

HHS / OIG Fiscal Year Work Plan: Mid-Year Update 2016

HHS / OIG FISCAL YEAR WORK PLAN: MID-YEAR
UPDATE 2016

HHS / OIG

Introductory Message from the Office of Inspector General

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Work Plan Mid-Year Update (Work Plan) for fiscal year (FY) 2016 summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the current fiscal year and beyond.

OIG's 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 (CMS), Administration for Children and Families (ACF), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH).

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 78 percent in 2015). 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 We Operate

OIG operates by providing 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 conducts audits of HHS programs and operations through 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 the economy, efficiency, and effectiveness of programs and operations 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. OEI also oversees the state Medicaid Fraud Control Units, which investigate and prosecute providers for Medicaid fraud as well as patient abuse or neglect.

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, the District of Columbia, and Puerto Rico, 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, self-disclosure, 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.

How 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 HHS programs and operations 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 potential projects to undertake, we consider a number of factors, including:

- mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget (OMB);
- top management and performance challenges (TMCs) facing HHS;
- work performed by other oversight organizations (e.g., GAO);
- management's actions to implement OIG recommendations from previous reviews; and
- potential for positive impact.

The Work Plan and Top Management & Performance Challenges Facing HHS

OIG annually prepares a summary of the most significant management and performance challenges facing HHS, the associated recommendations for improvement, and the Department's progress toward addressing them. Some of the TMCs reflect persistent and concerning vulnerabilities that OIG has highlighted for HHS over many years. Others forecast new and emerging issues that HHS will face in the upcoming year and beyond. To view the TMC website, visit <http://oig.hhs.gov/reports-and-publications/top-challenges/2015/>.

The 2015 HHS Top Management & Performance Challenges are below:

1. [Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse](#)

Enrollment in Medicaid and CHIP programs has grown by 15 million people since October 2013. Medicaid remains a top management priority given long-standing program integrity issues and expanding eligibility. CMS continues to make progress in addressing the challenges through new regulations and fresh dialogue with states. In addition to this progress, OIG has identified the following areas where CMS should take further action: oversight of Medicaid expansion, oversight of Medicaid Managed Care, improving the effectiveness of Medicaid data and systems, State policies that inflate Federal costs, and ensuring quality care for Medicaid beneficiaries.

2. [Fighting Fraud, Waste, and Abuse in Medicare Parts A and B](#)

The Department must be vigilant in reducing wasteful spending and promoting better health outcomes at lower costs. HHS faces challenges—and opportunities—in reducing improper payments, preventing and deterring fraud, and fostering economical payment policies. The Department has made progress in key areas, but more needs to be done to protect Medicare from waste, including fraud. CMS needs to better ensure that Medicare payments are accurate and appropriate. When Medicare improper payments occur, CMS needs to identify and recover them in a timely manner and must implement safeguards, as needed, to prevent recurrence. CMS relies on contractors for most of these crucial

functions; therefore, ensuring effective contractor performance is essential. Finally, the Medicare appeals system needs fundamental changes to resolve appeals efficiently, effectively, and fairly. OIG has recommended numerous actions to advance these outcomes.

3. [The Meaningful and Secure Exchange and Use of Electronic Information and Health Information Technology](#)

Health IT, including electronic health records (EHRs), offers opportunities for improved patient care, more efficient practice management, and improved overall public health. It will become increasingly important to measure the extent to which EHRs and other health IT achieve the Department's goals, and the Department must ensure that adopted policies advance the Nation towards those goals. The Department continues to face challenges safeguarding privacy and security of health IT, improving information flow, and ensuring a return on health IT investments. Threats to information privacy and security are evolving, and the Department must remain vigilant. The Department has made progress with respect to the privacy and security of its own information, but more remains to be done. The Department must also use available policy levers to address health IT privacy and security issues. As for the flow of information, the Department must do more to improve the flow, subject to appropriate privacy and security safeguards.

4. [Administration of Grants, Contracts, and Financial and Administrative Management Systems](#)

HHS is the largest grant-making organization in the Federal government with over \$402 billion awarded in FY 2014. The Department faces challenges with oversight of these Federal program dollars, specifically in response to grants and contract management, financial statement audit revelations of defective system controls, and improper payments. Recently, the Department has worked to strengthen its grants and contracts program integrity efforts. However, more can be done to identify poorly performing grantees and those at risk of mispending Federal dollars. More sustained focus is needed to address vulnerabilities and ensure that recipients use funds according to the award terms and consistent with the law.

5. [Ensuring Appropriate Use of Prescription Drugs](#)

CMS provides prescription drug coverage for 41 million Medicare Part D (Part D) and 71 million Medicaid beneficiaries. Part D is the fastest growing component of the Medicare program. The Department's management of its prescription drug programs faces numerous challenges in oversight, drug abuse and diversion, and questionable and inappropriate utilization. These ongoing and growing challenges elicit concern for beneficiary and community safety in addition to the integrity of the benefit itself. CMS has taken steps to improve data sharing and increase oversight by enrolling prescribers. Further actions are needed to achieve effective oversight, such as requiring sponsors to report probable fraud, waste, and abuse identified and corresponding actions.

