

**OFFICE OF  
INSPECTOR GENERAL**

U.S. Department of Health and Human Services

# **WORK PLAN**

Fiscal Year 2016

# 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 (*Work Plan*) for fiscal year (FY) 2016 summarizes new and ongoing OIG reviews and with respect to HHS programs and operations.

## 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 are focused on other HHS 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?

**Who we are.** OIG provides independent and objective oversight that promotes economy, efficiency, and effectiveness in the programs and operations of HHS. OIG's program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), Department of Justice (DOJ), and the Inspector General community. OIG carries out its mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs through a nationwide network of audits, investigations, and evaluations conducted by the following operating components with assistance from OIG counsel and management.

- **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.

- **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 civil monetary penalties (CMP).
- **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 about the anti-kickback statute and other OIG enforcement authorities.
- **Executive Management (EM).** EM is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. EM is responsible for overseeing the activities of OIG's components; setting vision and direction, in collaboration with the components, for OIG's priorities and strategic planning; ensuring effective management of budget, finance, information technology (IT), human resources, and other operations; and serving as a liaison with HHS, Congress, and other stakeholders. EM plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies.

## What do we accomplish?

For FY 2015, we reported expected recoveries of more than \$3 billion, consisting of nearly \$1.13 billion in audit receivables and about \$2.22 billion in investigative receivables, which include about \$286.6 million in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution. We also identified about \$20.6 billion in savings estimated for FY 2015 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 2015 exclusions of 4,112 individuals and entities from participation in Federal health care programs; 925 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 682 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 OIG recommendations from previous reviews; and
- timeliness.

## A Note About This Edition:

This edition of the *Work Plan*, effective October 2015, describes OIG audits, evaluations, and certain legal and investigative initiatives that are continuing. 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 fiscal year (FY) 2016 and beyond, OIG will expand its focus on delivery system reform and the effectiveness of alternate payment models, coordinated care programs, and value-based purchasing. Areas under consideration for new work include, for example, a holistic examination of HHS' efforts to reduce opioid abuse, adherence to safety standards in Administration for Children and Families' Unaccompanied Children Program, and evaluation of CMS's Fraud Prevention System.

OIG will periodically update its online *Work Plan*, available at <http://www.oig.hhs.gov>.

The body of the *Work Plan* is followed by Appendix A, which describes OIG 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](mailto: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 (MAC) to administer Medicare Part A and Medicare Part B and to process claims for both parts.

OIG has focused its efforts on identifying and offering recommendations to reduce improper payments, prevent and deter fraud, and foster economical payment policies. Future planning efforts for FY 2016 and beyond will include: additional oversight of hospice care, including oversight of certification surveys and hospice-worker licensure requirements; oversight of Skilled Nursing Facilities' (SNF) compliance with patient admission requirements; and evaluation of CMS's Fraud Prevention System.

## Hospitals

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Acronyms and Abbreviations for Selected Terms:

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-00-14-35451; W-00-15-35451; various reviews; expected issue date: FY 2016)

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

We will determine how hospitals' use of outpatient and inpatient stays changed under Medicare's two-midnight rule, as well as how Medicare and beneficiary payments for these stays changed, by comparing claims for hospital stays in the year prior to the effective date of the two-midnight rule to stays in the year following the effective date of that rule. We will also determine the extent to which the use of outpatient and inpatient stays varied among hospitals. CMS implemented the two-midnight rule on October 1, 2013. This rule represents a substantial change to the criteria that 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 impact on beneficiary safety and quality of care, as well as the costs to Medicare, resulting from additional use of medical services associated with defective medical devices. Any determination of the impact on beneficiaries from a quality and safety perspective, and program costs, will require a determination of a reasonable means of tracking services from the recall of the medical devices in question. CMS has expressed concerns about the impact of the cost of replacement devices, including ancillary cost, on Medicare payments for inpatient and outpatient services. (OAS; W-00-15-35516; various reviews; expected issue date: FY 2016)

➤ 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. Employee compensation may be included in allowable provider costs only to the extent that it represents reasonable remuneration for managerial, administrative, professional, and other services related to the operation of the facility and furnished in connection with patient care. (CMS's *Provider Reimbursement Manual*, Part 1, Pub. No. 15-1, Ch. 9 § 902.2.) Medicare does not provide any specific limits on the salary amounts that can be reported on the hospital cost report. (OAS; W-00-13-35713; expected issue date: FY 2016)

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

We will determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing. We will also determine the extent to which provider-based facilities meet requirements described in 42 CFR Sec. 413.65 and CMS Transmittal A-03-030, and whether there were any challenges associated with the provider-based attestation review process. 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. The Medicare Payment Advisory Commission (MedPAC) has 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 2016)

### ➤ Comparison of provider-based and freestanding clinics

We will review and compare Medicare payments for physician office visits in provider-based clinics and freestanding clinics to determine the difference in payments made to the clinics for similar procedures and assess the potential impact on Medicare 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 2016)

## 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; W-00-15-35575; various reviews; expected issue date: FY 2016)

### ➤ 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 2016)

### ➤ 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 2016)

## ➤ 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 2016)

## ➤ 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. 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; W-00-15-35603; various reviews; expected issue date: FY 2016)

## ➤ 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; W-00-15-35721; various reviews; expected issue date: FY 2016)

## ➤ 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-00-14-35715; W-00-15-35715; various reviews; expected issue date: FY 2016)

## ➤ 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 2016)

#### ➤ **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 2016)

#### ➤ **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)

#### ➤ **NEW Medical device credits for replaced medical devices**

We will determine whether Medicare payments for replaced medical devices were made in accordance with Medicare requirements. Medical devices are implanted during an inpatient or an outpatient procedure. Such devices may require replacement because of defects, recalls, mechanical complication, etc. Federal regulations require reductions in Medicare payments for the replacement of implanted devices. (42 CFR §§ 412.89 and 419.45). Prior OIG reviews have determined that MACs have made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices. (OAS; W-00-15-35745; various reviews; expected issue date: FY 2016; work in progress)

#### ➤ **NEW Medicare payments during MS-DRG payment window**

We will review Medicare payments to acute care hospitals to determine whether certain outpatient claims billed to Medicare Part B for services provided during inpatient stays were allowable and in accordance with the inpatient prospective payment system. Certain items, supplies, and services furnished to inpatients are covered under Part A and should not be billed separately to Part B. (42 CFR §§ 409.10 and 410.3). Prior OIG audits, investigations, and inspections have identified this area

as at risk for noncompliance with Medicare billing requirements. (OAS; W-00-15-35752; 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 2016)

### ➤ 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)

### ➤ 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)

### ➤ 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)

### ➤ **NEW CMS validation of hospital-submitted quality reporting data**

We will determine the extent to which CMS validated hospital inpatient quality reporting data. Section 1886(b)(3)(B)(viii)(XI) of the Social Security Act gives CMS the authority to conduct validation of its quality reporting program. CMS uses these quality data for the hospital value-based purchasing program and the hospital acquired condition reduction program. Therefore their accuracy and completeness are important. This study will also describe the actions that CMS has taken as a result of its validation. (OEI-01-15-00320; expected issue date: FY 2016, ACA)

## Nursing Homes

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Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act

SNF—skilled nursing facility

CMS—Centers for Medicare & Medicaid Services

### ➤ **National Background Check Program for long-term-care employees**

We will report on the implementation status and early results for the National Background Check Program for long-term-care employees from the first 4 years of the program. 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 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. (OEI; 07-10-00420; expected issue date: FY 2016; ACA)

### ➤ **NEW Skilled nursing facility prospective payment system requirements**

We will review compliance with various aspects of the skilled nursing facility (SNF) prospective payment system, including the documentation requirement in support of the claims paid by Medicare. Prior OIG reviews have found that Medicare payments for therapy greatly exceeded SNF's cost for therapy. In addition, we have found that SNFs have increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. We will determine whether SNF claims were paid in accordance with Federal laws and regulations. All documentation requirements specified in 42 CFR § 483.20 must be met to ensure that SNF care is reasonable and necessary. (77 Fed. Reg. 46214, 78 Fed. Reg. 47936). Such SNF documentation includes (1) a physician order at the time of admission for the resident's immediate care (2) a comprehensive assessment, and (3) a comprehensive plan of care prepared by an interdisciplinary team that includes the attending physician, a registered nurse, and other appropriate staff. Prior OIG audits, investigations, and inspections have identified areas at risk for noncompliance with SNF Medicare billing requirements. (OAS; W-00-15-35744; various reviews; expected issue date: FY 2016; work in progress)

