires OIG to assess such

evaluations and report the results of its assessments to Congress. (MMA, § 912.)
(OAS; W-00-14-41010; W-00-15-41010; expected issue date: FY 2015)

Other Part A and Part B Program Management Issues

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
ACO—accountable care organizations

CMS—Centers for Medicare & Medicaid Services
EHR—electronic health record

Provider Eligibility

➤ Enhanced enrollment screening process for Medicare providers

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 ACA, § 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. 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 site visits, fingerprinting, and background checks, as well as an automated provider screening process. (OEI; 03-13-00050; expected issue date: FY 2015; ACA.)

Delivery System Reform

➤ Risk Assessment of CMS's administration of the Pioneer Accountable Care Organization Model

We will conduct a risk assessment of the Pioneer Accountable Care Organization (ACO) Model. An ACO is a group of providers and suppliers of services (e.g., hospitals and physicians and others involved in patient care) that will work together to coordinate care for the Medicare fee-for-service beneficiaries they serve. The Centers for Medicare & Medicaid Innovation was created to test innovative care and service delivery models and is administering the Pioneer ACO Model. (ACA, § 3021.) We will conduct a risk assessment of internal controls over administration of the Pioneer ACO Model. (OAS; W-00-15-35708; expected issue date: FY 2015; ACA)

➤ **NEW** Use of electronic health records to support care coordination through ACOs

We will review the extent that providers participating in ACOs in the Medicare Shared Savings Program use electronic health records (EHRs) to exchange health information to achieve their care coordination goals. We will also assess providers' use of EHRs to identify best practices and possible challenges in their progression toward interoperability (the extent that information systems can exchange data and have the ability to interpret those shared data). The Medicare Shared Savings Program promotes accountability of hospitals, physicians, and other providers for a patient population, coordinates items and services, and encourages investment in infrastructure and

redesigned care processes for high quality and efficient service delivery. (ACA, § 3022.) OEI; 00-00-00000; expected issue date: FY 2016

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 under contract with 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. (MMA.) Part D is a voluntary benefit available to Medicare beneficiaries.

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act

CDC—Centers for Disease Control and Prevention

CMS—Centers for Medicare & Medicaid Services

DIR—direct and indirect remuneration

MA—Medicare Advantage

PDE—prescription drug event

P&T—Pharmacy & Therapeutics

Part C – 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.

Efforts for FY 2015 and beyond may include additional work examining the soundness of rates and risk and payment adjustments in the MA Program.

MA Organizations' Compliance With Part C Requirements

➤ Use of Medicare Advantage encounter data – CMS oversight of data integrity

We will review CMS's oversight and coordination of MA encounter data validation and assess the extent to which CMS's Integrated Data Repository contains valid and complete MA encounter data. In 2012, CMS began requiring MA organizations to submit a more comprehensive set of encounter data reflecting the items and services provided to MA plan enrollees. Prior CMS and OIG audits have indicated vulnerabilities in the accuracy of data reporting by MA organizations. (OEI; 03-15-00060; expected issue date: FY 2016).

➤ Risk adjustment data—Sufficiency of documentation supporting diagnoses

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. Prior OIG reviews have shown that

medical record documentation does not always support the diagnoses submitted to CMS by 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; W-00-15-35078; various reviews; expected issue date: FY 2015)

Part D – Prescription Drug Program

Part D administration depends upon extensive coordination and information sharing between 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.

CMS provides prescription drug coverage for over 37 million Medicare beneficiaries through Part D. In 2012, Medicare Part D expenditures totaled almost \$67 billion. Ensuring the appropriate use of prescription drugs in Medicare is vital for financial reasons as well as patient safety and quality of care. Future OIG work planning efforts for FY 2015 and beyond will consider prescribing policies and practices and the efficacy of safeguards intended to protect beneficiaries and the programs from drug overutilization and improper payments.

Medicare, Sponsor, and Manufacturer Policies and Practices

➤ Savings potential of adjusting risk corridors

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. 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; 02-14-00320; expected issue date: FY 2016)

➤ **NEW** Part D oversight portfolio

We will summarize OIG audits, evaluations, legal opinions, and investigative work on Medicare Part D and provide progress information on recommendations to improve CMS, Plan Sponsors, and MEDIC oversight of the Part D program. Since the inception of Part D, numerous OIG reports have identified weaknesses in the oversight of the program, including oversight by Part D plan sponsors, MEDICs, and CMS. (OEI; 03-15-00180; expected issue date: FY 2015).

Sponsor Compliance With Part D Requirements

➤ Documentation of administrative costs in sponsors' bid proposals

We will review the sufficiency of Part D sponsors' documentation supporting the administrative costs they included in their annual bid proposals to CMS. Part D sponsors submit bids for the costs of providing prescription drug coverage, including administrative costs. (Social Security Act, § 1860D-11(b), and 42 CFR § 423.265(c)(1).) 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)

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

We will determine whether Part D sponsors complied with Medicare requirements for reporting direct and indirect remunerations (DIR). 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 2015)

➤ Reconciliation of payments—Reopening final payment determinations

We will review CMS policies, procedures, instructions, and processes for reopening final payment determinations and determine the adequacy of Part D sponsor compliance and sponsor-submitted data. 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; W-00-15-35621; various reviews; expected issue date: FY 2015)

➤ Ensuring dual eligibles' access to drugs under Part D

We will review the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries, as required. 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 ACA, § 3313, requires OIG to conduct this review annually. (OEI; 05-15-00120; expected issue date: FY 2015; ACA)

➤ Recommendation followup – Oversight of conflicts of interest in Medicare prescription drug decisions

We will determine what steps CMS has taken to improve its oversight of Part D sponsors' Pharmacy and Therapeutics (P&T) committee conflict-of-interest procedures. Federal law and regulations require Medicare Part D P&T committees to make prescription drug coverage decisions on the basis

of scientific evidence and standards of practice. To comply with the law, Part D sponsors' P&T committees must prevent conflicts of interest from influencing members to give preference to certain drugs. The OIG report *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions* (OEI-05-10-00450) found that CMS does not adequately oversee Part D sponsors' P&T committee compliance with Federal conflict-of-interest requirements. (OEI; 00-00-00000; expected issue date: FY 2015)

Part D Billing and Payments

➤ Documentation of pharmacies' prescription drug event data

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. 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 2015)

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

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. The ACA 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 ACA, § 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; ACA)

➤ **NEW** Billing trends for Part D drugs and commonly abused opioids

We will describe trends in Part D billing from 2006 to 2014, including changes in billing for commonly used opioid drugs. We will also describe billing trends associated with pharmacies in 2014. Drug diversion and prescription drug abuse are growing problems. CDC considers prescription drug abuse to be an epidemic, and deaths from drug overdose are now one of the leading causes of accidental death. OIG is also seeing a significant increase in Part D fraud and has a wide portfolio of work involving pharmaceutical matters, including prescription drug diversion. (OEI; 02-15-00190; expected issue date: FY 2015).

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

Protecting an expanding Medicaid program from fraud, waste, and abuse takes on a heightened urgency as the program continues to grow in spending and in the number of people it serves. Our continuing and new reviews of Medicaid in FY 2015 address: 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.

Planning for FY 2015 and beyond may include examinations of beneficiary eligibility determinations and FMAP assignments, data and methodologies used to ensure program integrity, and inefficient payment policies or practices—targeting areas prone to payment errors. Going forward, OIG expects to expand its portfolio examining protections to ensure quality of care and access to services, as well as work examining drug diversion and abuse.

Medicaid Prescription Drug Reviews

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
AMP—average manufacturer price
CMS—Centers for Medicare & Medicaid Services
CPI-U—consumer price index for urban consumers

DRA—Deficit Reduction Act
DUR—drug utilization review
MCO—managed care organization
NDA—new drug application

State and Manufacturer Compliance With Medicaid Requirements

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

We will review the education and enforcement actions that 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. We also will review State oversight of MCOs' DUR programs and any resulting actions related to inappropriate dispensing of opiates. 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 2016)

➤ **Manufacturer compliance with AMP reporting requirements**

We will determine whether manufacturer compliance with average manufacturer price (AMP) reporting requirements has changed since 2008 and identify actions that CMS has taken to improve compliance with AMP reporting requirements. Manufacturer-reported AMPs play a critical role in Federal cost containment strategies for prescription drugs. 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). 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. (OEI; 03-14-00150; expected issue date: FY 2016)

➤ **States' collection of rebates on physician-administered drugs**

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. 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 2015)

➤ **States' collection of rebates for drugs dispensed to Medicaid MCO enrollees**

We will determine whether the States are collecting prescription drug rebates from pharmaceutical manufacturers for Medicaid MCOs. Drugs dispensed by Medicaid MCOs were excluded from this requirement until March 23, 2010. Section 2501 (c) of the ACA expanded the rebate requirement to include drugs dispensed to MCO enrollees. Medicaid MCOs are required to report enrollees' drug utilization to the State for the purpose of collecting rebates from manufacturers. (OAS; W-00-14-31483; W-00-15-31483; various reviews; expected issue date: FY 2015; ACA)

➤ **NEW Manufacturer rebates – Federal share of rebates**

We will review States' reporting of the Federal share of Medicaid rebate collections to determine whether States are correctly identifying and reporting the increases in rebate collections. Section 2501 of the Affordable Care Act increased the Medicaid drug rebates (both single source and multiple source drugs) for Medicaid outpatient drugs and required that those additional rebate amounts attributable to the increase be given solely to the Federal Government. (OAS; W-00-15-31450; various reviews; expected issue date: FY 2016; new start; ACA)