6. [Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care](#)

As Americans continue to live longer and with more chronic medical conditions, the Department must ensure that beneficiaries receive high-quality nursing home, hospice, and home- and community-based

services (HCBS), including personal care services. Challenges exist with fraud, waste, and abuse with nursing home and hospice care and HCBS. The Department continues efforts to improve the quality of these services through implementation of new systems such as the Five Star Quality Rating System. OIG believes more should be done to prioritize quality care for this community to improve internal controls and offer better guidance and training for surveyors to ensure that nursing homes with recorded quality and safety issues correct their deficiencies.

7. [Implementing, Operating, and Overseeing the Health Insurance Marketplaces](#)

The health insurance marketplaces are critical components of the reforms enacted through the Patient Protection and Affordable Care Act (ACA). Implementation, operation, and oversight of the marketplaces were among the most significant challenges for the Department in recent years. Looking forward, OIG anticipates challenges with payments, eligibility determinations, management and administration, and the security of the marketplaces. Recently, the Department has reported improvement in the operations of the Federal marketplace; however, CMS must continue to strengthen operations of the Federal Marketplace and work with state-based marketplaces to ensure compliance with Federal requirements.

8. [Reforming Delivery and Payment in Health Care Programs](#)

In January 2015, Secretary Burwell announced goals to foster better care, smarter spending, and healthier people. To do this, HHS set specific goals to tie traditional Medicare payments to alternative payment models (APMs), and to quality and value. HHS is working with Medicaid programs, Medicare Advantage plans, and others to make comparable reforms. CMS must establish policy, infrastructure, data systems, program integrity and oversight mechanisms to successfully implement these and other changes. CMS must also strengthen Medicare Advantage to ensure that benefits are provided only to eligible beneficiaries, that data are available for fraud prevention and detection, and that plans have programs to address fraud and abuse.

9. [Effectively Operating Public Health and Human Services Programs](#)

The Department funds and operates public health and human services programs to promote health, and economic and social well-being. Effective management is essential to ensure that these programs achieve their goals and best serve the programs' intended beneficiaries. Specifically, the Department must focus on public health preparedness and emergency response, enabling access to and quality of services, and protecting vulnerable populations. OIG believes the Department should continue to collaborate with Federal, State, and community stakeholders and initiatives aimed at disaster response.

10. [Ensuring the Safety of Food, Drugs, and Medical Devices](#)

The Department, through the FDA, must ensure the safety, efficacy, and security of drugs, biologics, medical devices, dietary supplements, tobacco, and much of our Nation's food supply. Some areas are of particular high risk and pose challenges to the Department, including: compounded drugs, imported food and drugs, food facilities, off-label promotion and kickbacks, and dietary supplements. FDA has

taken steps to enhance its authority, warn consumers, and enforce actions. It must continue to protect consumers from potentially dangerous products.

What this Document Contains

Work planning is an ongoing and evolving process, and the Work Plan is updated throughout the year. OIG publically releases its Work Plan twice each year. This edition of the Work Plan describes OIG audits and evaluations that are underway or planned, and certain legal and investigative initiatives that are continuing. It also notes items that have been completed, postponed, or canceled and includes new items that have been started or planned since October 2015.

OIG posts its Work Plan and Work Plan Update online at <http://oig.hhs.gov/reports-and-publications/workplan/index.asp>. Because we make continuous adjustments to our work, as appropriate, we do not provide status reports on the progress of the reviews. However, if you have other questions about this publication, please contact us at public.affairs@oig.hhs.gov.

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What's New

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CMS: Medicare Parts A and B

- **COMPLETED:** Medicare Did Not Pay Select Inpatient Claims for Bone Marrow and Stem Cell Transplant Procedures in Accordance with Medicare Requirements ([A-09-14-02037](#)) – Issued February 2016.
- **COMPLETED:** Hospices Inappropriately Billed Medicare Over \$250 Million for General Inpatient Care ([OEI-02-10-00491](#)) – Issued March 2016.
- **COMPLETED:** CMS Has Not Performed Required Closeouts of Contracts Worth Billions ([OEI-06-14-00680](#)) – Issued December 2015.
- **COMPLETED:** National Background Check Program for Long-Term-Care Employees: Interim Report ([OEI-07-10-00420](#)) – Issued January 2016.
- **COMPLETED:** Enhanced Enrollment Screening Process for Medicare Providers: Early Implementation Results ([OEI-03-13-00050](#)) – Issued April 2016.
- **COMPLETED:** Part B Payments for 340B Purchased Drugs ([OEI 12-14-00030](#)) – Issued November 2015.
- **NEW:** Outpatient Outlier Payments for Short-Stay Claims
- **NEW:** Skilled Nursing Facility Prospective Payment System Requirements
- **NEW:** National Background Checks for Long-Term-Care Employees
- **NEW:** Potentially Avoidable Hospitalizations of Medicare and Medicaid Eligible Nursing Home Residents for Urinary Tract Infections
- **NEW:** Accountable Care Organizations: Beneficiary Assignment and Shared Savings Payments
- **NEW:** Medicare Home Health Fraud Indicators
- **NEW:** CMS' Implementation of New Medicare Payment System for Clinical Diagnostic Laboratory Tests
- **NEW:** Intensity-Modulated Radiation Therapy
- **REVISED:** Medicare Oversight of Provider-Based Status
- **REVISED:** Analysis of Salaries Included in Hospital Cost Reports
- **REVISED:** Home Health Prospective Payment System Requirements
- **REVISED:** Histocompatibility Laboratories – Supplier Compliance with Payment Requirements
- **REVISED:** Covered Uses for Medicare Part B Drugs
- **REVISED:** Inpatient Rehabilitation Facility Payment System Requirements
- **REMOVED:** Imaging Services – Payments for Practice Expenses
- **REMOVED:** End-Stage Renal Disease Facilities – Payment System for Renal Dialysis Services and Drugs
- **REMOVED:** Contract Management at the Centers for Medicare & Medicaid Services