## Hospices

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Acronyms and Abbreviations for Selected Terms:

CoP—conditions of participation

### ➤ REVISED Hospice general inpatient care

We will review the use of the general inpatient care level of the Medicare hospice benefit. 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 billed when that level of service is not medically necessary. We will review beneficiaries' plans of care and determine whether they meet key requirements. 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.) In addition, we will also determine whether Medicare payments for hospice services were made in accordance with Medicare requirements. (OEI; 02-10-00491; 02-10-00492; expected issue date: FY 2016; and OAS; W-00-15-35744; various reviews; expected issue date: FY 2016)

## Home Health Services

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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-00-13-35712; W-00-14-35712; W-00-15-35712; various reviews; expected issue date: FY 2016)

# Medical Equipment and Supplies

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## 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-00-15-35461; expected issue date: FY 2016)

### ➤ 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 2016)

### ➤ NEW Orthotic braces—reasonableness of Medicare payments compared to amounts paid by other payers

We will determine the reasonableness of Medicare fee schedule amounts for orthotic braces. We will compare Medicare payments made for orthotic braces to amounts paid by non-Medicare payers, such as private insurance companies, to identify potentially wasteful spending. We will estimate the financial impact on Medicare and on beneficiaries of aligning the fee schedule for orthotic braces with those of non-Medicare payers. (OAS; W-00-15-35756; expected issue date: FY 2016).

### ➤ NEW Osteogenesis stimulators—lump-sum purchase versus rental

We will determine whether potential savings can be achieved by Medicare and its beneficiaries if osteogenesis stimulators are rented over a 13-month period rather than acquired through a lump-sum purchase. These devices, also known as bone-growth stimulators, apply an electric current or ultrasound to the spine or a long bone (e.g., the femur) and are used when a fusion or fracture failed to heal or after a multilevel spinal fusion. Medicare payments from 2012 – 2014 were approximately \$286 million. Because osteogenesis stimulators are categorized as “inexpensive and other routinely purchased items,” the beneficiary has the option of either purchasing or renting the stimulators. (OAS; W-00-15-35747; expected issue date: FY 2016).

## Equipment and Supplies—Billing and Payments

### ➤ Power mobility devices—supplier compliance with payment requirements

We will review Medicare Part B payments for suppliers of power mobility devices (PMD) to determine whether such payments were in accordance with Medicare requirements. We will focus particularly on whether 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-00-15-35703; various reviews; expected issue date: FY 2016)

### ➤ 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. For calendar year (CY) 2014, Medicare paid approximately \$632.8 million for inhalation drugs. With an improper payment rate of 42 percent, inhalation drugs were sixth on a list of the top 20 DMEPOS services with the highest improper payments in the 2014 Comprehensive Error Rate Testing report. 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 include utilization guidelines and documentation requirements. (OAS; W-00-14-35465; W-00-15-35465; expected issue date: FY 2016)

### ➤ 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 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-00-14-35604; W-00-15-35604; various reviews; expected issue date: FY 2016)

### ➤ NEW Orthotic braces—supplier compliance with payment requirements

We will review Medicare Part B payments for orthotic braces to determine whether durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers' claims were medically necessary and were supported in accordance with Medicare requirements. Prior OIG work indicated that some DMEPOS suppliers were billing for services that were medically unnecessary (e.g. beneficiaries receiving multiple braces and referring physician did not see the beneficiary) or were not documented in accordance with Medicare requirements. Medicare requires that such items be "reasonable and necessary." (Social Security Act § 1862(a)(1)(A).) Further, LCDs issued by the four

Medicare contractors that process DMEPOS claims include utilization guidelines and documentation requirements for orthotic braces. (OAS; W-00-15-35749; expected issue date: FY 2016).

#### ➤ **NEW Increased billing for ventilators**

We will describe billing trends for ventilators, Respiratory Assist Devices (RAD), and Continuous Positive Airway Pressure (CPAP) devices from 2011-2014 as well as examine factors associated with the increase in ventilator claims. CMS and its contractors have expressed concerns about the increase in billing for ventilators, specifically HCPCS code E0464 [a pressure support ventilator with volume control mode and a noninvasive interface (e.g., mask)]. From 2013 to 2014, there has been a 127 percent increase in allowed amounts for E0464. The number of beneficiaries receiving a pressure support ventilator increased from 8,633 in 2013 to 19,085 in 2014. Suppliers may be inappropriately billing for ventilators for beneficiaries with non-life-threatening conditions, which would not meet the medical necessity criteria for ventilators and might instead be more appropriately billed to codes for RADs or CPAPs. The CMS National Coverage Determination Manual §280.1 stipulates that ventilators are covered for the treatment of severe conditions associated with “Neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.” Ventilators would not be considered reasonable and necessary to treat any of the conditions described in the LCDs for either CPAPs or RADs. We will also examine the impact of the Competitive Bidding Program on ventilator billing trends. (OEI; 12-15-00370; expected issue date: FY 2016)

## Equipment and Supplies—Quality of Care and Safety

#### ➤ **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 show 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

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### 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 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; W-00-15-35423; various reviews; expected issue date: FY 2016)

### ➤ 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 implementing 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; W-00-15-35608; various reviews; expected issue date: FY 2016)

### ➤ NEW Ambulatory surgical centers—quality oversight

We will review Medicare's quality oversight of ASCs. Previous OIG work found problems with Medicare's oversight system, including finding spans of five or more years between certification surveys for some ASCs, poor CMS oversight of State survey agencies and ASC accreditors, and little public information on the quality of ASCs. Medicare sets minimum health and safety requirements for ASCs through the conditions of coverage. (Social Security Act, § 1832 (a) (2) (F) (i).) CMS requires that ASCs become Medicare-certified by a State survey and certification agency or privately accredited to show that they meet the conditions. (Social Security Act, § 1865 and 42 CFR Part 416) (OEI; 01-15-00400; expected issue date: FY 2017)

## 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 would endanger the beneficiary. (Social Security Act, § 1861(s)(7).) Medicare pays for different levels of ambulance service, including basic life support, advanced life support and specialty care transport. (42 CFR § 410.40(b).) (OAS; W-00-11-35574; W-00-12-35574; W-00-13-35574; W-00-14-35574; various reviews; expected issue date: FY 2016)

#### ➤ **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 2016)

#### ➤ **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 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-00-13-35606; W-00-14-35606; W-00-15-35606; various reviews; expected issue date: FY 2016)

#### ➤ **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; W-00-16-35770; OIG-12-14-03; expected issue date: FY 2016)

#### ➤ **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; W-00-15-35219; various reviews; expected issue date: FY 2016)

#### ➤ **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 we will 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 2016)

#### ➤ **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 that are 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; 00-00-00000; expected issue date: FY 2016)

#### ➤ **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 2016)

➤ **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-00-15-35464; various reviews; expected issue date: FY 2016)

➤ **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 Terminology<sup>1</sup> 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; W-00-15-35521; various reviews; expected issue date: FY 2016)

➤ **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

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<sup>1</sup> 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)

#### ➤ **NEW Physicians–referring/ordering Medicare services and supplies**

We will review select Medicare services, supplies and durable medical equipment (DME) referred/ordered by physicians and non-physician practitioners to determine whether the payments were made in accordance with Medicare requirements. Pursuant to ACA Sec. 6405, CMS requires that physicians and non-physician practitioners who order certain services, supplies and/or DME are required to be Medicare-enrolled physicians or nonphysician practitioners and legally eligible to refer/order services, supplies and DME. If the referring/ordering physician or non-physician practitioner is not eligible to order or refer, then Medicare claims should not be paid. (OAS; W-00-15-35748; expected issue date: FY 2016, ACA)

#### ➤ **NEW Anesthesia services–non-covered Services**

We will review Medicare Part B claims for anesthesia services to determine whether they were supported in accordance with Medicare requirements. Specifically, we will review anesthesia services to determine whether the beneficiary had a related Medicare service. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, §1862(a)(1)(A)) (OAS; W-00-15-35749; expected issue date: FY 2016)

#### ➤ **NEW Physician home visits–reasonableness of services**

We will determine whether Medicare payments to physicians for evaluation and management home visits were reasonable and made in accordance with Medicare requirements. Since January 2013, Medicare made \$559 million in payments for physician home visits. Physicians are required to document the medical necessity of a home visit in lieu of an office or outpatient visit. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, §1862(a)(1)(A)) (OAS; W-00-15-35754; expected issue date: FY 2016)