➤ **NEW Analysis of generic price increases compared to price index**

We will analyze generic drug prices over a period of time to determine whether prices increased more than the increases in inflation as measured by the consumer price index for urban consumers (CPI-U). Under the Medicaid drug rebate program, manufacturers are required to pay an additional rebate when the AMP for a brand-name drug increases more than the CPI-U increases. Generally,

the amount of the additional rebate is based on the amount that the drug's reported AMP exceeds its inflation-adjusted baseline AMP (Social Security Act, § 1927(c)(2)). There is no similar inflation-based rebate provision for generic drugs. Our review will quantify any potential savings from requiring an inflation-based additional rebate for generic drugs. (OAS; W-00-15-31501; expected issue date: FY 2016)

➤ **NEW Treatment of authorized generic drugs**

We will review drug manufacturers' treatment of sales of authorized generics in their calculation of AMP for the Medicaid drug rebate program. We will determine whether manufacturers included sales of authorized generics to secondary manufacturers in their AMP calculations. An authorized generic drug is one that the manufacturer holding the title to the original new drug application (NDA) permits another manufacturer to sell under a different national drug code. Provisions in 42 CFR §§ 447.506(b) provide that the manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer directly to a wholesaler. Manufacturers that also include the sales of an authorized generic to a secondary manufacturer could lower AMP and consequently a lower rebate to be paid to the State. (OAS; W-00-15-31499; expected issue date: FY 2016)

State Claims for Federal Reimbursement

➤ **Medicaid payments for multiuse vials of Herceptin**

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. 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 2015)

Home Health Services and Other Community-Based Care

Acronyms and Abbreviations for Selected Terms Used in This Section:

CDT—continuing day treatment

CMS—Centers for Medicare & Medicaid Services

HCBS—home and community-based services

HHA—home health agency

OMB—Office of Management and Budget

Billing and Payments

➤ **Adult day health care services**

We will review Medicaid payments by States for adult day care services to determine whether providers complied with Federal and State requirements. 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.) Prior OIG work shows that these payments do not always comply with State and Federal requirements. (OAS; W-00-12-31386; W-00-13-31386; various reviews; expected issue date: FY 2015)

➤ Continuing day treatment mental health services

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. CDT providers render an array of services to people with mental illnesses. CDT providers bill Medicaid on the basis of the number of hours of services 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*, Attachment A, § C.1.c.) (OAS; W-00-13-31128; W-00-14-31128; various reviews; expected issue date: FY 2015)

State Claims for Federal Reimbursement

➤ Room and board costs associated with HCBS waiver program payments

We will determine whether selected States claimed Federal reimbursement for unallowable room and board costs associated with services provided under the terms and conditions of 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. 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; W-00-14-31465; various reviews; expected issue date: FY 2015)

Quality of Care and Safety of Beneficiaries

➤ Home health services—Screenings of health care workers

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. 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; various reviews; expected issue date: FY 2015)

Other Medicaid Services, Equipment, and Supplies

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
CFC—Community First Choice
CMS—Centers for Medicare & Medicaid Services

EPSDT—Early and Periodic Screening, Diagnostic, and Treatment (services)
FMAP—Federal medical assistance percentage
LTSS—long-term services and support

Policies and Practices

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

We will determine whether opportunities exist for lowering Medicaid payments for some 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. 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; W-00-15-31390; various reviews; expected issue date: FY 2015)

Billing and Payments

➤ Transportation services—Compliance with Federal and State requirements

We will determine the appropriateness of Medicaid payments by States to providers for transportation services. Federal regulations require States to ensure necessary transportation for Medicaid beneficiaries to and from providers. (42 CFR § 431.53.) Each State may have different Medicaid coverage criteria, reimbursement rates, rules governing covered services, and beneficiary eligibility for services. (OAS; W-00-13-31121; various reviews; expected issue date: FY 2015)

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

We will determine whether selected States made Medicaid payments for hospital care associated with health-care-acquired conditions and provider-preventable conditions and quantify the amount of Medicaid payments for such conditions. As of July 1, 2011, Federal payments to States are prohibited for any amounts expended for providing medical assistance for health-care-acquired conditions. (Social Security Act, § 1903, and ACA, § 2702.) Federal regulations prohibit Medicaid payments by States for services related to health-care-acquired conditions and for provider-preventable conditions as defined by CMS or included in the Medicaid State Plan. (42 CFR § 447.26.) (OAS; W-00-14-31452; various reviews; expected issue date: FY 2015; ACA)

State Claims for Federal Reimbursement

➤ Dental services for children—Inappropriate billing

We will review Medicaid payments by States for dental services to determine whether States have properly claimed Federal reimbursement. 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-00-13-31135; various reviews; expected issue date: FY 2015)

➤ Family planning services—Claims for enhanced Federal funding

We will review family planning services in several States to determine whether States improperly claimed enhanced Federal funding for such services and the resulting financial impact on Medicaid. Previous OIG work found improper claims for enhanced funds for family planning services. States may claim Federal reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. (Social Security Act, § 1903(a)(5).) (OAS; W-00-13-31078; W-00-14-31078; W-00-15-31078; various reviews; expected issue date: FY 2015)

➤ Community First Choice State plan option under the Affordable Care Act

We will review Community First Choice (CFC) payments to determine whether the payments are proper and allowable. The ACA, section 2401, added section 1915(k) to the Social Security Act, a new Medicaid State plan option that allows States to provide statewide home and community-based attendant services and support to individuals who would otherwise require an institutional level of care. States taking up the option will receive a 6-percent increase in their FMAP for CFC services. To be eligible for CFC services, beneficiaries must otherwise require an institutional level of care and meet financial eligibility criteria. (OAS; W-00-15-31495; expected issue date: FY 2016; ACA)

➤ Payments to States under the Balancing Incentive Program

We will review expenditures the States claimed under the Balancing Incentive Program (BIP) to ensure that they were for eligible Medicaid long-term services and support (LTSS) and determine whether the States used the additional enhanced Federal match in accordance with § 10202 of the ACA. Under the BIP, eligible States can receive either a 2-percent or 5-percent increase in their FMAP for eligible Medicaid LTSS expenditures. Funding to States under the BIP cannot exceed \$3 billion over the program’s 4-year period (i.e., October 1, 2011, through September 30, 2015). To receive payments, participating States agree to make structural changes to increase access to noninstitutional LTSS. Additionally, the States must use the additional Federal funding to provide new or expanded offerings of non-institutional LTSS. (OAS; W-00-15-31482; various reviews; expected issue date: FY 2016; ACA)

Quality of Care and Safety of Beneficiaries

➤ Access to pediatric dental care for children enrolled in Medicaid

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 dental services in these States. In recent years, a number of dental providers and chains have been prosecuted for providing unnecessary dental procedures and causing harm to Medicaid children. In addition, children's access to dental services has been a longstanding Medicaid problem. Medicaid covers comprehensive dental care for approximately 37 million low-income children through the EPSDT benefit. Under EPSDT, States must cover dental services and dental screening services for children. (OEI; 02-14-00490; various reviews; expected issue date: FY 2016)

➤ Medicaid beneficiary transfers from group homes and nursing facilities to hospital emergency rooms

We will review the rate of and reasons for transfer from group homes or nursing facilities to hospital emergency departments. High occurrences of emergency transfers could indicate poor quality of care. Prior OIG work examined transfers to hospital emergency departments, raising concerns about the quality of care provided in some nursing facilities. There is congressional interest in this area. (OAS; W-00-15-31040; various reviews; expected issue date: FY 2015)

State Management of Medicaid

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
CHIP—Children's Health Insurance Program
CMS—Centers for Medicare & Medicaid Services
CPE—certified public expenditures
FFP—Federal financial participation
FMAP—Federal medical assistance percentage

Form CMS-64—Quarterly Medicaid Statement of Expenditures
MIP—Medicaid Integrity Program
MFCU—Medicaid Fraud Control Unit
OMB—Office of Management and Budget
RMSS—random moment sampling systems

How States Fund Their Medicaid Programs

➤ State use of provider taxes to generate Federal funding

We will review State health-care-related taxes imposed on various Medicaid providers to determine whether the taxes comply with applicable Federal requirements. Our work will focus on the mechanism States use to raise revenue through provider taxes and determine the amount of Federal funding generated. Previous OIG work 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-00-14-31455; various reviews; expected issue date: FY 2015)

➤ **State compliance with Federal Certified Public Expenditures regulations**

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-00-14-31110; various reviews; expected issue date: FY 2015)

State Claims for Federal Reimbursement

➤ **State cost allocations that deviate from acceptable practices**

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. 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 Federal financial participation (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; W-00-14-31467; various reviews; expected issue date: FY 2015)

➤ **Enhanced Federal Medical Assistance Percentage**

We will review States' Medicaid claims to determine whether the States correctly applied enhanced FMAP payment provisions of the ACA. The ACA, § 2001, authorized the use of an FMAP of 100 percent for individuals who are newly eligible because of Medicaid expansion. In addition, the ACA, § 2012, required that Medicaid payments to primary care providers be at least those of the Medicare rates in effect for calendar years 2013 and 2014. (OAS; W-00-14-31480; W-00-15-31480; various reviews; expected issue date: FY 2015; ACA)