CMS: Medicare Parts C and D

- **NEW:** Increase in Prices for Brand-Name Drugs under Part D
- **NEW:** Generic Drug Price Increases in Medicare Part D
- **NEW:** Part D Data Brief Update
- **REVISED:** Review of Financial Interests Reported under the Open Payments Program
- **REVISED:** Federal Payments for Part D Catastrophic Coverage
- **REVISED:** Medicare Part D Eligibility Verification Transactions
- **REMOVED:** Reconciliation of Payments – Sponsor Reporting of Direct and Indirect Remuneration

CMS: Medicaid

- **COMPLETED:** Inconsistencies in State Implementation of Correct Coding Edits May Allow Improper Medicaid Payments ([OEI-09-14-00440](#)) Issued April 2016.
- **COMPLETED:** Most Children With Medicaid in Four States Are Not Receiving Required Dental Services ([OEI-02-14-00490](#)) – Issued January 2016.
- **NEW:** Physician-Administered Drugs for Dual Eligible Enrollees
- **NEW:** Oversight and Effectiveness of Medicaid Waivers
- **NEW:** State Medicaid Fraud Control Unit FY 15 Annual Report
- **NEW:** States' Compliance with Requirements for Treatment of Health-Care Related Taxes on Medicaid Managed Care Organizations
- **NEW:** State Medicaid Agency Breach Protections and Responses
- **REVISED:** Medical Loss Ratio
- **REMOVED:** Analysis of Generic Price Increases Compared to Price Index

CMS: Health Insurance Marketplace Reviews

- **COMPLETED:** HealthCare.gov: Case Study of CMS Management of the Federal Marketplace ([OEI-06-14-00350](#)) – Issued February 2016.
- **NEW:** CMS Oversight of Risk Adjustment Data: Timelines, Validity, and Completeness
- **NEW:** Risk Corridors: Insights from 2014 and 2015
- **REVISED:** Consumer Operated and Oriented Plan Loan Program – CO-OP Conversion of Start-up Loans and CMS Monitoring Activities
- **REVISED:** CMS Oversight of Eligibility Determinations at State-Based Marketplaces

PHP: Food and Drug Administration

- **NEW:** FDA – Review of Prescription Drug User Fees
- **NEW:** FDA's Review of Networked Medical Device Cybersecurity during the Device Approval Process

PHP: Health Resources and Services Administration

- **REVISED:** HRSA – Oversight of Vulnerable Health Center Grantees

PHP: Indian Health Service

- **NEW:** Performance Improvement in IHS Hospitals: Application of Root Cause Analysis
- **NEW:** Case Study of IHS Management of Poorly Performing Hospitals
- **REVISED:** IHS – Hospital Oversight

PHP: National Institutes of Health

- **REMOVED:** NIH – Use of Appropriated Funds for Contracting

PHP: Substance Abuse and Mental Health Services Administration

- **NEW:** SAMHSA – Controls Over Opioid Treatment Programs

PHP: Other Public Health-Related Reviews

- **COMPLETED:** The Response to Superstorm Sandy Highlights the Importance of Recovery Planning for Child Care Nationwide ([OEI-04-14-00410](#)) – Issued December 2015.
- **NEW:** HHS Coordination of Roles and Responsibilities for Ebola Response Efforts
- **REMOVED:** Grantees’ Use of Prevention and Public Health Funds

HSR: Administration for Children and Families

- **NEW:** Head Start – Review of A-133 Audit Findings and Recommendations
- **NEW:** ORR – Unaccompanied Children Program Grantee Reviews
- **NEW:** Review of States’ CCDF Program Integrity Activities
- **NEW:** Recommendation Follow-Up: Office of Refugee Resettlement’s Post-Placement Activities for Unaccompanied Children

HSR: Administration for Community Living

- **NEW:** ACL: Senior Medicare Patrol Projects’ Performance Data

HSR: Other HHS-Related Reviews

- **NEW:** HHS Implementation of Recommendations Regarding its National Security Information Program

- **REVISED:** Audits of FYs 2015 and 2016 Consolidated HHS Financial Statements and Financial-Related Reviews
- **REVISED:** Compliance with Reporting Requirements for Improper Payments
- **REVISED:** Requests for Audit Services
- **REMOVED:** Office for Civil Rights' Oversight of the Security of Electronic Protected Health Information

Acronyms and Abbreviations

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ASPR	Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CY	calendar year
DHS	Department of Homeland Security
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
EHR	electronic health record
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FMAP	Federal Medical Assistance Percentage
FY	fiscal year
GAO	General Accountability Office
HHS	Department of Health and Human Services
HSR	Human Services Reviews
IHS	Indian Health Service
HRSA	Health Resources and Services Administration
MA	Medicare Advantage
MCO	managed care organization
MFCU	Medicaid Fraud Control Unit
NIH	National Institutes of Health
OIG	Office of Inspector General
OMB	Office of Management and Budget
PHP	Public Health Programs
Recovery Act	American Recovery and Reinvestment Act
SAMHSA	Substance Abuse and Mental Health Services Administration
SSA	Social Security Act
USDA	U.S. Department of Agriculture

Centers for Medicare & Medicaid Services

The programs of the Centers for Medicare & Medicaid Services (CMS), which include Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), account for over 80 percent of HHS's budget. The programs provide medical coverage for adults and children in certain statutorily defined categories. CMS is also responsible within HHS for the health insurance marketplaces and related programs under the ACA.