#### ➤ **NEW Prolonged services–reasonableness of services**

We will determine whether Medicare payments to physicians for prolonged evaluation and management (E/M) services were reasonable and made in accordance with Medicare requirements. Prolonged services are for additional care provided to a beneficiary after an evaluation and management service has been performed. Physicians submit claims for prolonged services when they spend additional time beyond the time spent with a beneficiary for a usual companion evaluation and management service. The necessity of prolonged services are considered to be rare and unusual. The Medicare Claims Process (MCP) manual includes requirements that must be met in order to bill a prolonged E/M service code. (MCP manual, Pub. 100-04, Ch. 12, Sec. 30.6.15.1(OAS; W-00-15-35755; expected issue date: FY 2016)

➤ **NEW Histocompatibility laboratories—supplier compliance with payment requirements**

We will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements. From March 31, 2013, through September 30, 2014, histocompatibility laboratories reported \$131 million in reimbursable costs on their most recent cost reports. Histocompatibility laboratories are reimbursed on the basis of reasonable costs. Costs claimed in the cost report must be related to the care of beneficiaries; reasonable, necessary, and proper; (42 CFR § 413.9(a), (b), and (c)(3)) and cost information must be accurate and in sufficient detail to support payments made for services provided (42 CFR § 413.24(a) and (c)). (OAS; W-00-15-35742; expected issue date: FY 2016)

## Prescription Drugs

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Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price

FDA—Food and Drug Administration

ASP—average sales price

MAC—Medicare Administrative Contractor

CMS—Centers for Medicare & Medicaid Services

### 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 (ASP) to average manufacturer prices (AMP) and identify drug prices that exceed a designated threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. 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 2016)

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

We will determine the financial impact on 340B-covered entities, the Medicare program, and Medicaid beneficiaries of three different shared savings arrangements that would enable Medicare and its beneficiaries to share in the cost savings resulting from 340B discounts. We will also calculate the amount by which ASP-based payments exceed 340B prices. The 340B Drug Discount Program enables eligible health care providers (generally those that serve a disproportionate share of needy patients) to purchase prescription drugs at statutorily discounted prices while charging paying patients and insurers (including Medicare and, in some cases, Medicaid) full price for the drugs. Previous OIG work found that some Medicare payments to providers for 340B-purchased drugs substantially exceeded the providers' costs. Under the 340B Program design and Part B payment rules, the difference between what Medicare pays and what it costs to acquire the drugs is fully retained by the participating 340B entities, allowing them to stretch scarce Federal dollars. However, policymakers have questioned whether some of the savings mandated through the 340B

Program should be passed on to Medicare and its beneficiaries. (OEI; 12-14-00030; expected issue date: FY 2016)

## 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 2016)

## Prescription Drugs—Quality of Care and Safety

### ➤ REVISED 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 drug uses that are not medically accepted. 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 2016)

## Part A and Part B Contractors

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### 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 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 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 that 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; W-00-15-35005; various reviews; expected issue date: FY 2016)

### ➤ 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 2016)

### ➤ 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 2016)

➤ **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; W-00-15-35095; various reviews; expected issue date: FY 2016)

## Contractor Functions and Performance

➤ **REVISED Medicare benefit integrity contractors' activities in 2012 and 2013: a data compendium**

We will review the level of benefit integrity activity performed by Medicare benefit integrity contractors in CYs 2012 and 2013. This review will highlight trends in integrity activities and allow for a quick comparison of program results across years, across contractors, and across the parts of the Medicare program. CMS contracts with entities to carry out benefit integrity activities to safeguard Medicare 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)

➤ **Collection status of ZPIC and PSC—identified Medicare overpayments**

We will determine the total amount of overpayments that ZPICs and PSCs identified and referred to claims processors in 2014 and the amount of these overpayments that claims processors collected. We will also review the procedures for tracking collections of 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 Medicare. (OEI; 03-13-00630; expected issue date: FY 2017)

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

We will review independent evaluations of information systems security programs of 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 MACs and requires OIG to assess such evaluations and report the results of its assessments to Congress. (MMA, § 912.) (OAS; W-00-15-41010; W-00-16-41010; expected issue date: FY 2016)

## Other Part A and Part B Program Management Issues

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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 2016; ACA.)

### Delivery System Reform

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

We will review the extent to which 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 to the exchange and use of health data, such as degree of interoperability, financial barriers, or information blocking. 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 2017; ACA)

#### ➤ NEW Accountable Care Organizations: Strategies and Promising Practices

We will review ACOs that participate in the Medicare Shared Savings Program (established by section 3022 of the Affordable Care Act). We will describe their performance on the quality measures and cost savings over the first three years of the program and describe the characteristics of those ACOs that performed well on measures and achieved savings. In addition, we will identify ACOs' strategies for and challenges to achieving quality and cost savings. The Medicare Shared Savings Program is a key component of the Medicare delivery system reform initiatives and is a vehicle through which providers who work in ACOs can share in Medicare cost-savings while providing high-quality care to patients. (OEI; 02-15-00450; expected issue date: FY 2017; ACA)

## Billing and Payments

### ➤ NEW Medicare payments for unlawfully present beneficiaries in the United States – mandated review

We will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to unlawfully present beneficiaries in the United States. Pursuant to section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, CMS's *Medicare Claims Processing Manual*, Ch. 1, §10.1.4.8 states that Medicare payment may not be made for items and services furnished to alien beneficiaries who are not lawfully present in the United States. Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted in April 2015, requires the Secretary of Health and Human Services to establish and maintain procedures to ensure that payment is not made for Medicare services rendered to individuals not lawfully present in the United States. Prior OIG review identified \$91.6 million of improper payments made to providers for services rendered to unlawfully present beneficiaries for CYs 2009 through 2011. OIG is required to submit to Congress a report on such activities established by CMS no later than 18 months after the date of the enactment (MACRA, §502(b).) (OAS; W-00-15-35625; various reviews; expected issue date: FY 2016; work in progress)

### ➤ NEW Medicare payments for incarcerated beneficiaries–mandated review

We will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to incarcerated beneficiaries. Medicare, in general, does not pay for services rendered to incarcerated beneficiaries because they do not have a legal obligation to pay (Social Security Act, § 1862); however, the regulation does permit Medicare payment where an incarcerated beneficiary has an obligation for the cost of care. (42 CFR § 411.4.) Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted in April 2015, requires the Secretary of Health and Human Services to establish and maintain procedures to ensure that Medicare does not pay for services rendered to incarcerated beneficiaries. Prior OIG review identified \$33.6 million of improper payments made to providers for services rendered to incarcerated beneficiaries for CYs 2009 through 2011. OIG is required to submit to Congress a report on such activities established by CMS no later than 18 months after the date of the enactment (MACRA§502(b).) (OAS; W-00-15-35624; W-00-16-35624; various reviews; expected issue date: FY 2016; work in progress)

### ➤ NEW CMS management of the ICD-10 implementation

We will review aspects of CMS's early management of the implementation of the 10<sup>th</sup> version of the International Classification of Diseases (ICD-10) codes in Medicare Parts A and B. This may include reviewing CMS's and its contractors' (e.g., MACs) assistance and guidance to hospitals and physicians and assessing how the transition to ICD-10 is affecting claims processing, including claims resubmissions, appeals, and medical reviews. We may also determine how ICD-10 diagnosis codes are being applied to selected CMS payment rules and safeguards (e.g., national or local coverage decisions related to coverable conditions). Starting on October 1, 2015, Medicare claims with a date of service on or after October 1, 2015, are required to contain a valid ICD-10 code. The ICD-10 system includes about 70,000 diagnosis codes and replaces the use of ICD-9 in Medicare, which included only about 15,000 codes. CMS has advised providers that it will allow for some flexibility during the first 12 months of implementation; e.g., Medicare review contractors will not deny claims billed under the Part B physician fee schedule based solely on the specificity of the ICD-10 diagnosis

code as long as the physician/practitioner used a code from the correct “family” of codes. (OEI; 00-00-00000; expected issue date: FY 2017).