➤ **Medicaid eligibility determinations in selected States**

We will determine the extent to which selected States made inaccurate Medicaid eligibility determinations. We will examine eligibility inaccuracy for Medicaid beneficiaries in selected States that expanded their Medicaid programs pursuant to the ACA and in States that did not. We will also assess whether and how the selected States addressed issues that contributed to inaccurate determinations. For some States, we will calculate a Medicaid eligibility error rate and determine the amount of payments associated with beneficiaries who received incorrect eligibility determinations. The ACA, § 2001, required significant changes affecting State processes for Medicaid enrollment, modified criteria for Medicaid eligibility, and authorized the use of an enhanced FMAP of 100 percent for newly eligible individuals. (OAS; W-00-14-31140; W-00-15-31140; various reviews; and OEI; 06-14-00330; expected issue date: FY 2016; ACA)

State Adjustments of Federal Reimbursement

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

We will review the Medicaid monetary drawdowns that States received from the Federal Reserve System to determine whether they were supported by actual expenditures reported by the States on Quarterly Medicaid Statement of Expenditures (Form CMS-64). States draw monetary advances against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee throughout a quarter. (42 CFR § 430.30(d)(4).) After the end of each quarter, States must submit 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 Form CMS-64 should reconcile the monetary advances for a quarter. (OAS; W-00-13-31456; various reviews; expected issue date: FY 2015)

➤ State reporting of Medicaid collections on Form CMS-64

We will determine whether States accurately captured Medicaid collections on Form CMS-64 and returned the correct Federal share related to those collections. Previous OIG work revealed multiple errors in compiling collection amounts on 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-00-14-31457; various reviews; expected issue date: FY 2015)

➤ State use of incorrect FMAP for Federal share adjustments

We will review States' Medicaid claims records to determine whether the States used the correct FMAP when processing claim adjustments reported on Form CMS-64. We reviewed the claim adjustments reported on Form CMS-64 for one State and determined that it did not use the correct FMAP for the majority of adjustments. The Federal Government is required to reimburse a State at the FMAP rate in effect at the time the expenditure was made. (Social Security Act, § 1903(a)(1).) (OAS; W-00-14-31460; various reviews; expected issue date: FY 2015)

State Program Integrity Activities and Compliance With Federal Requirements

➤ State actions to address vulnerabilities identified during CMS reviews

We will review corrective actions that State Medicaid agencies have implemented to address the findings and recommendations from State Medicaid program integrity reviews conducted by CMS. We will determine why States have not implemented all corrective actions, examine the followup CMS performed to ensure that corrective actions were taken by States, and examine the evidence CMS reviews to ensure that corrective actions were implemented. As part of 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 DRA, § 6034. (OEI; 00-00-00000; expected issue date: FY 2016)

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

We will review States' compliance with a new requirement that they terminate their Medicaid program providers that have been terminated under Medicare or by a Medicaid program of another State. 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. The new requirement became effective January 1, 2011. (Social Security Act, § 1902(a)(39), as amended by the ACA, § 6501.) (OEI; 06-12-00030; expected issue date: FY 2015; ACA)

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

We will review providers' patient accounts to determine whether there are Medicaid overpayments in accounts with credit balances. 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 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-00-13-31311; various reviews; expected issue date: FY 2015)

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

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. Finally, we will test the accuracy and completeness of ownership information by comparing ownership information sampled providers gave to CMS to enroll in Medicare to the ownership information the same providers gave to OIG and to the States to enroll in Medicaid. 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 controlling interest in the provider entity. (see e.g., 42 CFR § 455.104 and 42 CFR § 420.206.) (OEI; 04-11-00590, 04-11-00591; expected issue date: FY 2015)

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

We will review States' use of enhanced screenings that assess risk for fraud, waste, and abuse for moderate- and high-risk enrolling and revalidating Medicaid providers and suppliers. We will also determine the results of States' efforts to prevent risky providers and suppliers from participating in Medicaid before and after the implementation of enhanced screenings. The ACA, § 6402, requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment, 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 2016; ACA)

➤ Provider payment suspensions during pending investigations of credible fraud allegations

We will review payments to providers with allegations of fraud deemed credible by States. We will also review States' processes for suspending payments. FFP in Medicaid 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 ACA, § 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 Medicaid Fraud Control Units (MFCUs) or to appropriate law enforcement agencies in States with no certified MFCUs. (42 CFR § 455.23(d).) We will determine whether select Medicaid State agencies are in compliance with these provisions. (OAS; W-00-14-31473; various reviews; expected issue date: FY 2015; and OEI; 09-14-00020; expected issue date: FY 2015; ACA)

OIG Oversight of State Medicaid Fraud Control Units

➤ Reviews of State Medicaid Fraud Control Units

We will continue to conduct indepth onsite reviews of the management, operations, and performance of a sample of MFCUs. We will identify effective practices and areas for improvement in MFCU management and operations. As part of its responsibility for administering Federal grants to MFCUs, OIG provides oversight and guidance to MFCUs, assesses MFCU compliance with Federal regulations and policy, and evaluates MFCU performance under established performance standards. The onsite reviews are part of OIG's program of oversight for MFCUs that includes annual recertification, training, and collection and reporting of statistical information. (OEI; 00-00-00000; various reviews; expected issue date: FY 2015)

Medicaid Information System Controls and Security

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
MSIS—Medicaid Statistical Information System

NCCI—National Correct Coding initiative

Controls To Prevent Improper Medicaid Payments

➤ Duplicate payments for beneficiaries with multiple Medicaid identification numbers

We will review duplicate payments made by States on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and identify States' procedures or other controls for preventing such payments. 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-00-14-31374; various reviews; expected issue date: FY 2015)

➤ **National Correct Coding Initiative edits and CMS oversight**

We will review selected States' implementation of National Correct Coding initiative (NCCI) edits for Medicaid claims and describe CMS's oversight of NCCI edits. The NCCI consists 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 methodologies compatible with NCCI for Medicaid claims filed on or after October 1, 2010. (Social Security Act, § 1903(r), as amended by the ACA, § 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-00-15-31459; various reviews; expected issue date: FY 2015; and OEI; 09-14-00440; expected issue date: FY 2016, ACA)

Controls To Ensure the Security of Medicaid Systems and Information

➤ **CMS oversight of States' Medicaid information systems 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. 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-00-14-40019; W-00-15-40019; various reviews; expected issue date: FY 2015)

➤ **NEW Completeness of data in Transformed Medicaid Statistical Information System: early implementation**

We will determine whether States are submitting complete Transformed Medicaid Statistical Information System (T-MSIS) data. T-MSIS is designed to be a detailed national database of Medicaid and Children's Health Insurance Program information to cover a broad range of user needs, including program integrity. It is a continuation of CMS's past attempts to improve nationally available Medicaid data after OIG and others found that the data were not complete, accurate, or timely. (OEI; 05-15-00050; expected issue date: FY 2016)

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 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:

ACA—Affordable Care Act

CMS—Centers for Medicare & Medicaid Services

GAO—Government Accountability Office

MCO—managed care organization

MSIS—Medicaid Statistical Information System

OMB—Office of Management and Budget

State Payments to Managed Care Entities

➤ Medicaid managed care reimbursement

We will review States' managed care plan reimbursements to determine whether 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) and (iv).) Previous work by the GAO 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)

➤ Medical loss ratio

We will review States and managed care plans without contract provisions that require a minimum percentage of total costs to be expended for medical services (medical loss ratio) to determine the extent of potential Medicaid program savings if the States had required Medicaid MCOs to meet the medical loss ratio standards established by the ACA. The ACA established standards for the amount of premium revenue that certain commercial health insurers and Medicare Advantage plans can spend on costs other than health care-related expenses and provide rebates to enrollees if the minimum standards are not met. While the standards established by the ACA do not apply to Medicaid, some States have applied similar standards to their contracts with Medicaid MCOs and require the MCOs to issue rebates to the appropriate Medicaid State agencies if the insurers do not meet minimum MLR standards. The Federal Government is entitled to the Federal share of the net amount recovered by a State with respect to its Medicaid program. (OAS; W-00-13-31372; various reviews; expected issue date: FY 2016)

➤ MCO payments for services after beneficiaries' deaths

We will identify Medicaid managed care payments made on behalf of deceased beneficiaries. We will also identify trends in Medicaid claims with service dates after beneficiaries' dates of death. Prior OIG reports have found that Medicare paid for services that purportedly started or continued after beneficiaries' dates of death. (OAS; W-00-15-31497; expected issue date: FY 2016)

➤ **MCO payments for ineligible beneficiaries**

We will identify Medicaid managed care payments made on behalf of beneficiaries that were not eligible for Medicaid. We will also identify trends in Medicaid claims within this population. Section 1903(m) of the Social Security Act authorizes payments to States for eligible Medicaid beneficiaries enrolled in an MCO. Prior OIG work has found that Medicaid paid for services that purportedly started or continued during periods when the beneficiary was not eligible for Medicaid. (OAS; W-00-15-31498; expected issue date: FY 2016)

Data Collection and Reporting

➤ **State reporting of managed care encounter data**

We will determine the extent to which complete Medicaid managed care encounter data are reported to the Medicaid Statistical Information System (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. 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. (ACA, § 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; ACA)