Total Federal program spending for Medicare, Medicaid, and CHIP was close to \$985 billion for FY 2015.¹ The amount spent on Medicare for this time period was approximately \$615 billion, which includes inpatient hospital, skilled nursing, home health, hospice, and physician services payments, as well as incentive payments for adopting health information technology, such as EHRs.² Enrollment in Medicaid and CHIP has grown by 14.1 million people since October 2013 to a total of 71 million individuals enrolled at the end of November 2015.³ Total Medicaid spending for FY 2014 was \$500 billion,⁴ including for payments for hospital, nursing facilities, home health care, prescription drugs, and personal care services.

Medicare Parts A and B

Medicare Part A covers certain inpatient services in hospitals and skilled nursing facilities (SNFs) 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. CMS uses Medicare Administrative Contractors to administer Medicare Part A and Medicare Part B and to process claims for both parts. In calendar year (CY) 2014, Medicare Parts A and B served approximately 34 million people and provided approximately \$350 billion in program payments.⁵

OIG has focused its Medicare oversight 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

¹ CMS.gov/fastfacts

² CMS.gov/fastfacts

³ Medicaid & CHIP: November 2015 Monthly Applications, Eligibility Determinations and Enrollment Report, <https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/november-2015-enrollment-report.pdf>

⁴ Medicaid & CHIP: November 2015 Monthly Applications, Eligibility Determinations and Enrollment Report, <https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/november-2015-enrollment-report.pdf>

Medicaid and CHIP Payment and Access Commission, <https://www.macpac.gov/macstats/program-enrollment-and-spending/>

⁵ CMS.gov/fastfacts

certification surveys and hospice-worker licensure requirements; oversight of SNFs' compliance with patient admission requirements; and evaluation of CMS's Fraud Prevention System.

Hospitals

NEW: Outpatient Outlier Payments for Short-Stay Claims

We will determine the extent of potential Medicare savings if hospital outpatient stays were ineligible for an outlier payment. CMS makes an additional payment (an outlier payment) for hospital outpatient services when a hospital's charges, adjusted to cost, exceed a fixed multiple of the normal Medicare payment (Social Security Act (SSA) § 1833(t)(5)). The purpose of the outlier payment is to ensure beneficiary access to services by having the Medicare program share in the financial loss incurred by a provider associated with individual, extraordinarily expensive cases. Prior OIG reports have concluded that a hospital's high charges, unrelated to cost, lead to excessive inpatient outlier payments.

OAS: W-00-16-35775. Expected to be issued in FY 2017

NEW: Intensity-Modulated Radiation Therapy

We will review Medicare outpatient payments for intensity-modulated radiation therapy (IMRT) to determine whether the payments were made in accordance with Federal requirements. 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. In addition, IMRT is provided in two treatment phases: planning and delivery. 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, effective January 1, 2008.)

OAS: W-00-15-35733; various reviews. Expected to be issued in FY 2016

REVISED: Medicare Oversight of Provider-Based Status

We will determine the number of provider-based facilities that hospitals own and review CMS oversight of provider-based billing. We will also determine the extent to which selected 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 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 to be issued in FY 2016

REVISED: 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 Medicare. Medicare does not provide any specific limits on the salary amounts that can be reported on the hospital cost report. We will analyze the amounts of salaries included in Medicare cost reports, report on the range of salaries, and determine the cost savings that could be achieved at various Federal compensation benchmarks.

OAS: W-00-13-35713. Expected to be issued in 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. We will also assess the potential impact on Medicare and beneficiaries of hospitals' claiming provider-based status for such facilities. Provider-based facilities often receive higher payments for some services than freestanding clinics. The requirements that a facility must meet to be treated as provider-based are at 42 CFR § 413.65(d).

OAS: W-00-14-30026; W-00-15-30026. Expected to be issued in FY 2016

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. 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).) 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.

OAS: W-00-14-35451; W-00-15-35451; W-00-16-35778; various reviews. Expected to be issued in 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 by comparing claims for hospital stays in the year prior to and 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, to address concerns about hospitals' use of short inpatient and long outpatient stays. The rule establishes that it is generally appropriate to admit beneficiaries as inpatients if their care is expected to last at least 2 midnights; otherwise, they should be treated as outpatients. This rule represents a 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 to be issued in FY 2017

Medicare Costs Associated with Defective Medical Devices

We will review Medicare claims to identify the costs resulting from additional use of medical services associated with defective medical devices and determine the impact of those additional services on the Medicare Trust Fund. CMS has previously expressed concerns about the impact of the cost of replacement devices, including medical care/services resulting from defective devices, on Medicare payments for inpatient and outpatient services.

OAS: W-00-15-35516; various reviews. Expected to be issued in FY 2016

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 Medicare Administrative Contractors have made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices.

OAS: W-00-15-35745; various reviews. Expected to be issued in FY 2016

Medicare Payments for Overlapping Part A Inpatient Claims and Part B Outpatient Claims

We will review Medicare payments to certain types of inpatient hospitals to determine whether outpatient claims billed to Medicare Part B for services provided during inpatient stays were made in accordance with Federal requirements. 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 reviews and investigations have identified this area as at-risk for noncompliance with Medicare billing requirements.