## 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 plans 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.

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Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act

MA—Medicare Advantage

CDC—Centers for Disease Control and Prevention

PDE—prescription drug event

CMS—Centers for Medicare & Medicaid Services

P&T—Pharmacy & Therapeutics

DIR—direct and indirect remuneration

## Part C – Medicare Advantage

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MA plans provide all Part A and Part B services and generally provide additional services not covered by traditional Medicare. Beneficiaries usually pay monthly premiums and copayments that are often less than the coinsurance and deductibles under the original Medicare Part A and Part B. In most cases, these plans also offer Part D prescription drug coverage. Costs and benefits vary by plan.

### MA Organizations’ Compliance With Part C Requirements

#### ➤ **REVISED Medicare Advantage encounter data—CMS oversight of data integrity**

We will review CMS's oversight of MA encounter data validation and assess the extent to which CMS's Integrated Data Repository contains timely, valid, and complete MA encounter data. In 2012, CMS began collecting from MA organizations 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. Realizing the potential benefits of the MA encounter data for payment and program integrity oversight is contingent upon the data's completeness, validity and timeliness. (OEI; 03-15-00060; expected issue date: FY 2017).

#### ➤ **Risk adjustment data—sufficiency of documentation supporting diagnoses**

We will review the medical record documentation to ensure that it supports the diagnoses that 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 2016)

#### ➤ **NEW Medicare Advantage organization practices in Puerto Rico**

We will determine whether Medicare Advantage (MA) organization provider networks in Puerto Rico were established in accordance with Federal requirements. We will review MA organizations networks to determine whether MA beneficiaries have access to appropriate medical care. We will also determine whether providers in the network complied with Federal, State, and local credentialing requirements. Among other requirements, MA organizations may select the providers from whom the benefits under the plan are provided as long as the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner that assures continuity in the provision of benefits. MA organizations provide access to appropriate providers, including credentialed specialists for medically necessary treatment and services. (SSA Sec. 1852 (d)(1) (A) and (D).) MA organizations shall disclose to each plan enrollee the plan's service area, and the number, mix, and distribution of plan providers. This is to be done at enrollment and at least annually thereafter in a clear, accurate, standardized form. (SSA Sec. 1852 (c)(1)(A) and (C). (OAS; W-00-15-35734; expected issue date: FY 2016)

## Part D – Prescription Drug Program

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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.

### 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 2017)

#### ➤ **NEW Medicare Part D beneficiaries' exposure to inappropriate drug pairs**

We will determine whether Medicare Part D beneficiaries are being prescribed drugs that should not be prescribed in combination with other drugs. These would include drugs that have a severe interaction when used in combination with other drugs and drugs that should not be co-prescribed

with component drugs, i.e. drugs that contain more than one active ingredient and with one of the active ingredients prescribed individually. (OAS; W-00-15-35750; expected issue date: FY 2017)

➤ **REVISED 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 are valid. 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, ACA).

## Sponsor Compliance With Part D Requirements

➤ **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 2016)

➤ **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; 00-00-00000; expected issue date: FY 2016; ACA)

➤ **Recommendation follow up—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 2016)

#### ➤ **NEW Medicare Part D Eligibility Verification transactions**

We will review E1 transactions to assess the validity of the data. An E1 transaction is a Medicare Eligibility Verification transaction that is submitted by the pharmacy to determine beneficiary's eligibility to the Part D program and Part D insurance coverage information to the TrOOP (True Out-of-Pocket) facilitator. The TrOOP facilitator returns information to the pharmacy that is needed to submit the prescription drug event. E1 transactions are part of the real-time process of the Coordination of Benefits and calculating the TrOOP balance (CMS, Medicare Prescription Drug Benefit Manual, Pub. No. 100-18, ch.14 § 30.4) (OAS; W-00-15-35751; expected issue date: FY 2017)

#### ➤ **NEW Part D Pharmacy Enrollment**

We will review CMS's ability to oversee Part D pharmacies. We will also determine the extent to which pharmacies that bill for Part D drugs—especially those identified as high risk—are enrolled in Medicare. Since the inception of Part D, numerous OIG reports have raised concerns about the oversight of Part D and pharmacy-related fraud. In addition, in June 2015, OIG participated in the largest national health care fraud takedown in history, resulting in over 240 subjects being charged with defrauding Medicare and Medicaid. Much of this alleged fraud involved prescription drugs and pharmacies. (OEI; OEI-02-15-00440; expected issue date: FY 2017).

### 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 2016)

#### ➤ **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-00-15-35611; various reviews; expected issue date: FY 2016; ACA)

➤ **NEW Increase in prices for brand-name drugs under Part D**

We will evaluate the extent to which pharmacy reimbursement for brand-name drugs under Medicare Part D changed between 2010 and 2014 and compare the rate of change in pharmacy reimbursement for brand name drugs under Medicare Part D to the rate of inflation for the same period. Prices for the most commonly used brand-name drugs have risen substantially since 2002. For example, prices for the most commonly used brand-name drugs increased nearly 13 percent in 2013; this increase was eight times greater than the general inflation rate for the same year. (OEI; 03-15-00080; expected issue date: FY 2017)

## Medicaid Program

The Federal Government and States jointly fund Medicaid, which 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. Additional Medicaid work for FY 2016 and beyond may examine: new health care payment and delivery models; Medicaid managed care focusing on county operated MCOs; State financing mechanisms focusing on compliance with upper payment limits; drug diversion and abuse; and States' lock-in programs that restrict beneficiaries to a limited number of pharmacies or prescribers to reduce prescription drug abuse. Going forward, OIG also expects to examine beneficiary access to, and program integrity of, mental and behavioral health services.

## Medicaid Prescription Drug Reviews

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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

➤ **REVISED States' actions based on Medicaid drug utilization reviews**

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 drugs, including opiates. We also will review State oversight of and coordination with 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 programs should involve ongoing

and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care. Other DUR program functions may involve implementing corrective action when needed (42 CFR § 456.709). (OEI; 05-13-00550; expected issue date: FY 2016)

#### ➤ **Manufacturer compliance with AMP reporting requirements**

We will determine manufacturer compliance with AMP reporting requirements and identify actions that CMS has taken to improve compliance with those 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 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). 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; W-00-15-31400; various reviews; expected issue date: FY 2016)

#### ➤ **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 2016; ACA)

#### ➤ **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)

### ➤ 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)

### ➤ 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)

### ➤ NEW Specialty drug pricing and reimbursement in Medicaid

We will determine how State Medicaid agencies (States) define specialty drugs, how much States paid for specialty drugs, how States determine payment methodologies for specialty drugs, and the differences in reimbursement amounts for these drugs among the States. Specialty pharmacies dispense prescription drugs that often require special handling or administration. These specialty drugs are often expensive and are used to treat rare conditions, such as Hepatitis C, HIV, and certain cancers. States use CMS's national average drug acquisition cost to set Medicaid pharmacy reimbursement amounts. However, this average does not include the cost of drugs sold at specialty pharmacies. Therefore, States that use the national average drug acquisition cost data to assist in setting Medicaid pharmacy reimbursement amounts may have difficulty determining Medicaid pharmacy reimbursement amounts for specialty drugs. (OEI; 00-00-00000; expected issue date: FY 2017)

## 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; W-00-15-31476; various reviews; expected issue date: FY 2016)

# Home Health Services and Other Community-Based Care

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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

## ➤ 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 2016)

## ➤ 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 that is based on annual cost reports or prospective rates with rate adjustments that are based on cost report data and cost-trending factors. (OAS; W-00-14-31465; various reviews; expected issue date: FY 2016)

# Other Medicaid Services, Equipment, and Supplies

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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

## ➤ NEW Express Lane Eligibility

We will determine the extent to which selected States made inaccurate eligibility determinations using the Express Lane Option for Medicaid and the Children's Health Insurance Program (CHIP). The

Express Lane Option permits States to rely on eligibility findings made by other programs, such as Head Start and Temporary Assistance to Needy Families. We will also assess whether and how the selected States addressed issues that contributed to inaccurate determinations. We will calculate an eligibility error rate and determine the amount of payments associated with beneficiaries who received incorrect eligibility determinations for Medicaid and CHIP beneficiaries under the Express Lane Option. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) §305 requires OIG to submit a report to Congress on the use of the Express Lane Option under Medicaid and CHIP within 18 months of enactment. An additional review will describe States' use of the different Express Lane Eligibility (ELE) models, the reported benefits of such use, and the efforts and barriers to employing and extending ELE to renewal and adult applications. (OAS; W-00-16-31485; A-04-15-08043; OEI-06-15-00410; expected issue date: FY 2016)