Program Integrity in Managed Care

➤ **Medicaid managed care entities' identification of fraud and abuse**

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. 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; 02-15-00260; expected issue date: FY 2016)

Beneficiary Protections in Managed Care

➤ **Medicaid managed care beneficiary grievances and appeals process**

We will review the extent to which States monitor Medicaid MCOs' grievances and appeals systems for compliance with Federal requirements. States are required to provide an opportunity for a fair

hearing to any beneficiary whose Medicaid claim for assistance is denied or not acted upon promptly. (Social Security Act, § 1902(a)(3).) Medicaid 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 2016)

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

We will review State Medicaid agencies' oversight policies, procedures, and activities to determine the extent to which States monitor Medicaid 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. 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 2016)

CMS-Related Legal and Investigative Activities

Acronyms and Abbreviations for Selected Terms:

CIA—corporate integrity agreement
CMP—civil monetary penalty
CMS—Centers for Medicare & Medicaid Services
CPG—compliance program guidance

DOJ—Department of Justice
HEAT—Health Care Fraud Prevention and Enforcement
Action Team
MFCU—[State] Medicaid Fraud Control Unit

Legal Activities

OIG's resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalties (CMPs) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIAs) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the anti-kickback statute, and 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 FY 2014, OIG excluded 4,017 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; 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 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 CIAs. For example, we conduct site visits to entities that are subject to CIAs to verify compliance, to confirm information submitted to us by the entities, and to assess the providers' compliance programs. We review a variety of types 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 CIA 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 anti-kickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful advice on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and CPG for specific areas. 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 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 self-disclosures to OIG 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. 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 100 HHS programs and operations. The investigations include Medicare and Medicaid fraud, failure-of-care cases, child support enforcement violations, grant and contract fraud, network 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 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, the U.S. Postal Inspection Service, the Internal Revenue Service, and MFCUs.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by 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 as appropriate. 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 anti-kickback 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, were not rendered, or were not rendered as prescribed or in which 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 MFCUs in investigating 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 HHS generally include the following:

- **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 incomes 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 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 include overseeing the protection of volunteers involved in research.

Effective management of public health programs is essential to ensure that they achieve their goals and best serve the programs' intended beneficiaries. In its work planning activities in FY 2015 and beyond, OIG will consider key risk areas, such as the adequacy of CDC and its public health partners' preparedness to respond to public health emergencies, including disease outbreaks. Future work planning will also include examinations of access to quality services and health and safety protections, including the integrity of the food, drug, and medical supply chain.

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
 AIDS—acquired immunodeficiency syndrome
 BPA—Bisphenol A
 CDC—Centers for Disease Control and Prevention
 CoP—conditions of participation
 DHS—Department of Homeland Security
 FDA—Food and Drug Administration
 FDAA—Food and Drug Amendments Act of 2007
 FSMA—Food Safety Modernization Act
 HCP—Health Center Program
 HIPAA—Health Insurance Portability and Accountability Act
 HRSA—Health Resources and Services Administration
 IC—Institute/Center (NIH)
 IHS—Indian Health Service
 MCO—managed care organization

OMB—Office of Management and Budget
 NIEHS—National Institute of Environmental Health Sciences
 NIH—National Institutes of Health
 NOM—national outcome measure
 NTP—National Toxicology Program
 PEPFAR—President's Emergency Plan for AIDS Relief
 PMR—postmarketing requirement
 PPHF—Prevention and Public Health Fund
 SAMHSA—Substance Abuse and Mental Health Services Administration
 SAPTBG—Substance Abuse Prevention and Treatment Block Grant
 SSBG—Social Services Block Grant
 USDA—United States Department of Agriculture
 WTCHP—World Trade Center Health Program

Centers for Disease Control and Prevention

➤ CDC—World Trade Center Health Program – Review of medical claims

We will review World Trade Center Health Program (WTCHP) expenditures to assess whether internal controls have been established in the WTCHP in accordance with OMB Circular A-123, *Management's Responsibility for Internal Control*. As part of our review, we will determine whether the internal controls are adequate to (1) detect and prevent fraudulent or duplicate billing and payment for inappropriate medical services and (2) prevent excessive administrative payments in accordance with OMB Circular A-122, *Cost Principle for Non-Profit Organizations*. Prior Federal audits found that CDC did not reliably estimate costs for monitoring and treating program beneficiaries. Pursuant to the legislative requirements, 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 2015)

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

We will review CDC's award process for the cooperative agreements it has 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 foreign and domestic recipients. 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 2015)

➤ **NEW CDC—Award process for Ebola preparedness and response funding**

We will review CDC's process for awarding funding for Ebola preparedness and response activities to ensure compliance with applicable laws, regulations, and departmental guidance. The review will include awards made to foreign and domestic recipients. Previous OIG reviews have noted possible deficiencies in CDC's award process, 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. The Consolidated and Further Continuing Appropriations Act, 2015, enacted on December 9, 2014, provided \$2.7 billion in emergency funding to HHS for Ebola preparedness and response activities. Of this, \$1.771 billion was allocated to CDC to prevent, prepare for, and respond to Ebola domestically and internationally (OAS; W-00-15-58300; expected issue date: FY 2016)

➤ **CDC—Accountability for property**

We will determine whether CDC implemented recommendations that OIG previously made on the basis of an audit of CDC's property system. 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 2015)

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

We will review CDC's efforts to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss. We will use guidelines established in the Department of Homeland Security's (DHS) *Physical Security Manual* to assess security risks at selected stockpiles. 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 2015)

Food and Drug Administration

➤ **FDA—Oversight of postmarketing studies of approved drugs**

We will determine the extent to which FDA requires postmarketing studies and clinical trials (referred to as "postmarketing requirements," or PMRs) for new drug applications. We will also assess how FDA monitors PMRs and takes enforcement action against applicants that do not comply with them. Section 505(o)(3) of the Food and Drug Administration Amendments Act of 2007

(FDAAA) provides FDA new authority to require additional testing of an approved prescription drug or biological product to assess serious risk related to its use. Under this authority, FDA may require an applicant to conduct PMRs at the time of approval or after approval if FDA becomes aware of new safety information or an unexpected serious risk associated with the use of the drug. (OEI; 01-13-00390; expected issue date: FY 2016)

➤ **FDA—FDA inspections of high-risk food facilities**

We will assess FDA's designation and inspection of high-risk food facilities. FDA is responsible for safeguarding the Nation's food supply by ensuring that all food ingredients are safe and that food is free of disease-causing organisms, chemicals, or other harmful substances. To carry out this responsibility, FDA inspects food facilities to ensure food safety and compliance with regulations. The Food Safety Modernization Act (FSMA) mandated that FDA increase the frequency of its inspections of domestic food facilities and inspect facilities on the basis of risk; it also indicated the criteria for designating a facility as high risk. (OEI; 02-14-00420; expected issue date: FY 2016)

➤ **FDA—Review of information exchange in the drug supply chain**

We will review drug supply chain trading partners' (e.g., drug manufacturers, wholesale distributors, dispensers) early experiences in exchanging transaction information and transaction history as required by section 202 of the Drug Supply Chain Security Act. Transaction information includes basic information about the drug (e.g., the strength and dosage form of the product, the National Drug Code, etc.), and the transaction history includes transaction information for every prior transaction for that drug back to the manufacturer. Together, this information forms the foundation of drug traceability and the security of the drug supply chain. Except for dispensers, trading partners must comply with the new exchange requirements by January 1, 2015 (dispensers have until July 1, 2015, to comply). We will interview trading partners about how they have successfully exchanged this information and what, if any, obstacles they have faced. (OEI; 05-14-00640; expected issue date: FY 2016)

➤ **NEW FDA - FDA's monitoring of imported food recalls**

We will review FDA's monitoring of imported food recalls. The audit will determine the extent FDA has implemented FSMA regarding the recall of food products and whether it has an effective recall process in place to ensure the safety of the Nation's food supply. FSMA authorized the Secretary of HHS to conduct mandatory recalls and assess and collect fees related to food facility reinspections and food recall orders. The U.S. Department of Agriculture (USDA) estimates that imported food accounts for about 17 percent of total U.S. food consumption, highlighting the importance of ensuring the safety of this large component of the American diet. (OAS; W-00-15-50004; expected issue date: FY 2016).