OAS: W-00-15-35752. Expected to be issued in FY 2016

Inpatient Claims for Mechanical Ventilation

We will review Medicare payments for inpatient hospital claims that require mechanical ventilation to determine whether hospitals' Diagnosis Related Group (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. 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 to be issued in 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 reviews and investigations 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 to be issued in 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 determined that hospitals 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 to be issued in FY 2016

Indirect Medical Education Payments

We will review provider data to determine whether hospitals' indirect medical education (IME) payments were made in accordance with Federal requirements. We will determine whether the IME payments were calculated properly. Prior OIG reviews determined that hospitals received excess reimbursement for IME costs. Teaching hospitals with residents in approved graduate medical education programs receive additional payments for each Medicare discharge to reflect the higher indirect patient care costs of teaching hospitals relative to those of nonteaching hospitals. (42 U.S.C. § 1395ww (d) (5) (B).) The additional payments, known as the IME adjustments, are calculated using the hospital's ratio of resident full time equivalents to available beds.

OAS: W-00-14-35722; W-00-15-35722. Expected to be issued in 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 Federal requirements. OIG audits have indicated that

hospitals received Medicare reimbursement for non-covered dental services, resulting in significant overpayments. Dental services are generally excluded from Medicare coverage, with a few exceptions. (SSA § 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. 10002, Ch. 15, § 150).

OAS: W-00-14-35603; W-00-15-35603; various reviews. Expected to be issued in 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 Federal 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.

OAS: W-00-14-35721; W-00-15-35721; various reviews. Expected to be issued in 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. 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 to be issued in 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. (SSA § 1886(d)(3) and 1886(d)(3)(E).)

OAS: W-00-14-35725; W-00-15-35725; various reviews. Expected to be issued in FY 2016

CMS Validation of Hospital-Submitted Quality Reporting Data

We will determine the extent to which CMS validated hospital inpatient quality reporting data. CMS is required to establish a process to conduct validation of its quality reporting program (SSA § 1886(b)(3)(B)(viii)(XI)). 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 to be issued in FY 2016

Rehabilitation 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 postacute care in rehabilitation hospitals. 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. Rehabilitation hospitals 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 acute care hospital, beneficiaries often require extensive services to improve functioning before returning home. In 2012, 236 rehabilitation hospitals provided care to Medicare beneficiaries with a total of \$2.3 billion in Medicare spending.

OEI: 06-14-00110. Expected to be issued in 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 skilled nursing facilities and inpatient rehabilitation facilities, accounting for nearly 11 percent of Medicare costs for post-acute care (\$5.4 billion in FY 2011).

OEI: 06-14-00530. Expected to be issued in FY 2017

Hospital Preparedness and Response to Emerging Infectious Diseases

We will describe hospitals' efforts to prepare for the possibility of public health emergencies resulting from emerging infectious disease threats. Several HHS agencies, including CDC, Office of the Assistant Secretary for Preparedness and Response (ASPR), and CMS provide resources, i.e., guidance and support, for hospitals as they prepare for emerging infectious disease threats. Additionally, we will determine hospital use of HHS resources and identify lessons and challenges faced by hospitals as they prepare to respond to emerging infectious disease threats, 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 to be issued in FY 2017

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-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 electronic protected health information (45 CFR, Part 164 § 308(7)(i)).

OEI: 01-14-00570. Expected to be issued in FY 2016

Nursing Homes

NEW: Skilled Nursing Facility Prospective Payment System Requirements

We will review compliance with the skilled nursing facility (SNF) prospective payment system requirement related to a 3-day qualifying inpatient hospital stay. Medicare requires a beneficiary to be an inpatient of a hospital for at least 3 consecutive days before being discharged from the hospital, in order to be eligible for SNF services (SSA § 1861(i)). If the beneficiary is subsequently admitted to a SNF, the beneficiary is required to be admitted either within 30 days after discharge from the hospital or within such time as it would be medically appropriate to begin an active course of treatment. Prior OIG reviews found that Medicare payments for SNF services were not compliant with the requirement of a 3-day inpatient hospital stay within 30 days of an SNF admission.

OAS: W-00-15-35744. Expected to be issued in FY 2017

NEW: Potentially Avoidable Hospitalizations of Medicare and Medicaid Eligible Nursing Home Residents for Urinary Tract Infections

We will review nursing home records for residents hospitalized for urinary tract infections (UTI) to determine if the nursing homes provided services to prevent or detect UTIs in accordance with their care plans before they were hospitalized. A CMS-sponsored study identified UTIs as being associated with potentially avoidable hospitalizations and found that UTIs are generally preventable and manageable in the nursing home setting. UTIs acquired during the course of health and medical care could indicate poor quality of care. In a hospital setting, there are payment implications for hospital-acquired catheter-associated urinary tract infections. Nursing homes must develop and follow comprehensive care plans addressing each resident's care needs, which includes urinary incontinence (42 CFR § 483.25(d)).

OAS: W-00-14-31040. Expected to be issued in FY 2016

NEW: National Background Checks for Long-Term-Care Employees — Mandatory Review

We will review the procedures implemented by participating States for long-term-care facilities or providers to conduct background checks on prospective employees and providers who would have direct access to patients and determine the costs of conducting background checks. We will determine

the outcomes of the States' programs and determine whether the checks led to any unintended consequences. This mandated work will be issued at the program's conclusion as required, which is expected to be 2018 or later. (ACA, § 6201.)