## 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-00-15-31121; various reviews; expected issue date: FY 2016)

### ➤ 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; W-00-15-31452; various reviews; expected issue date: FY 2016; 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-00-15-31135; various reviews; expected issue date: FY 2016)

### ➤ 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-00-15-31078; W-00-16-31078; various reviews; expected issue date: FY 2016)

### ➤ 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; W-00-16-31495; 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. The States also must use the additional Federal funding to provide new or expanded offerings of noninstitutional LTSS. (OAS; W-00-15-31482; various reviews; expected issue date: FY 2016; ACA)

## Quality of Care and Safety of Beneficiaries

### ➤ Utilization of pediatric dental services 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 required dental services in these States. Children's low utilization of 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 2016)

### ➤ NEW 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-00-16-31502; various reviews; expected issue date: FY 2017)

## State Management of Medicaid

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### Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act	Form CMS-64—Quarterly Medicaid Statement of Expenditures
CHIP—Children’s Health Insurance Program	MIP—Medicaid Integrity Program
CMS—Centers for Medicare & Medicaid Services	MFCU—Medicaid Fraud Control Unit
CPE—certified public expenditures	OMB—Office of Management and Budget
FFP—Federal financial participation	RMSS—random moment sampling systems
FMAP—Federal medical assistance percentage	

## 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 2017)

### ➤ 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 2016)

## 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-00-14-31467; W-00-15-31467; various reviews; expected issue date: FY 2016)

### ➤ 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 CYs 2013 and 2014. (OAS; W-00-15-31480; various reviews; expected issue date: FY 2016; 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-00-15-31140; 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-00-14-31456; various reviews; expected issue date: FY 2016)

#### ➤ 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; W-00-15-31457; various reviews; expected issue date: FY 2016)

#### ➤ 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; W-00-15-31460; various reviews; expected issue date: FY 2016)

### State Program Integrity Activities and Compliance with Federal Requirements

#### ➤ REVISED State and CMS oversight of provider ownership information

We will determine the extent to which States collect required ownership information for provider entities enrolled in Medicare and Medicaid, and we will describe the extent to which they verify the collected information. We will also determine whether States and CMS checked exclusions databases for enrolling and enrolled providers, as required. Finally, we will compare the ownership information that selected providers gave to States to enroll in Medicaid, and that providers gave to CMS to enroll in Medicare, to the ownership information that the same providers gave to OIG for the purposes of this study. Federal regulations require Medicaid and Medicare providers to disclose ownership information, such as the name and address of each person and corporation 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 2016)

#### ➤ REVISED States' experiences with enhanced provider screening

We will review whether States are conducting 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 extent to which States have screened moderate- and high-risk providers and suppliers using these risk-based screenings. The ACA, §6402, requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment, or revalidation in Medicare, Medicaid, and 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)

➤ **REVISED 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' use of payment suspensions. 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 2016; and OEI; 09-14-00020; expected issue date: FY 2016; ACA)

## OIG Oversight of State Medicaid Fraud Control Units

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

We will continue to conduct in-depth 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 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 2016)

## Medicaid Information System Controls and Security

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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; W-00-15-31374; various reviews; expected issue date: FY 2016)

➤ **REVISED 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. (OEI; 09-14-00440; expected issue date: FY 2016, ACA)

## Controls to Ensure the Security of Medicaid Systems and Information

➤ **REVISED 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. 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 information system security. CMS is responsible for ensuring that appropriate security controls have been implemented. (OAS; W-00-15-40019; W-00-16-40019; various reviews; expected issue date: FY 2016)

➤ **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 CHIP 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

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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.

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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' ratesetting 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 2017)

#### ➤ 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; W-00-15-31372; 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 2017)

➤ **NEW Medical loss ratio—recoveries of MCO rebates from profit-limiting arrangements**

We will review States and managed care plans with contract provisions that require rebates from managed care plans if a minimum percentage of total costs to be expended for medical services (medical loss ratio) is not met to ensure that the Federal share of recoveries of MCO payments that States received through profit-limiting methodologies is returned to the Federal Government.

Pursuant to section 1903(a)(1) of the Act, CMS reimburses each State at the FMAP for the quarter in which the expenditure was made. In accordance with section 1903(d)(2) of the Act, the CMS State Medicaid Manual, section 2500.6(B), requires that when a State recovers a prior expenditure, it refunds the Federal share by reporting the recovery on the CMS-64 report at the FMAP used to calculate the amount it originally had received. (OAS; W-00-16-31508; various reviews; expected issue date: FY 2017)

➤ **NEW Review of States' methodologies for assigning Managed Care organization payments to different Medicaid FMAPs**

We will review methodologies for assigning managed care organization payments to different Medicaid FMAPs (e.g., the regular FMAP, the family planning FMAP, the Indian Health Services FMAP, etc.). According to section 1905(b) of the Social Security Act, the Federal Government pays its share of a State's medical assistance expenditures under Medicaid on the basis of the Federal medical assistance percentage (FMAP), which varies depending on the State's relative per capita income. Additionally, certain Medicaid services receive a higher FMAP, including family planning services (90 percent) and services provided through an Indian Health Service facility (100 percent). The FMAPs under the Medicaid program are varied, and the actual services provided are less transparent under a managed care model. Therefore, the burden is on States to create accurate and reasonable methodologies to assign managed care payments to those FMAPs. (OAS; W-00-16-00000; various reviews; expected issue date: FY 2017)

➤ **NEW Managed long-term-care reimbursements**

We will review States' reimbursements made to managed long-term-care (MLTC) plans to determine whether those reimbursements complied with certain Federal and State requirements. Medicaid managed care plans are subject to Federal requirements (42 CFR Part 438). State contracts with MCOs include terms for eligibility and enrollment of beneficiaries. In addition, Federal financial participation (FFP) is available in expenditures for payments under an MCO contract only for the periods during which the contract is in effect (42 CFR 438.802(b)). (OAS; W-00-16-00000; various reviews; expected issue date: FY 2017)

## Program Integrity in Managed Care

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

We will determine whether Medicaid MCOs identified and addressed incidents of potential fraud and abuse. 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 2017)

# CMS-Related Legal and Investigative Activities

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## 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

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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](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 guidance on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and compliance program guidance 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

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OIG investigates allegations of fraud, waste, and abuse in all of the Department's programs. Our largest body of work involves investigating matters related to Medicare and Medicaid. This can include billing for services not rendered, medically unnecessary and misrepresented services, and patient harm. OIG's work also includes the illegal billing, sale, diversion, and off-label marketing of prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in the fraud scheme and illegal referral arrangements between physicians and medical companies.

Specific case types include health care fraud schemes related to:

- controlled and noncontrolled prescription drugs;
- home health agencies, personal care, and home and community based services;
- ambulance transportation;
- durable medical equipment; and
- diagnostic radiology and laboratory testing.

OIG also conducts investigations involving organized criminal activity, including medical identity theft and fraudulent medical schemes established for the sole purpose of stealing Medicare dollars. Investigators are seeing an increase in individuals, including both health care providers and patients,

engaging in these health care fraud schemes. Those who participate in these schemes may face heavy fines, jail time, and exclusion from participating in Federal health care programs.

In addition to investigating Medicare and Medicaid fraud, OIG investigates fraud, waste, and abuse in other HHS operating divisions, including the Administration for Children and Families, the Administration for Community Living, Health Resources and Services Administration, and Indian Health Service. OIG also investigates potential misuse of grants and contracts funds awarded by the Centers for Disease Control and Prevention, National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and other HHS agencies (HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government). Under certain circumstances, OIG investigates noncustodial parents who fail to pay court-ordered child support. Additionally, OIG investigates allegations of employee misconduct, whistleblower reprisals, and wrongdoing by HHS agency officials.

OIG conducts joint investigations with other investigative agencies when investigative authorities overlap Federal, State, or local statutes. OIG works with the FBI, U.S. Attorneys' Offices, State agencies, such as MFCUs, and the State police. OIG may also work with local investigative agencies, such as a county sheriff's office or a municipal police department and program integrity partners, including the CMS Center for Program Integrity and associated Medicare contractors.

In addition to collaboration with law enforcement and program integrity partners, OIG engages with external stakeholders to enhance the relevance and impact of our work to combat health care fraud, as demonstrated by our leadership in the Healthcare Fraud Prevention Partnership (HFPP) and our association with the National Health Care Anti-Fraud Association (NHCAA).