Health Resources and Services Administration

➤ **HRSA – Community health centers’ compliance with grant requirements of the Affordable Care Act**

We will determine whether community health centers that received funds pursuant to the ACA, § 10503, are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems that assess and account for program income. The review is based in part on requirements of the Public Health Service Act, § 330, and Federal regulations. (OAS; W-00-14-5928; various reviews; expected issue dates: FY 2015; ACA)

➤ **HRSA—Duplicate discounts for 340B purchased drugs**

We will assess the risk of duplicate discounts for 340B-purchased drugs paid through Medicaid MCOs and describe States’ efforts to prevent them. The ACA, § 2501, required States to begin collecting rebates for drugs paid through Medicaid MCOs and prohibited duplicate discounts under the 340B Program for such drugs. However, existing tools and processes used to prevent duplicate discounts in fee-for-service Medicaid may not be sufficient for drugs paid through Medicaid MCOs. (OEI; 05-14-00430; expected issue date: FY 2016; ACA)

➤ **HRSA—Oversight of vulnerable health center grantees**

We will determine the extent to which HRSA awards grant money to Health Center Program (HCP) grantees that have documented compliance or performance issues. HRSA has a variety of processes in place to monitor HCP grantees on program compliance, clinical performance, and financial health. However, even with all of these data available, HRSA may still continue to fund grantees with serious, ongoing compliance or performance issues. (OEI; 05-14-00470; expected issue date: FY 2016)

➤ **NEW HRSA - State agency oversight of HRSA Maternal, Infant, and Early Childhood Home Visiting grants**

We will review selected States’ controls to monitor and report on Maternal, Infant, and Early Childhood Home Visiting program grant activities. The ACA, § 2951 (P.L. 111-148), provided \$1.5 billion over 5 years for States, territories, and nonprofits to provide evidence-based home visiting programs to promote: improvement in maternal and newborn health; prevention of child injuries, child abuse, neglect, or maltreatment; reduction of emergency department visits; improvement in school readiness and achievement; reduction in crime or domestic violence; improvements in family economic self-sufficiency; and improvement in coordination and referrals for other community resources and supports. (OAS; W-00-15-59000; various reviews; expected issue dates: FY 2016; ACA)

Indian Health Service

➤ IHS—Hospital oversight

We will assess IHS's efforts to monitor and ensure that IHS hospitals provide quality care and comply with Medicare standards. We will also describe the challenges affecting IHS hospitals and their ability to provide that care and will report observations from two site visits. IHS operates 28 acute care hospitals that provide inpatient care to eligible American Indians and Alaska Natives. IHS requires its hospitals to be Medicare certified or accredited by an approved organization. (OEI; 09-13-00280; 06-14-00010; expected issue dates: FY 2015 and FY 2016)

National Institutes of Health

➤ NIH—Superfund financial activities for fiscal year 2014

We will review payments, obligations, reimbursements, and other uses of Superfund money by NIH's National Institute of Environmental Health Sciences. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities. (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k).) (OAS; W-00-15-59050; expected issue date: FY 2015)

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

We will assess colleges' and universities' compliance with selected cost principles issued by OMB in Circular A-21, *Cost Principles for Educational Institutions*. We will conduct reviews at selected colleges and universities on the basis of the dollar value of Federal grants received and 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 2016)

➤ NIH—Oversight of grants management policy implementation

We will examine NIH's oversight of three basic requirements for postaward grants administration among the 24 institutes and centers (ICs) that award extramural grants. We will also examine NIH's oversight of each IC's compliance with regulations, HHS directives, and agency policies. NIH issues grants administration policy to the ICs and oversees ICs' compliance with Federal regulations and HHS 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; expected issue date: FY 2015)

➤ **NIH—Use of appropriated funds for contracting**

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 to quantify any errors. 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 2016)

➤ **NEW A Review of the National Institute of Environmental Health Sciences' Funding for Bisphenol A safety research**

We will determine the extent to which the National Institute of Environmental Health Sciences (NIEHS) has conducted and funded research on the safety of BPA since 2000, as well as the roles that other Department programs and agencies (the National Toxicology Program (NTP), FDA, and CDC) play in planning, funding, and conducting NIEHS's BPA research. We will also determine the extent to which NIEHS followed its grant application processes related to peer review when awarding funds for BPA research. BPA, a chemical used primarily in the production of polycarbonate plastics, which are used in food and drink packaging, may leach into food or drink and be consumed by humans. NTP, a Departmental body made up of staff from the NIEHS, FDA, and CDC, issued a report that raised "some concern for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to Bisphenol A." (OEI; 01-15-00150; expected issue date: FY 2016).

Substance Abuse and Mental Health Services Administration

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

We will assess the data collection methods used by States to report on national outcome measures (NOMs) for the Substance Abuse Prevention and Treatment Block Grant (SAPTBG) program. We will also determine the extent to which SAMHSA oversees States' reporting of NOMs. SAMHSA is required to collect performance data and analyze the effectiveness of its programs, including the SAPTBG program. To do so, SAMHSA developed NOMs that aim to measure performance and improve accountability. However, SAMHSA has acknowledged a lack of specificity, uniformity, and quality in its data collection and reporting procedures. (OEI; 04-12-00160; expected issue date: FY 2015)

Other Public-Health-Related Reviews

➤ Audits of Superstorm Sandy Disaster Relief Act

The Disaster Relief Appropriations Act, 2013, P.L. No. 113-2 (Disaster Relief Act), provided funding to HHS for use in aiding Hurricane Sandy disaster victims and their communities. After sequestration, HHS received \$759.5 million in Disaster Relief Act funding. Of this amount, \$733.6 million was allocated to three operating divisions: the Administration for Children and Families (ACF), NIH, and SAMHSA. We plan to perform audits of grantees that have received Disaster Relief Act grant funding through one of the above-mentioned HHS operating divisions. We will review grantees' internal controls related to the oversight of Disaster Relief Act funds. Additionally, we plan to review the allowability of costs claimed and the appropriateness of costs that were budgeted but not yet expended. (OAS; W-00-15-59052; various reviews; expected issue date: FY 2015)

➤ Superstorm Sandy—Social Services Block Grant guidance, disbursement, and reporting summary

We will examine the oversight of ACF's Social Services Block Grant (SSBG) funding for expenses resulting from Superstorm Sandy and identify any challenges States and their subgrantees experienced in using and accounting for the funding. The Disaster Relief Act 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, childcare facilities, and other social services facilities. (OEI; 09-15-00200; expected issue date: FY 2016)

➤ Hospitals' electronic health record system contingency plans

We will determine the extent to which hospitals comply with contingency planning requirements of the Health Insurance Portability and Accountability Act (HIPAA). We will also compare hospitals' contingency plans with government- and industry-recommended practices. The HIPAA Security Rule requires covered entities to have a contingency plan that establishes policies and procedures for responding to an emergency or other occurrence that damages systems that contain protected health information (45 CFR, Part 164 § 308(7)(i)). (OEI; 01-14-00570; expected issue date: FY 2016)

➤ Grantee's Use of Prevention and Public Health Funds

We will determine selected grantees' compliance with grant requirements. Section 4002 of the ACA established the Prevention and Public Health Fund (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 \$2.2 billion during FYs 2010–2013, representing 66 percent of total PPHF dollars. Recent legislation may change CDC's PPHF allotment. (OAS; W-00-14-59027; expected issue date: FY 2015; ACA)

➤ **NEW** Grantee's use of President's Emergency Plan for AIDS Relief funds

We will determine whether selected foreign grantees managed President's Emergency Plan for AIDS Relief (PEPFAR) funds in accordance with the award requirements. PEPFAR funds support international programs for acquired immunodeficiency syndrome (AIDS) prevention, treatment, and

care. In previous audits of foreign PEPFAR grantees, we identified unallowable expenditures and internal control weaknesses. (OAS; W-00-15-57300; various reviews; expected issue date: FY 2016)

Public Health Legal Activities

OIG assists 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

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

Human Services Reviews

The 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 the Temporary Assistance for Needy Families (TANF) program; the national child support enforcement system; the Head Start program for preschool children; and assistance for childcare, 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.

Effective management of these programs is essential to ensure that they achieve their goals and best serve the programs' intended beneficiaries. OIG's planning efforts for 2015 and beyond will focus on planning for emergencies, access to quality services, and compliance with safety requirements.

Acronyms and Abbreviations for Selected Terms:

ACF—Administration for Children and Families
ACL—Administration for Community Living
AoA—Administration on Aging
CCDF—Child Care and Development Fund

CSBG—Community Services Block Grant [program]
OCC—Office of Child Care
SMP—Senior Medicare Patrol

Descriptions of OIG's human services work in progress for FY 2015 follow.

Administration for Children and Families

➤ **NEW** Foster care – Monitoring the health and safety of children through the complaint resolution and licensing process

We will review whether the States' complaint procedures for handling allegations or referrals of abuse and noncompliance of health and safety requirements for Foster Care Children under Title IV-E of the Social Security Act, are reported, investigated and resolved in accordance with Federal and State requirements. We will also review State's oversight process to ensure licensing requirements are met for foster care family homes. Social Security Act Title IV-E Section 471(a)(9) and Title IV-E Section 472(c)(1). (OAS; W-00-15-25056; various reviews; expected issue date: FY 2015)

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

We will continue to encourage and coordinate enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases. Project Save Our Children seeks to identify, investigate, and prosecute individuals who fails to meet their court-ordered support obligations. The project brings together OIG, the U.S. Marshals Service, DOJ, the Department of State, local law enforcement agencies and prosecutors, State child support agencies, and others to enforce Federal and State criminal child support statutes.