OEI: 07-16-00160. Expected issue date: FY 2019

Hospices

Hospice General Inpatient Care

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. OIG has multiple ongoing reviews involving hospice care examining a variety of issues. We will assess the content of election statements for hospice beneficiaries who receive general inpatient care. We will also review hospice medical records to address concerns that a certain 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. In addition, we will also determine whether Medicare payments for hospice services were made in accordance with Medicare requirements.

OEI: 02-10-00492; OAS: W-00-15-35743; various reviews. Expected to be issued in FY 2016

Home Health Services

NEW: Medicare Home Health Fraud Indicators

We will describe the extent that potential indicators associated with home health fraud are present in home health billing for 2014 and 2015. We will analyze Medicare claims data to identify the prevalence of potential indicators of home health fraud. The Medicare home health benefit has long been recognized as a program area vulnerable to fraud, waste, and abuse. OIG has a wide portfolio of work involving home health fraud, waste, and abuse.

OEI: 05-16-00031. Expected to be issued in FY 2016

REVISED: Home Health Prospective Payment System Requirements

We will review compliance with various aspects of the home health prospective payment system, 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 requirements. 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; W-00-16-35712; various reviews. Expected to be issued in FY 2016

Medical Equipment and Supplies

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; W-00-16-35756; various reviews. Expected to be issued in FY 2016

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 (the period of consecutive months of rental at which the Medicare payment is capped) 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 for these devices from 2012 to 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; W-00-16-35747; various reviews. Expected to be issued in FY 2016

Power Mobility Devices – Lump-Sum Purchase versus Rental

We will determine whether potential savings can be achieved by Medicare if certain power mobility devices are rented over a 13-month period (the period of consecutive months of rental at which the Medicare payment is capped) rather than acquired through a lump-sum purchase. Power Operated Vehicles (POVs) – also known as scooters – and Power Wheelchairs (PWCs) are collectively classified as PMDs and covered under the Medicare Part B Durable Medical Equipment (DME) benefit. CMS defines a PMD as a covered DME item that a patient uses in the home. From 2010 to 2014, Medicare payments for complex PMDs totaled \$343 million. Effective January 1, 2011, the ACA eliminated the lump-sum purchase option for standard PWCs. For PMDs not affected by ACA, the beneficiary has the option of either purchasing or renting the PMD.

OAS: W-00-15-35223; various reviews. Expected to be issued in FY 2016

Competitive Bidding for Medical Equipment Items and Services – Mandatory Review

We will review the process CMS used to conduct competitive bidding and to make subsequent pricing determinations for certain medical equipment items and services in selected competitive bidding areas

under rounds 1 and 2 of the competitive bidding program. Federal law requires OIG to conduct post-award audits to assess this process. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(1)(E).)

OAS: W-00-13-35241; W-00-14-35241; various reviews. Expected to be issued in FY 2016

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." (SSA § 1862(a)(1)(A).) Further, local coverage determinations issued by the four Medicare contractors that process DMEPOS claims include utilization guidelines and documentation requirements for orthotic braces.

OAS: W-00-15-35749; W-00-16-35749. Expected to be issued in FY 2016

Increased Billing for Ventilators

We will describe billing trends for ventilators, Respiratory Assist Devices (RAD), and Continuous Positive Airway Pressure (CPAP) devices from 2011 to 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 local coverage determinations 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 to be issued in FY 2016

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-00-15-35223; W-00-16-35223; various reviews. Expected to be issued in 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 CY 2014, Medicare paid approximately \$632.8 million for inhalation drugs. A preliminary OIG review identified that at least 50 percent of claims reviewed were not paid in accordance with Medicare requirements. Medicare requires that such items be "reasonable and necessary." (SSA § 1862(a)(1)(A).) Further, the local coverage determinations 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 to be issued in 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 local coverage determinations (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." (SSA, § 1862(a)(1)(A).)

OAS: W-00-14-35604; W-00-15-35604; W-00-16-35604; various reviews. Expected to be issued in FY 2016

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 DMEPOS subject to competitive bidding. In an effort to reduce waste, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 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 particular geographic areas. Anecdotal reports allege that competitive bidding has led to reduced access to DMEPOS and, in turn, compromised the quality of care that beneficiaries receive.

OEI: 01-15-00040; various reviews. Expected to be issued in FY 2016

Other Providers and Suppliers

NEW: CMS' Implementation of New Medicare Payment System for Clinical Diagnostic Laboratory Tests – Mandatory Review

We will assess CMS's ongoing activities and progress toward implementing CMS's new Medicare payment system for clinical diagnostic laboratory tests. CMS is required to replace its current system of determining payment rates for Medicare Part B clinical diagnostic laboratory tests with a new market-based approach that will use rates paid to laboratories by private payers (Protecting Access to Medicare Act of 2014, § 216). OIG is also required to conduct analyses of the implementation and effect of the new payment system (Protecting Access to Medicare Act of 2014, § 216).