The HFPP is a groundbreaking partnership between the Federal and private sectors to share data and information for the purposes of detecting and combating fraud, waste, and abuse in health care. The HFPP was created as a voluntary public-private partnership, between the Federal Government, State officials, private health insurance organizations, and health care antifraud associations. The NHCAA is the leading national nonprofit organization focused exclusively on combating health care fraud and abuse. The NHCAA mission is to protect and serve the public interest by increasing awareness and improving the detection, investigation, civil and criminal prosecution, and prevention of health care fraud and abuse. Both organizations are engaged in efforts to combat the problem of health care fraud.

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

In 2009, HHS and DOJ partnered to establish the Health Care Fraud Prevention and Enforcement Action Team (HEAT). This initiative was created 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. Medicare Fraud Strike Force Teams harness data analytics and the combined resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. First established in March 2007, Strike Force teams operate in nine areas: Miami, Florida; Los Angeles, California; Detroit, Michigan; southern Texas; Brooklyn, New York; southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas.

These teams have a proven record of success in analyzing data and investigative intelligence to quickly identify fraud and bring prosecutions. The interagency collaboration also enhances the effectiveness of the Strike Force model. For example, OIG refers credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so that it can suspend payments to the suspected perpetrators, thereby immediately preventing losses from claims submitted by Strike Force targets.

Strike Force teams have shut down health care fraud schemes around the country, arrested more than a thousand criminals, and recovered millions of taxpayer dollars.

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

## 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 program goals and best serve the intended beneficiaries. In its future work planning activities, OIG may consider key risk areas surrounding the access to and quality of services, including: dietary supplement manufacturers' use of structure/function claims to persuade consumers to purchase and use their products; regulation of veterinary antibiotics; use of unique device identifiers; and safety in food, drugs, and medical devices.

New and expanded reviews of the FDA may include: investigations of fraud and misconduct at FDA facilities; oversight of blood establishments and laboratory-developed diagnostic tests; FDA's management of IT modernization initiatives; hospital contracting with compounding pharmacies that have registered with the FDA; and FDA prescription drug user fees.

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Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act	OMB—Office of Management and Budget
AIDS—acquired immunodeficiency syndrome	NIEHS—National Institute of Environmental Health Sciences
BPA—Bisphenol A	NIH—National Institutes of Health
CDC—Centers for Disease Control and Prevention	NOM—national outcome measure
CoP—conditions of participation	NTP—National Toxicology Program
DHS—Department of Homeland Security	PEPFAR—President's Emergency Plan for AIDS Relief
FDA—Food and Drug Administration	PMR—postmarketing requirement
FDAA—Food and Drug Amendments Act of 2007	PPHF—Prevention and Public Health Fund
FSMA—Food Safety Modernization Act	SAMHSA—Substance Abuse and Mental Health Services Administration
HCP—Health Center Program	SAPTBG—Substance Abuse Prevention and Treatment Block Grant
HIPAA—Health Insurance Portability and Accountability Act	SSBG—Social Services Block Grant
HRSA—Health Resources and Services Administration	USDA—United States Department of Agriculture
IC—institution/center (NIH)	WTCHP—World Trade Center Health Program
IHS—Indian Health Service	
MCO—managed care organization	

## Centers for Disease Control and Prevention

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### ➤ 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 2016)

#### ➤ **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 2016)

#### ➤ **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 had 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 2016)

#### ➤ **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 2016)

#### ➤ NEW CDC—oversight of the Select Agent Program

We will examine CDC's oversight of the Select Agent Program (SAP), including CDC's inspections of entities registered with SAP. This program regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public health and safety. CDC may conduct inspections of applying or registered entities to ensure compliance with regulatory requirements (42 CFR §§73.7 (f) and 73.18). We will examine the number, frequency, and results of inspections, as well as CDC's response to and followup on noncompliance with regulatory requirements identified during inspections. (OEI-04-15-00430; expected issue date: FY 2017)

## Food and Drug Administration

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#### ➤ 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; 01-14-00390; expected issue date: FY 2016)

#### ➤ 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. 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 2017)

#### ➤ **REVISED FDA- monitoring of domestic and imported food recalls**

We will review FDA's monitoring of domestic and imported food recalls. The audit will determine the extent to which 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 re-inspections 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).

#### ➤ **NEW Controls over networked medical devices at hospitals**

We will examine whether FDA's oversight of hospitals' networked medical devices is sufficient to effectively protect associated electronic protected health information (ePHI) and ensure beneficiary safety. Computerized medical devices, such as dialysis machines, radiology systems, and medication dispensing systems that are integrated with electronic medical records (EMRs) and the larger health network, pose a growing threat to the security and privacy of personal health information. Such medical devices use hardware, software, and networks to monitor a patient's medical status and transmit and receive related data using wired or wireless communications. Medical device manufacturers provide Manufacturer Disclosure Statement for Medical Device Security (MDS2) forms to assist health care providers in assessing the vulnerability and risks associated with ePHI that is transmitted or maintained by a medical device. (OAS; W-00-16-42020; expected issue date: FY 2016)

#### ➤ **NEW FDA–tobacco establishment compliance with the Family Smoking Prevention and Tobacco Control Act**

We will evaluate whether tobacco establishments are registering with FDA and submitting product lists as required under Section 905 of the Family Smoking Prevention and Tobacco Control Act of 2009. A tobacco establishment is an entity that manufactures or processes tobacco products. This evaluation will also assess the extent to which FDA verifies the information in the registry and takes action against establishments that do not comply with the Act. The actions include labeling products as misbranded or adulterated. (OEI; 01-15-00300; expected issue date: FY 2016)

## Health Resources and Services Administration

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### ➤ 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 2016; 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)

### ➤ REVISED HRSA—oversight of vulnerable health center grantees

We will determine the extent to which HRSA awarded grant money to Health Center Program (HCP) grantees that have documented compliance or financial issues. HRSA collects data on HCP grantees’ compliance and financial statuses when evaluating their applications and can take a variety of actions to help them resolve any identified compliance or financial issues. Having compliance or financial issues does not disqualify health centers from receiving HRSA grants, but having these types of issues may put health centers at risk for mismanaging their grant funds. (OEI; 05-14-00470; expected issue date: FY 2016)

### ➤ NEW HRSA—compliance with Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Requirements

We will review compliance by States with terms and conditions of grants received under the MIECHV program, specifically, whether States (1) used funding in accordance with Federal requirements, (2) adequately monitored the activities of subrecipients who provided program services, and (3) reported to HRSA on the activities in accordance with Federal laws and regulations. The MIECHV program is designed to strengthen and improve the programs and activities carried out under Title V, improve coordination of services for at-risk communities, and identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities. The ACA, section 2951, provided \$1.5 billion for States and territories over five years, beginning in 2010, to deliver evidence-based home visiting services to eligible families with children prenatal to age 5. Program funding has been extended through 2017. HRSA administers the MIECHV program in partnership with HHS’s Administration for Children and Families. (OAS; W-00-15-59000; various reviews; expected issue dates: FY 2016; ACA)

## Indian Health Service

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### ➤ REVISED IHS—hospital oversight

We will assess IHS's efforts to monitor and oversee its federally operated hospitals, and will describe challenges that affect IHS hospitals and their ability to provide quality care and comply with Medicare standards. IHS directly operates 28 acute care hospitals that provide free inpatient care to eligible American Indians and Alaska Natives. Although IHS requires its hospitals to be Medicare certified or accredited by an approved organization, reports of inadequate health care services are a subject of concern. (OEI; 06-14-00010; 06-14-00011; expected issue dates: FY 2016)

### ➤ NEW IHS—charge card program review

We will review IHS's charge card programs (e.g. purchase and travel cards) to determine if the programs comply with Federal requirements. Pursuant to the Charge Card Act, OIG performed a risk assessment of HHS's charge card program for FY 2013. We used the results of the risk assessment to identify high-risk and high-impact areas warranting an audit. (OAS; W-00-16-51000; expected issue date: FY 2016)

## National Institutes of Health

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### ➤ NIH—Superfund financial activities for fiscal year 2015

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 2016)

### ➤ 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—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 NIH—controls over subcontracting of NIH grant and contract work

We will assess colleges' and universities' controls over the subcontracting of NIH grant and contract work. Specifically, we will determine whether colleges and universities effectively monitor the services subcontracted to other organizations and ensure that Federal funds are spent on allowable goods and services in compliance with selected cost principles and the terms and conditions of the grants and subcontracts. Cost principles for Educational Institutions at 2 CFR 220, are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles shall also be used in determining the costs of work performed by such institutions under subgrants, cost-reimbursement subcontracts, and other awards made to them under sponsored agreements. We will conduct reviews at selected organizations based on the dollar value of Federal grants received and on input from NIH. (OAS; W-00-15-51001; various reviews; expected issue date: FY 2016; new start)

#### ➤ 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, 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. (OEI; 01-15-00150; expected issue date: FY 2016).