➤ **Superstorm Sandy—Emergency preparedness and response plans for child care facilities**

We will determine the extent to which States develop and/or update emergency preparedness and response plans specific to childcare services and programs. We will also describe emergency responses and experiences of States and childcare providers during and after recent disasters. In February 2011, the Office of Child Care (OCC) in ACF recommended that States develop plans to address preparedness, response, and recovery efforts specific to childcare services and programs. OCC outlined a framework that States should consider when developing and updating these plans. (OEI; 04-14-00410; expected issue date: FY 2016)

➤ **Head Start—Implementation of Head Start grant competition**

We will determine the extent to which Head Start grant competition resulted in new entities' competing for and winning Head Start grants in 2013 and 2014. The Improving Head Start for School Readiness Act of 2007 required that grantees be awarded 5-year (rather than indefinite) grants. Grantees who provide high-quality services receive future 5-year grants on a noncompetitive basis. Regulations at 45 CFR § 1307.3 describe seven deficiency conditions under the Designation Renewal System; if a grantee meets any of the seven conditions, it is not deemed a high-quality grantee and must compete for renewal. We will also describe the characteristics of grantees that were not deemed "high quality" by the Head Start Designation Renewal System in 2013 and 2014. (OEI; 12-14-00650; expected issue date: FY 2016)

➤ **NEW States' CCDF payment rates and access to childcare services**

We will determine the extent to which States' payment rates under the Child Care and Development Fund (CCDF) are sufficient to ensure access to childcare for low-income families. We will also review States' processes for calculating CCDF payment rates, as well as ACF's methods for determining whether States' CCDF payment rates are sufficient to ensure access to childcare services. Reauthorized in the Child Care and Development Block Grant Act of 2014, CCDF is the primary Federal funding source devoted to subsidizing the childcare expenses of low-income families. Payment rates for childcare providers are set by each State and overseen by ACF. States must certify that payment rates "are sufficient to ensure equal access, for eligible families in the area served by the [State], to child care services comparable to those provided to families not eligible" for CCDF subsidies. (45 CFR § 98.43) (OEI; 03-15-00170; expected issue date: FY 2016).

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

We will summarize our work conducted in 10 different States that reviewed 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. Our previous reviews of CCDF child care providers found many instances of noncompliance with applicable health and safety requirements. We will also identify actions ACF has taken to implement and oversee the Child Care and Development Block Grant (CCDBG) Act's new requirements at the State level. On November 19, 2014, the Child Care and Development Block Grant Act of 2014, P.L. No. 113-186, reauthorized the CCDF program and enacted additional childcare health, safety, and quality requirements. Federal regulations for the CCDF require States to certify that they have licensing and health and safety requirements applicable to childcare services pursuant to 45 CFR §§ 98.15, 98.40 and 98.41. (OAS; W-00-15-25052; expected issue date: FY 2016)

Administration for Community Living

➤ **ACL—Senior Medicare Patrol projects' performance data**

We will review performance measures for Senior Medicare Patrol (SMP) projects, including documentation supporting expected recoveries for the Medicare and Medicaid programs. 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 these performance data annually. The information was requested by AoA, which is part of ACL, and will support ACL's efforts to evaluate and improve the performance of the projects. (OEI; 02-15-00100; expected issue date: FY 2015)

Other HHS-Related Reviews

Certain financial, performance, and investigative issues cut across HHS programs. The OIG's 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 CMS.

The American health care system is increasingly relying on health information technology (health IT) and the electronic exchange and use of health information. Health IT, including EHRs, offers opportunities for improved patient care, more efficient practice management, and improved overall public health. OIG's future planning efforts may consider the significant challenges that exist with respect to overseeing expenditures for health IT, the interoperability and effective sharing and use of health care data for medical care, and emergency preparedness and response. Future work may also examine practices intended to protect sensitive information and the broad use of data and technology to manage HHS programs.

Acronyms and Abbreviations for Selected Terms:

AFR—Agency Financial Report
CFO Act—Chief Financial Officers Act of 1990
CMS—Centers for Medicare & Medicaid Services
FISMA—Federal Information Security Management Act of 2002
GAO—Government Accountability Office
GMRA—Government Management Reform Act of 1994

health IT—health information technology
GPO—group purchasing organization
IPERA— Improper Payment Elimination and Recovery Act of 2010
OMB—Office of Management and Budget
SAM—System for Award Management

Financial Statement Audits and Related Reviews

➤ Audit of fiscal year 2015 consolidated HHS financial statements and financial-related reviews

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. 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. (CFO, as amended by GMRA; Government Auditing Standards; and OMB Bulletin 14-02, "Audit Requirements for Federal Financial Statements.") The audited consolidated FY 2015 financial statements for HHS are due to OMB by November 16, 2015. The audit reports on the HHS Special Purpose Financial Statements entered into the Governmentwide Financial Report System are 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 audits of the FY 2015 financial statements. The purpose of the financial-related reviews is to fulfill requirements in OMB Bulletin 14-02, §§ 6.1 through 13. (OAS; W-00-15-40009; A-17-15-00001; A-17-15-00006; expected issue date: FY 2016)

➤ Fiscal year 2015 Centers for Medicare & Medicaid Services' financial statements

We will review the independent auditor's workpapers to determine whether the financial statement audit of the Centers for Medicare & 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. (CFO Act, as amended by the GMRA; Government Auditing Standards; and OMB Bulletin 14-02, "Audit Requirements for Federal Financial Statements.") (OAS; W-00-15-40008; A-17-15-02015; expected issue date: FY 2016)

Financial Reviews

➤ Compliance with reporting requirements for improper payments

We will review certain aspects of HHS's compliance with the Improper Payments Information Act of 2002, as amended, regarding reporting improper payments. We will also assess HHS's compliance with the Improper Payment Elimination and Recovery Act of 2010 (IPERA) and the data presented in HHS's Agency Financial Report (AFR) and provide recommendations for modifying the reporting and addressing the goals of the reporting requirements, as needed. Pursuant to the OMB Circular A-123, Appendix C, Requirements for Effective Estimation and Remediation of Improper Payments 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 and 1.5 percent, or \$100 million regardless of the improper payment rate, the agency must report to Congress the actions that the agency is taking to reduce those payments. (OAS; W-00-16-40047; expected issue date: FY 2016)

➤ **Evaluation of predictive analytics for reducing improper payments**

We will evaluate HHS'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 we will follow up on corrective actions made in response to our prior year's recommendations. We will also assess HHS's use of the technologies and determine whether improvements could be made to increase Medicare savings. The Small Business Jobs Act of 2010 required HHS to implement predictive analytics technologies for reducing improper payments in Medicare fee for service. HHS must report annually on the progress of the programs and certify certain amounts it reports. (OAS; W-00-14-40060; W-00-15-40060; various reviews; expected issue date: FY 2015)

➤ **HHS contract management review**

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. 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 2015)

➤ **HHS agencies' annual accounting of drug-control funds**

We will review HHS agencies' compliance with the requirement that agencies expending funds on National Drug Control Program activities submit to the Office of National Drug Control Policy an annual accounting of the expenditure of 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 2014 annual accounting. (OAS; W-00-15-41020; various reviews; expected issue date: FY 2016)

➤ **OIG reviews of non-Federal audits**

We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*. State, local, and Indian tribal governments; colleges and universities; and nonprofit organizations receiving Federal awards are required to have annual organizationwide audits of all Federal funds that they receive. Our reviews ensure that the

audits and reports meet applicable standards, identify any followup work needed, and identify issues that may require management attention. 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 2015)

➤ **OIG reimbursable 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*. 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-00-15-50012; various reviews; expected issue date: FY 2015)

➤ **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-00-15-41021; various reviews; expected issue date: FY 2015)

➤ **NEW Review of financial interests reported under the Open Payments Program**

We will determine the number and nature of financial interests that were reported to CMS under the Open Payments Program. We will also determine the extent to which CMS oversees manufacturers' and group purchasing organizations' (GPOs') compliance with data reporting requirements and whether the required data for physician and teaching hospital payments is accurately and completely displayed in the publicly available database. The Affordable Care Act, § 6002, requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals. Manufacturers and GPOs must also report ownership and investment interests held by physicians. The Open Payments Program provides public transparency about provider-industry relationships; it is important that the information be complete and accurate to serve the needs of consumers making educated decisions about their health care choices. (OEI; 03-15-00220; expected issue date: FY 2016).

Automated Information Systems

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

We will review various HHS operating divisions' compliance with FISMA. 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-00-15-40016; W-00-14-42001; W-00-15-42001; various reviews; expected issue date: FY 2015)

➤ Penetration testing of HHS and operating division networks

We will conduct network and Web application penetration testing to determine HHS's and its operating divisions' network security posture and determine whether these networks and applications are susceptible to hackers. 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-00-14-42020; W-00-15-42020; various reviews; expected issue date: FY 2015)

Other HHS-Related Issues

➤ HHS efforts to address grantee risks

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. HHS is the largest grantmaking agency in the Federal Government. In FY 2013, HHS awarded nearly \$344 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 for implementing those regulatory requirements is contained in the HHS *Grants Policy Directives*, which apply across HHS. (OEI; 07-12-00110; expected issue date: FY 2015)

➤ Prevent grant awards to individuals and entities that were suspended and/or debarred

We will determine whether HHS operating divisions are taking adequate precautions to ensure that individuals and entities suspended or debarred are not awarded Federal grants or contracts. To protect the Government's interests, Federal agencies are required to make awards only to responsible sources—those that are determined to be reliable, dependable, and capable of performing required work. One way to protect the Government's interests is through suspensions

and debarments, which are actions taken to preclude firms or individuals from receiving contracts or assistance because of various types of misconduct. A suspension is a temporary exclusion typically pending the completion of an investigation or legal proceeding, while a debarment is for a fixed term that depends on the seriousness of the cause, but generally is for a period of 3 years. These exclusions are reported in the System for Award Management (SAM), maintained by the General Services Administration, along with violations of certain statutes and regulations. A previous report by GAO found that some agency programs need greater attention and that governmentwide oversight could be improved. (OAS; W-00-15-59024; expected issue date: FY 2016)

➤ **HHS's Government purchase, travel, and integrated charge card programs**

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. 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 card 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-00-15-00000; expected issue date: FY 2015)

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Appendix A

Affordable Care Act Reviews

OIG is focused on promoting the economy, efficiency, and effectiveness of ACA¹ programs across HHS. The ACA vested in the Department substantial responsibilities for increasing access to health insurance for those who are eligible for coverage, improving access to and the quality of health care, and lowering health care costs and increasing value for taxpayers and patients. OIG's ongoing and planned reviews for FY 2015 will assess the Department's implementation and operation of ACA programs and progress toward achieving program goals. To this end, we are prioritizing work in three main areas: the health insurance marketplaces, including financial assistance payments; Medicare and Medicaid reforms; and grant expenditures for public health programs.