OEI: 09-16-00100. Expected to be issued in FY 2016

REVISED: Inpatient Rehabilitation Facility Payment System Requirements

We will review compliance with various aspects of the inpatient rehabilitation facility (IRF) prospective payment system (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 requirements. IRFs provide rehabilitation for patients recovering 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 must be met to ensure that IRF care is reasonable and necessary (42 CFR § 412.622(a)(3), (4) & (5); CMS's Medicare Benefit Policy Manual, Pub. 100-02, Ch. 1, § 110). (74 Fed. Reg. 39762, 39788).

OAS: W-00-15-35730. Expected to be issued in FY 2016

REVISED: Histocompatibility Laboratories – Supplier Compliance with Payment Requirements

We will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements. Histocompatibility laboratories provide matching tests in preparation for organ and tissue transplantation. These laboratories may be hospital-based or independent. 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; must be 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 to be issued in FY 2017

Ambulatory Surgical Centers – Quality Oversight

We will review Medicare's quality oversight of ambulatory surgical centers (ASCs). Previous OIG work found problems with Medicare's oversight system, including finding spans of 5 or more years between certification surveys for some ASCs, poor CMS oversight of State survey agencies, and little public

information on the quality of ASCs. Medicare sets minimum health and safety requirements for ASCs through the conditions for coverage. (SSA, § 1832(a)(2)(F)(i).) CMS requires that ASCs become Medicare-certified to show that they meet these conditions. (SSA, § 1865 and 42 CFR Part 416.)

OEI: 01-15-00400. Expected to be issued in FY 2017

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. CMS was required 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.) Prior OIG work identified potential savings of as much as \$15 billion for CYs 2012 through 2017 if CMS reduces outpatient department payment rates for ASC-approved procedures to ASC payment levels for procedures performed on beneficiaries with low-risk and no-risk clinical needs.

OAS: W-00-13-35423; W-00-14-35423; W-00-15-35423; W-00-16-35423; various reviews. Expected to be issued in FY 2016

Payments for Durable Medical Equipment Referred or Ordered by Physicians

We will review select Medicare services, supplies, and DMEPOS referred/ordered by physicians and non-physician practitioners to determine whether the payments were made in accordance with Medicare requirements. CMS requires that physicians and non-physician practitioners who order certain services, supplies, and/or durable medical equipment (DME) are required to be Medicare-enrolled physicians or non-physician practitioners and legally eligible to refer/order services, supplies, and DME (ACA § 6405). 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; W-00-16-35748. Expected to be issued in FY 2016

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." (SSA, §1862(a)(1)(A).)

OAS: W-00-15-35749; W-00-16-35749. Expected to be issued in FY 2016

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. From January 2013 through December 2015, Medicare made \$718 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." (SSA, §1862(a)(1)(A).)

OAS: W-00-15-35754; W-00-16-35754. Expected to be issued in FY 2016

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 E/M 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 E/M 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; W-00-16-35755. Expected to be issued in FY 2016

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. (SSA, § 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; W-00-15-35574; W-00-16-35574; various reviews. Expected to be issued in 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. 10004, 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 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. (SSA, § 1833(e).)

OAS: W-00-13-35706; W-00-14-35706; W-00-15-35706; W-00-16-35706; various reviews. Expected to be issued in FY 2016

Chiropractic Services – Part B Payments for Non-Covered 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. 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. 10002, Ch. 15, § 30.5B.) Medicare will not pay for items or services that are not "reasonable and necessary." (SSA, § 1862(a)(1)(A).)

OAS: W-00-13-35606; W-00-14-35606; W-00-15-35606; W-00-16-35606; various reviews. Expected to be issued in 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. This planned work will offer recommendations to reduce Medicare chiropractic vulnerabilities that were detected in prior OIG work.

OAS: W-00-16-35770; OIG-12-14-03. Expected to be issued in 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. (SSA, § 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; W-00-16-35726; various reviews. Expected to be issued in FY 2016

Medicare Clinical Laboratory Payments: Annual Analysis of Top 25 Tests – Mandatory Review

We will analyze Medicare expenditures for the top 25 clinical laboratory tests performed in 2015, building upon our previous analysis of Medicare Part B laboratory test expenditures in 2014. The previous OIG work found that Medicare paid more than other insurers for certain high-volume and high-expenditure laboratory tests. CMS is required to replace its current system of determining payment rates for Medicare Part B clinical diagnostic laboratory tests with a new market-based approach that will use rates paid to laboratories by private payers (Protecting Access to Medicare Act of 2014, § 216). Pursuant to a requirement of the Protecting Access to Medicare Act, OIG will conduct an annual analysis and monitor Medicare expenditures and the new payment system for laboratory tests.

OEI: 09-16-00040. Expected to be issued in 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 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.” (SSA, § 1862(a)(1)(A).) Documentation requirements for therapy services are in CMS's Medicare Benefit Policy Manual, Pub. No. 10002, 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; W-00-16-35220; various reviews. Expected to be issued in 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; W-00-16-35464. Expected to be issued in 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 payment appropriateness and whether they were in accordance with other Medicare requirements. An OIG analysis of CY 2010 Medicare

payments for Current Procedural Terminology⁶ 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.” (SSA, § 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 to be issued in FY 2016

CMS Oversight of Provider Ownership Information

We will determine the extent to which CMS collects required ownership information for provider entities enrolled in Medicare, and we will describe the extent to which they verified the collected information. We will also determine whether CMS checked exclusions databases for enrolling and enrolled providers, as required. Finally, we will compare the ownership information that selected providers gave to CMS to enroll in Medicare, and that providers gave to States to enroll in Medicaid, to the ownership information that the same providers gave to OIG for the purposes of this study. Federal regulations require 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: 04-11-00591. Expected to be issued in FY 2016

Prescription Drugs

REVISED: Covered Uses for Medicare Part B Drugs

We will determine the methods and sources Part B contractors use to make and update drug coverage determinations. We will also identify challenges contractors face when making coverage decisions for drugs. If Part B Medicare Administrative Contractors (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 that are approved by FDA when they are used to treat conditions specified on the drug’s label. However, each MAC determines whether a particular use (including a use not approved by FDA) is covered in its jurisdiction, taking into consideration major drug compendia,

⁶ The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2015 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.

authoritative medical literature, and/or accepted standards of medical practice. (Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 15, § 50.4.2.)