## Other Public Health-Related Reviews

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#### ➤ 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 2016)

### ➤ Grantees' 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 2016; ACA)

### ➤ 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)

### ➤ NEW Controls over the preparation and receipt of select agent shipments

We will review NIH and FDA's controls for preparing and receiving select agent shipments. Federal regulations at 42 Code of Federal Regulations (CFR) §73.16 regulate the transfer of select agents. We will review controls in place at NIH and FDA that are designed to ensure shipments are made and received in accordance with regulations and related supporting laboratory guidance or instruction. (OAS; W-00-16-51002; various reviews; expected issue date: FY 2016)

### ➤ NEW Review of Office for Human Research Protections compliance evaluations to ensure human subject protection

Section 492 of the Public Health Service Act authorizes the office of Human Research Protections (OHRP) to establish a compliance oversight process to review violations of HHS regulations protecting human research subjects. We will describe the extent and scope of OHRPs' compliance evaluations from 2000 to 2014. We will also describe how OHRP works with relevant government entities and institutional review boards during its compliance evaluations, and how OHRP's working with these entities enhances or constrains its capacity to conduct compliance evaluations. (OEI; 01- 15-00350; expected issue date: FY 2016).

## Public Health Legal Activities

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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 FBI, and USDA to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

# Human Services Reviews

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.

OIG's future planning efforts will focus on human services program preparedness for emergencies and disasters. To this end, we will be prioritizing future planned work on the sufficiency and training of medical staff for disasters and severe infectious diseases, as well as the oversight of expenditures and adherence to safety standards in ACF's Unaccompanied Children Program. Further work may also include examinations of the inventory control policies and procedures for select agents.

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Acronyms and Abbreviations for Selected Terms:

ACF—Administration for Children and Families  
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 2016 follow.

## Administration for Children and Families

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### ➤ 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 States' 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 2016)

➤ **NEW Foster Care—States' protocols for the use and monitoring of psychotropic medications for children in foster care**

We will describe States' protocols for the appropriate use and monitoring of psychotropic medications for children in foster care. Pursuant to Section 422(b)(15)(A) of the Social Security Act (the Act), each State must develop a plan for ongoing oversight and coordination of health services for children in foster care, including oversight of prescription medicines (e.g. appropriate use and monitoring of psychotropic medications). For selected States, we will determine whether a sample of children in foster care enrolled in Medicaid received psychotropic medications in accordance with their State's protocols. Because ACF is responsible for the oversight of States' foster care programs, we will determine the extent to which the Agency ensures that children in foster care receive psychotropic drugs in accordance with States' protocols. (OEI; 07-15-00380; expected issue date: FY: 2017)

➤ **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 fail 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.

➤ **REVISED Head Start—implementation of Head Start grant recompetition**

We will describe Head Start program quality determinations and funding renewal decisions made under the Designation Renewal System (DRS) and grant recompetition. 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 determine the extent to which the DRS effectively identifies grantees that deliver a high-quality and comprehensive Head Start program. (OEI; 12-14-00650; expected issue date: FY 2016)

➤ **CCDF—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 2017).

➤ **NEW States' implementation of guardian ad litem requirements**

We will assess selected States' compliance with guardian ad litem requirements. Section 8 of the Child Abuse Prevention and Treatment Act requires that, as a condition of receiving Title IV-E foster care grant funding, States must ensure that all child victims of abuse and neglect undergoing judicial proceedings are assigned a guardian ad litem to represent the best interests of the child. States are also required to provide guardians ad litem with training appropriate to their role. We will also determine the number of children typically assigned to guardians ad litem in each selected State. (OEI; 00-00-00000; expected issue date: FY 2017)

➤ **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)

➤ **REVISED Superstorm Sandy—States' emergency preparedness, response, and recovery planning for child care**

We will determine the extent to which States develop and/or update emergency preparedness and response plans specific to child care services and programs. We will also describe emergency response and recovery experiences of States and child care providers during and after Superstorm Sandy. 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)

# Other HHS-Related Reviews

Certain financial, performance, and investigative issues cut across HHS programs. 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. OIG's future planned work includes a holistic examination of HHS' efforts to reduce opioid misuse and abuse, as well as further examinations of government-wide financial data standards related to expenditures of federal grants, contracts, and loans.

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 Modernization Act of 2014 (FISMA).

GMRA seeks to ensure that Federal managers have the financial information and flexibility necessary to make sound policy decisions and manage scarce resources. 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 has identified the meaningful and secure exchange and use of electronic information and health information technology, as top management challenge facing the Department. Going forward, OIG's planning efforts will consider the significant challenges that exist with respect to Health IT adoption; meaningful use; and interoperability across providers, across HHS, and between providers and patients. Future work may also examine the outcomes from health IT investments. OIG expects to broaden its portfolio regarding information privacy and security, including issues that arise from the continuing expansion of the Internet of Things.

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#### Acronyms and Abbreviations for Selected Terms:

AFR—Agency Financial Report	health IT—health information technology
CFO Act—Chief Financial Officers Act of 1990	GPO—group purchasing organization
CMS—Centers for Medicare & Medicaid Services	IPERA—Improper Payment Elimination and Recovery Act of 2010
FISMA—Federal Information Security Management Act of 2002	OMB—Office of Management and Budget
GAO—Government Accountability Office	SAM—System for Award Management
GMRA—Government Management Reform Act of 1994	

## Financial Statement Audits and Related Reviews

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➤ **REVISED** Audits of fiscal years 2015 and 2016 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 15-02, "Audit Requirements for Federal Financial Statements.") The audited consolidated FYs 2015 and 2016 financial statements for HHS are due to OMB by November 16, 2015, and November 15, 2016, respectively. 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 2016 financial statements. The purpose of the financial-related reviews is to fulfill requirements in OMB Bulletin 15-02, §§6.1 through 13. (OAS; W-00-15-40009; W-00-16-4009; A-17-15-00001; A-17-15-00006; A-17-16-00001; A-17-16-00006; expected issue dates: FY 2016 and FY 2017)

➤ Fiscal years 2015 and 2016 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 15-02, "Audit Requirements for Federal Financial Statements.") (OAS; W-00-15-40008, W-00-16-4008; A-17-15-02015, A-17-16-02015; expected issue dates: FY 2016 and FY 2017)

## Financial Reviews

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➤ **REVISED** Compliance with reporting requirements for improper payments

We will review certain aspects of HHS's compliance with the Improper Payments Information Act of 2002 (IPIA), as amended, regarding reporting improper payments. We will also assess HHS's compliance with the Improper Payment Elimination and Recovery Act of 2010 (IPERA), the Improper Payments Elimination and Recovery Act of 2012 (IPERIA) [IPIA will refer to this law as amended by IPERA and IPERIA], 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 OMB Circular A-123, Appendix C, “Requirements for Effective Estimation and Remediation of Improper Payments,” 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. IPIA 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)

### ➤ **HHS contract management review**

We will review the controls that 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 2016)

### ➤ **REVISED 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 that expresses a conclusion on the reliability of the agency’s assertions. We will submit this authentication with respect to HHS’s FY 2015 annual accounting. (OAS; W-00-15-41020; various reviews; expected issue date: FY 2017)

### ➤ **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 follow-up 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-00-16-40005; various reviews; expected issue date: FY 2016)

### ➤ 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; W-00-16-50012; various reviews; expected issue date: FY 2016)

### ➤ REVISED Requests for audit services

Throughout the year, Congress, HHS, and other Federal organizations request that we perform a variety of financial-related audit services, such as contract and grant closeouts, indirect cost audits, and bid proposal audits, 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 2016)

## Automated Information Systems

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### ➤ REVISED HHS compliance with the Federal Information Security Modernization Act of 2014

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-00-15-40016; W-00-16-40016; W-00-15-42001; W-00-16-42001; various reviews; expected issue date: FY 2016)

### ➤ 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-00-15-42020; W-00-16-42020; various reviews; expected issue date: FY 2016)

## Other HHS-Related Issues

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### ➤ **HHS 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 inspectors general (IG) 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 to establish and maintain safeguards and internal controls for purchase cards 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 2016)

### ➤ **NEW Office for Civil Rights' oversight of the security of electronic protected health information**

We will determine the adequacy of the Office for Civil Rights (OCR) oversight over the security of electronic protected health information (ePHI). Prior OIG audits reported that OCR had not assessed the risks, established priorities, or implemented controls for its HITECH Act requirement to provide for periodic audits of covered entities and business associates to ensure compliance with HITECH Act and HIPAA Rule requirements and, therefore, had limited assurance that covered entities and business associates adequately protected ePHI. Prior OIG audits have also summarized numerous vulnerabilities in the systems and controls to protect ePHI at selected covered entities. (OAS; W-00-16-42020; expected issue date: FY 2016)

# Appendices

## Appendix A

### Affordable Care Act Reviews

OIG is focused on promoting the economy, efficiency, and effectiveness of ACA<sup>2</sup> 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 2016 will continue to 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 continues to plan additional oversight work to initiate in FY 2016. That work will focus on key areas, such as emerging marketplace issues, premium stabilization programs, 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 work with other Federal and State oversight agencies, including the Treasury Inspector General for Tax Administration (TIGTA), to address emerging vulnerabilities.