OIG has initiated five additional reviews addressing ACA programs since October 2014 and continues to plan additional oversight work to initiate in FY 2015 focusing on key areas, such as emerging marketplace issues, Medicaid expansion and services, Medicare payment and delivery reform, program integrity, and public health program reform. OIG experts dedicated to ACA work planning employ a dynamic and flexible planning process that incorporates continuous risk assessment and stakeholder input, among other factors, to identify the most critical areas for additional reviews and the most appropriate methodologies to deliver timely and relevant results. As appropriate, we will work with other Federal and State oversight agencies to address emerging vulnerabilities. For example, we are working jointly with the Treasury Inspector General for Tax Administration (TIGTA) on work examining controls and processes for the Advance Premium Tax Credit (APTC) and Premium Tax Credit programs.

Acronyms and Abbreviations for Selected Terms:

APTC—Advance Premium Tax Credit
CMS—Centers for Medicare & Medicaid Services
CO-OP—Consumer Operated and Oriented Plan
CSR—Cost Sharing Reduction

FFM—Federally Facilitated Marketplace
HRSA—Health Services and Resources Administration
TIGTA—Treasury Inspector General for Tax Administration

Health Insurance Marketplaces, Financial Assistance Payments, and Market Stabilization Payments

OIG's FY 2015 oversight strategy for the marketplaces and related programs continues our focus on proper expenditure of taxpayer funds and the efficient and effective operation of the marketplaces. To this end, in FY 2015 we will continue to address key risks in the areas of payments, eligibility and enrollment, management and administration of marketplace programs, and security of information technology and consumer information. Many reviews will address questions in multiple areas.

¹ ACA, as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-148).

Payments—Are taxpayer funds being expended correctly for their intended purposes?

Ongoing and planned FY 2015 work looking at expenditures of taxpayer funds includes:

➤ **Accuracy of aggregate payments to qualified health plan issuers for advance premium tax credits and cost sharing reductions and effectiveness of related internal controls**

ACA, §§ 1401, 1402, 1411, and 1412. We will determine the accuracy of aggregate financial assistance payments – Advance Premium Tax Credit (APTC) and Cost Sharing Reduction (CSR) – made to qualified health plan issuers, and assess the related internal controls governing how those financial assistance amounts are calculated 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 systems managed by HHS to make these payments. Under the system, CMS makes financial assistance payments to issuers on the basis of aggregate enrollee information for each qualified health plan. (OAS; W-00-14-59018; various reviews; expected issue date: FY 2015)

➤ **Accuracy of financial assistance payments for individual enrollees**

ACA, §§ 1401, 1402, 1411, and 1412. We will determine whether CMS's internal controls were effective in ensuring the accuracy of financial assistance payments—APTC and Cost Sharing Reductions—for individual enrollees. Payment amounts vary according to income and family size. For enrollees who receive APTC but do not pay their portion of the premium for 3 consecutive months, qualified health plan (QHP) issuers are responsible for terminating coverage, returning APTC payments, and reporting this information to CMS. As part of our audit, we will verify that any overpayments made for individual enrollees have been returned in accordance with regulations. (OAS; W-00-15-59048; various reviews; expected issue date: FY 2015)

➤ **CMS's internal controls over Advance Premium Tax Credit obligations and payments Under the Affordable Care Act**

ACA, §§ 1401, 1402, 1411, and 1412. We will determine whether CMS has established adequate accountability and internal controls for generating, reviewing, and approving advance premium tax credit payments. We will assess CMS's process for obtaining premium tax credit information from issuers and subsequent processes for providing payment data to the Department of the Treasury. We will also assess the coordination processes between CMS and the Internal Revenue Service (IRS) to ensure that Advance Premium Tax Credits are accurate and are made to eligible policyholders. This review is part of a joint project with TIGTA. (OAS; W-00-15-59045; various reviews; expected issue date: FY 2015)

➤ **Review of Affordable Care Act establishment grants for State marketplaces**

ACA, § 1311. We will determine whether seven States complied with Federal requirements related to the development and implementation of a State marketplace in accordance with the terms and conditions of Federal cooperative agreements. The ACA authorized funding to States that elected to establish their own marketplaces. Several of these States encountered significant problems in the

launching of their marketplaces. As part of the review, we will assess whether Federal funds were used as intended and whether the State agencies' procurement process and internal controls for monitoring and oversight were effective. We will also review policies and procedures issued by CMS to State agencies relating to establishment grants for marketplaces. (OAS; W-00-14-59034; various reviews; expected issue date: FY 2015)

➤ **Payments to Federally Facilitated Marketplace contractors**

This review will examine HHS payments to contractors for work on the Federally Facilitated Marketplace (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-03-14-03002; expected issue date: FY 2015).

➤ **Consumer Operated and Oriented Plan Loan Program—Enrollment and profitability projections**

ACA, § 1322. In FY 2014, OIG issued one report 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. Our new work will determine whether CO-OP enrollment and profitability met initial program projections as of December 31, 2014. (OAS; W-00-14-59019; various reviews, expected issue date: FY 2015)

➤ **Review of grant awards to navigators in federally facilitated or State partnership marketplaces**

ACA, § 1311. We will determine whether navigators in the FFM or State partnership marketplaces met the required qualifications and costs allowable under the terms of the grants and applicable Federal regulations. Under the ACA, marketplaces are to establish a program under which they award grants to entities that facilitate education about and enrollment in qualified health plans. These organizations are known as navigators. As part of our review, we will determine whether navigators completed the required training, criminal background checks, and State training and registration before assisting consumers. We will also review costs claimed to determine whether they were allowable and were claimed in accordance with the terms of the grant awards and Federal regulations. (OAS; W-00-15-59047; various reviews; expected issue date: FY 2015)

➤ **NEW Review of funding to establish the Federally Facilitated Marketplace**

We will identify the source and amount of funding used to establish the FFM. We will determine whether the Department had overall visibility and accountability for funds used by CMS for the FFM; whether there were appropriate budgeting and management of these funds; how funds were tracked by the Department and CMS; and whether the funds were used in accordance with appropriation law in regard to purpose, time, and amount (31 U.S.C. § 1502 and 31 U.S.C § 1341(a)(1)). In addition, we will determine whether amount that the Department and CMS identified as FFM funding -was accurate and complete. (OAS; W-00-15-55000; expected issue date: FY 2016)

Eligibility—Are the right people getting the right benefits?

OIG's FY 2015 work reviewing the effectiveness and efficiency of marketplace eligibility and enrollment systems includes:

➤ Review of Affordable Care Act enrollment safeguards at additional State marketplaces

ACA, § 1411. In FY 2014, OIG issued two reports that identified vulnerabilities in eligibility and enrollment systems at the FFM and State-based marketplaces. Our new work will assess the effectiveness of internal controls in place at seven State-based marketplaces to ensure that accurate information is used to determine consumer eligibility for enrollment and financial assistance payments. We will determine whether internal controls implemented by the selected marketplaces were effective in ensuring that individuals were enrolled in a QHP in accordance with Federal requirements. Using a statistically valid sample of applicants, we will review whether each marketplace has performed the required verifications to determine eligibility for enrollment in a QHP and has appropriately resolved inconsistencies between applicant information and data sources used for verification. (OAS; W-00-14-42024; various reviews; expected issue date: FY 2015)

➤ Review of the Federally Facilitated Marketplace's eligibility verifications for Premium Tax Credits

ACA, §§ 1411 and 1412. We will assess whether the FFM's internal controls were effective in ensuring that individuals were eligible for the Premium Tax Credit in accordance with Federal regulations. The FFM is required to verify an applicant's information, including household income, to determine his or her eligibility for Premium Tax Credit. Using a statistically valid sample of applicants, we will review whether the FFM performed the required verifications when determining applicants' eligibility for Premium Tax Credits and resolved inconsistencies between applicant information and data sources used for verification. We will examine the FFM's procedures for verifying an applicant's information, which includes household income, using data provided to the FFM by the IRS and other sources. This work is planned to supplement a prior OIG review related to enrollment safeguards mandated by the Continuing Appropriations Act (CAA), 2014, § 1001(c). We are working, in consultation with IRS, to develop similar reviews at State marketplaces. (OAS; W-00-15-59046; various reviews; expected issue date: FY 2015)

➤ Inconsistencies in the Federally Facilitated Marketplace applicant data

We will determine the extent to which CMS was able to resolve inconsistencies between applicant self-attested information and data received through Federal and other data sources that occurred in the 2013-2014 open enrollment period of the FFM. We will also assess the extent to which CMS's new processes are resolving inconsistencies between applicant information and data sources used for verification. We will update this analysis of the FFM for the 2014-2015 open enrollment period. Previous OIG work found that the FFM was unable to resolve 2.6 million out of 2.9 million inconsistencies because CMS's eligibility system was not fully operational. (OEI; 01-14-00620, expected issue date: FY 2016)

Additional work examining Medicaid eligibility systems is described in the "Medicaid Reviews" section below.