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#### 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

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<sup>2</sup> ACA, as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-148).

# Health Insurance Marketplaces, Financial Assistance Payments, and Premium Stabilization Payments

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OIG's FY 2016 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 2016 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.

## Payments—Are Taxpayer Funds Being Expended Correctly for Their Intended Purposes?

Continuing and planned FY 2016 work looking at expenditures of taxpayer funds includes:

### ➤ 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-00-15-59018; various reviews; expected issue date: FY 2016)

### ➤ 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 2016)

### ➤ NEW Consumer Operated and Oriented Plan Loan Program—CO-OP compliance with requirements and CMS monitoring activities

We will follow up on prior OIG work that examined the loan award selection process, financial condition, and other factors that could impair the effectiveness of the Consumer Operated and Oriented Plan (CO-OP) loan program. In this new work, we will determine whether CO-OPs were in compliance with Federal regulations and program requirements in managing the Federal funds. In

addition, we will reassess the CO-OPs financial condition to determine whether any improvements were made in 2015 and identify actions CMS has taken to effectively oversee the loan program and monitor underperforming CO-OPs. ACA §1322 directs the Secretary of HHS to establish the CO-OP program by providing loans to assist the awardees with start-up costs and State solvency requirements; 45 CFR part 156 implements section 1322. (OAS; W-00-15-59019; various reviews, expected issue date: FY 2016)

### ➤ **NEW Allowability of contract expenditures**

ACA, §1311. We will review the allowability of expenditures for contractor services claimed for Federal reimbursement by selected health insurance marketplace grantees funded under the ACA Marketplace Establishment Grants. HHS award recipients often contract with organizations to provide services necessary to meet the performance requirements of the grant. Contractors that provide services specified in the grant award to beneficiaries are subject to the same requirements and cost principles as the grantee. (OAS; W-00-15-59034; expected issue date: FY 2016).

## Eligibility—Are The Right People Getting The Right Benefits?

OIG's FY 2016 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. We 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 2016)

### ➤ **NEW Rollup of State-based marketplace eligibility determination audits and CMS oversight**

We will (1) summarize the results of our reviews of seven State-based marketplaces (SBMs), which determined whether SBM internal controls were effective in ensuring that individuals were enrolled in qualified health plans (QHPs) according to Federal requirements, and (2) review CMS's oversight of eligibility determinations at the seven SBMs. In support of those objectives, we will assess CMS's efforts to address the deficiencies identified in our audit reports and contact the seven SBMs to understand how they worked with CMS to establish internal controls over eligibility determinations. Section 1321 of the ACA directs the Secretary of HHS to issue regulations that set standards for meeting the requirements under Title I of the ACA, which includes procedures for determining eligibility for enrollment in QHPs and for insurance affordability programs. (OAS; W-00-15-42024; expected issue date: FY 2016)

### ➤ Inconsistencies in the Federally facilitated marketplace applicant data

We will assess CMS's ability to utilize data to determine the extent to which it has resolved 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 Federally facilitated Marketplace (FFM). In previous OIG work, CMS reported to us 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 2016)

### ➤ 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 with 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)

## Security—Is Consumers' Personal Information Safe?

Reviews underway to address security in the Marketplaces include:

### ➤ REVISED State-based marketplaces information system security controls

We will determine whether information security controls for 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 performed by the States 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 2016)

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

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### Medicaid Reviews

The Medicaid section of the *Work Plan* describes the range of FY 2016 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 2016) *Work Plan* page 38.

➤ **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 38.

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

ACA, § 2401. (OAS; W-00-16-31495; expected issue date: FY 2016) *Work Plan* page 36.

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

ACA § 6402. (OEI; 05-13-00520; expected issue date: FY 2016) *Work Plan* page 39.

- **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 2016; OEI; 09-14-00020; expected issue date: FY 2016) *Work Plan* page 40.
- **National Correct Coding Initiative edits and CMS oversight**  
ACA, § 6507. (OAS; W-00-15-31459; various reviews; expected issue date: FY 2016; OEI; 09-14-00440; expected issue date: FY 2016) *Work Plan* page 41.
- **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 36.
- **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 2016) *Work Plan* page 32.
- **Health-care-acquired conditions—prohibition on Federal reimbursements**  
ACA, §2702. (OAS; W-00-14-31452; various reviews; expected issue date: FY 2016) *Work Plan* page 35.
- **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 32.

## Medicare Reviews

The ACA introduced Medicare program changes designed to improve efficiency and quality of care and promote program integrity and transparency. The Medicare sections of the FY 2016 *Work Plan* describe OIG's continuing 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 help the Department as it implements delivery system reform.

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 2016) *Work Plan* page 30.

- Ensuring dual eligibles' access to drugs under Part D  
ACA, §3313. (OEI; 00-00-00000; expected issue date: FY 2016) *Work Plan* page 29.
- National Background Check Program for long-term-care employees: interim report  
ACA, §6201. (OEI; 07-10-00420; expected issue date: FY 2016) *Work Plan* page 11.
- Enhanced enrollment screening process for Medicare providers  
ACA, §66401. (OEI; 03-13-00050; expected issue date: FY 2016) *Work Plan* page 25.
- 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 25.
- Review of financial interests reported under the Open Payments Program  
ACA, §6002. (OEI; 03-15-00220; expected issue date: FY 2016) *Work Plan* page 29.
- NEW Physicians—referring/ordering Medicare services and supplies  
ACA, §6405. (OAS; W-00-15-35748; expected issue date: FY 2016) *Work Plan* page 20.
- NEW Accountable Care Organizations: strategies and promising practices  
ACA, §3022. (OEI; 02-15-00450; expected issue date: FY 2017) *Work Plan* page 25
- NEW CMS validation of hospital-submitted quality reporting data  
ACA, §3301 (a). (OEI; 01-15-00320; expected issue date: FY 2016.)  
*Work Plan* page 11.

## Other Programs

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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 2016) *Work Plan* page 55.
- 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 2016) *Work Plan* page 53.

➤ **HRSA—duplicate discounts for 340B-purchased drugs**

ACA, § 2501. (OEI; 05-14-00430; 05-14-00431; expected issue date: FY 2016) *Work Plan* page 53.

➤ **NEW HRSA—compliance with Maternal, Infant, and Early Childhood Home Visiting (MIECHV) requirements**

ACA § 2951 (OAS; W-00-15-59000; various reviews; expected issue dates: FY 2016)  
*Work Plan* page 53.

## Appendix B

# Recovery Act Reviews

Pursuant to the American Recovery and Reinvestment Act of 2009 (Recovery Act), OIG received funding for discretionary oversight of HHS programs and operations 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 that they received for their 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.

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#### Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services

EHR—electronic health record

## Medicare and Medicaid

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### 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 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 July 2015, Medicare EHR incentive payments totaled more than \$20 billion. (OAS; W-00-14-31352; expected issue date: FY 2016; 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 July 2015, Medicaid EHR incentive payments totaled more than \$9 billion. Incentive payments will continue through 2021. (OAS; W-00-14-31351; W-00-15-31351; various reviews; expected issue date: FY 2016; 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 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-00-14-42002; W-00-15-42002; various reviews; expected issue date: FY 2016; Recovery Act)

## Cross-Cutting Enforcement Activities

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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 anti-reprisal 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)