Management and Administration—Is the Department managing and administering marketplace programs effectively and efficiently?

OIG's work in this area includes:

➤ Implementation of the Federally Facilitated Marketplace

We will review HHS's overall efforts in implementing the FFM. We will conduct document reviews and interviews to assess strengths and weaknesses found with CMS management and its use of contractors. 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. Our review will include an assessment of management and operational changes made after the launch and CMS implementation of the second open enrollment period, which began November 15, 2014. (OEI; 06-14-00350; expected issue date: FY 2015)

➤ Oversight of Federally Facilitated Marketplace contractors

This review will examine whether HHS exercised appropriate and adequate oversight and direction over contracts related to the FFM (including mechanisms that HHS and its contractors used to communicate problems or concerns about 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 ACA. (OAS; W-00-14-59032; A-03-14-03001; expected issue date: FY 2015)

Security—Is consumers' personal information safe?

Reviews underway to address security in the Marketplaces include:

➤ CMS's implementation of security controls over consumer information obtained in the Federally Facilitated Marketplace

We previously conducted a review of information system security of HealthCare.gov. In this review, we will determine whether information security controls for the systems outside the FFM containing and storing consumer information have been implemented in accordance with Federal requirements and recognized industry best practices. We may conduct vulnerability scans, when feasible, 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 and determine whether the vulnerabilities identified were remediated in a timely manner. (OAS; W-00-14-42023; expected issue date: FY 2015)

➤ State-based marketplaces information system security controls

We previously conducted reviews of information system security at two State-based marketplaces. We will determine whether information security controls for additional State-based marketplaces have been implemented in accordance with Federal requirements and recognized industry best practices. 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 State-based marketplace systems and determine whether the vulnerabilities identified were remediated in a timely manner. (OAS; W-00-15-42025; various reviews; expected issue date: FY 2015)

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 Web sites. Additional information about consumer protection can be found at: <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Medicaid and Medicare Reforms

Medicaid Reviews

The Medicaid section of the *Work Plan* describes the range of FY 2015 reviews planned and those 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.

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

- **Enhanced Federal Medical Assistance Percentage**
ACA, § 2001. (OAS; W-00-14-31480; various reviews; expected issue date: FY 2015) *Work Plan* page 32.
- **Medicaid eligibility determinations in selected States**
ACA, § 2001. (OAS; W-00-14-31140; W-00-15-31140; OEI; 06-14-00330; various reviews; expected issue date: FY 2016) *Work Plan* page 32.
- **Community First Choice State plan option under the Affordable Care Act**
ACA, § 2401. (OAS; W-00-15-00000; A-02-15-00000; expected issue date: FY 2016) *Work Plan* page 30.
- **States’ experiences with enhanced provider screening**
ACA § 6402. (OEI; 05-13-00520; expected issue date: FY 2015) *Work Plan* page 34.
- **Provider payment suspensions during pending investigations of credible fraud allegations**
ACA, § 6402(h)(2). (OAS; W-00-14-31473; various reviews; expected issue date: FY 2015; OEI; 09-14-00020; expected issue date: FY 2015) *Work Plan* page 35.

- **State terminations of providers terminated by Medicare or by other States**
ACA, § 6501. (OEI; 06-12-00030; expected issue date: FY 2015) *Work Plan* page 34.
- **State reporting of managed care encounter data**
ACA, § 6504. (OEI; 07-13-00120; expected issue date: FY 2015) *Work Plan* page 38.
- **National Correct Coding Initiative edits and CMS oversight**
ACA, § 6507. (OAS; W-00-15-31459; various reviews; expected issue date: FY 2015; OEI; 00-00-0000; expected issue date: FY 2015) *Work Plan* page 36.
- **Payments to States under the Balancing Incentive Program**
ACA, § 10202. (OAS; W-00-15-31482; various reviews; expected issue date: FY 2016) *Work Plan* page 30.
- **States' collection of rebates for drugs dispensed to Medicaid managed care organization enrollees**
ACA, § 2501(c). (OAS; W-00-14-31483; W-00-15-31483; various reviews; expected issue date: FY 2015) *Work Plan* page 26.
- **Health-care-acquired conditions—Prohibition on Federal reimbursements**
ACA, § 2702. (OAS; W-00-14-31452; various reviews; expected issue date: FY 2015) *Work Plan* page 29.
- **NEW Manufacturer rebates – Federal share of rebates Affordable Care Act**
ACA § 2501 (OAS; W-00-15-31450; various reviews; expected issue dates: FY 2016) *Work Plan* page 26.

Medicare Reviews

The ACA 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 2015 *Work Plan* describe OIG's ongoing 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 ACA.

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

- **Quality of sponsor data used in calculating coverage-gap discounts**
ACA, § 3301. (OAS; W-00-14-35611; various reviews; expected issue date: FY 2015) *Work Plan* page 24.

- **Ensuring dual eligibles' access to drugs under Part D**
ACA, § 3313. (OEI; 00-00-00000; expected issue date: FY 2015) *Work Plan* page 23.
- **Program for national background checks for long-term-care employees**
ACA, § 6201. (OEI; 07-10-00420; expected issue date: FY 2017) *Work Plan* page 7.
- **Enhanced enrollment screening process for Medicare providers**
ACA, § 6401. (OEI; 03-13-00050; expected issue date: FY 2015) *Work Plan* page 20.
- **Risk Assessment of CMS's administration of the Pioneer Accountable Care Organization Model**
ACA, § 3021. (OAS; W-00-00-00000; expected issue date: FY 2015) *Work Plan* page 20.
- **NEW Use of electronic health records to support care coordination through ACOs**
ACA, § 3022. (OEI; 00-00-00000; expected issue date: FY 2016) *Work Plan* page 20.
- **NEW Review of financial interests reported under the Open Payments Program**
ACA, § 6002. (OEI; 03-15-00220; expected issue date: FY 2016) *Work Plan* page 59.

Other Programs

OIG work in this area includes:

- **Grantees' Use of Prevention and Public Health Funds**
ACA, § 4002. (OAS; W-00-14-59027; expected issue date: FY 2015) *Work Plan* page 51.
- **HRSA—Community health centers' compliance with grant requirements of the Affordable Care Act**
ACA, § 10503. (OAS; W-00-14-59028; W-00-15-59028; various reviews, expected issue dates: FY 2015) *Work Plan* page 48.
- **HRSA—Duplicate discounts for 340B-purchased drugs**
ACA, § 2501. (OEI; 05-14-00430; expected issue date: FY 2015) *Work Plan* page 48.
- **NEW HRSA – State agency oversight of HRSA Maternal, Infant, and Early Childhood Home Visiting grants**
ACA § 2951 (OAS; W-00-xx-xxxxx; various reviews; expected issue dates: FY 2016) *Work Plan* page 48.

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 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:

CMS—Centers for Medicare & Medicaid Services

EHR—electronic health record

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

We will review Medicare incentive payments to eligible health care professionals and hospitals for adopting EHRs and 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 corrective actions taken regarding erroneous incentive payments. 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).) As of August 2014, Medicare EHR incentive payments totaled more than \$16 billion. (OAS; W-00-14-31352; expected issue date: FY 2015; Recovery Act)

➤ Medicaid incentive payments for adopting electronic health records

We will review Medicaid incentive payments to Medicaid providers and hospitals for adopting EHRs and CMS 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. 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. As of August 2014, Medicaid EHR incentive payments totaled more than \$8 billion. Incentive payments will continue through 2021. (OAS; W-00-13-31351; W-00-14-31351; various reviews; expected issue date: FY 2015; Recovery Act)

Systems and Information Security

➤ Security of certified electronic health record technology under meaningful use

We will perform audits of various covered entities receiving EHR incentive payments from CMS to determine whether they adequately protect electronic health information created or maintained by certified EHR technology. A core meaningful-use objective for eligible providers and hospitals is to protect electronic health information created or maintained by certified EHR technology by implementing 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. (45 CFR § 164.308(a)(1) and 45 CFR §§ 170.314(d)(1) – (d)(9).) (OAS; W-00-14-42020; W-00-15-42020; various reviews; expected issue date: FY 2015; 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

We will continue to evaluate credible allegations of improper expenditures of Recovery Act funds to identify cases in which criminal investigations should be opened and enforcement actions pursued. Recovery Act funding resulted in a significant increase in the number of grants and contracts awarded by HHS. The Recovery Act requires transparency and accountability in the awarding and spending of funds. (OI; various investigations; Recovery Act)

➤ Enforcement of whistleblower protections

We will continue to evaluate credible allegations of reprisals against whistleblowers by entities or individuals receiving Recovery Act funds to identify cases in which criminal investigations should be opened and antireprisal enforcement actions pursued. The Recovery Act extends whistleblower protection to employees who reasonably believe they are being retaliated against for reporting

misuse of Recovery Act funds received by their non-Federal employers. (Recovery Act, § 1553.) (OI; various investigations; Recovery Act)