OEI: 03-13-00450. Expected to be issued in FY 2016

Comparison of Average Sales Prices to Average Manufacturer Prices – Mandatory Review

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. (SSA, § 1847A(d)(2)(B).) Pursuant to the requirement, OIG conducts such reviews and issues quarterly and annual reports of its findings. When OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent), OIG notifies the Secretary of HHS, who may disregard the ASP for the drug when setting reimbursement amounts (e.g., apply a price substitution policy).

OEI: OEI-03-16-00230; OEI-03-16-00250. Expected to be issued in FY 2016

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 FDA-approved immunosuppressive drugs and drugs used in immunosuppressive therapy when a beneficiary receives an organ transplant for which immunosuppressive therapy is appropriate. (SSA, § 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 to be issued in FY 2016

Part A and B Contractors

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 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 to be issued in 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 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 to be issued in FY 2016

Contractor Postretirement Benefits and Supplemental Employee Retirement Plan Costs – Mandatory Review

We will review the postretirement health benefit costs and the supplemental employee retirement plans of Medicare fiscal intermediaries and carriers to determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts. 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 to be issued in FY 2016

Medicare Contractor Information Systems Security Programs: Annual Report to Congress – Mandatory Review

We will review independent evaluations of information systems security programs of Medicare Administrative Contractors (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-00-16-41010. Expected to be issued in FY 2016

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 and variations in integrity activities and allow for a quick comparison of program results across years, across contractors, and across 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 and Zone Program Integrity Contractors carry out benefit

integrity activities for Medicare Parts A and B, and a Medicare Drug Integrity Contractor carries out benefit integrity activities for Medicare Parts C and D.

OEI: 03-13-00620. Expected to be issued in FY 2016

Collection Status of ZPIC and PSC – Identified Medicare Overpayments

We will determine the total amount of overpayments that Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (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 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 to be issued in FY 2017

Other Part A and B Program Management Issues

Delivery System Reform

NEW: Accountable Care Organizations: Beneficiary Assignment and Shared Savings Payments

We will review the CMS Medicare Shared Savings Program (MSSP) to determine whether beneficiary assignment to Accountable Care Organizations (ACOs) and shared savings payments for assigned beneficiaries complied with Federal requirements. Our review will determine whether CMS properly performed the process of assigning beneficiaries to ACOs in the MSSP. We will also examine CMS's shared savings payments for beneficiaries who were assigned to ACOs under the MSSP to ensure that there is no duplication of payments for the same beneficiaries by other savings programs or initiatives. (42 CFR §425.402 and 42 CFR § 425.114 (c).)

OAS: W-00-16-35774; various reviews. Expected to be issued in FY 2017

Accountable Care Organizations: Strategies and Promising Practices

We will review Accountable Care Organizations (ACOs) that participate in the Medicare Shared Savings Program (MSSP, established by section 3022 of the ACA). We will describe their performance on the quality measures and cost savings over the first 3 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 MSSP 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 to be issued in FY 2017

Use of Electronic Health Records to Support Care Coordination through ACOs

We will review the extent to which providers participating in Accountable Care Organizations in the Medicare Shared Savings Program (MSSP) use 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 MSSP 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: 01-16-00180. Expected to be issued in FY 2017, ACA

Billing and Payments

Medicare Payments for Unlawfully Present Beneficiaries in the United States – Mandatory 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. Medicare payment may not be made for items and services furnished to individuals who are not lawfully present in the United States (Personal Responsibility and Work Opportunity Reconciliation Act of 1996, § 401; Medicare Claims Processing Manual, Ch. 1, §10.1.4.8). Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted in April 2015, requires the Secretary of HHS 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. A prior OIG review identified \$91.6 million in improper payments made to providers for services rendered to unlawfully present beneficiaries for CYs 2010 through 2012. 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 to be issued in FY 2016

Medicare Payments for Incarcerated Beneficiaries – Mandatory Review

We will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to incarcerated beneficiaries. In general, Medicare does not pay for services rendered to incarcerated beneficiaries because they do not have a legal obligation to pay (SSA, § 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 HHS to establish and maintain procedures to ensure that Medicare does not pay for services rendered to incarcerated beneficiaries. A prior OIG review identified \$33.6 million in 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 to be issued in FY 2016

CMS Management of the ICD-10 Implementation

We will review aspects of CMS's management of the implementation of the 10th version of the International Classification of Diseases (ICD-10) codes in Medicare Parts A and B. This may include reviewing CMS' 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 October 1, 2015, Medicare claims with a date of service on or after October 1, 2015, were 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 advised providers that it is allowing 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 to be issued in FY 2017

Medicare Parts C and D

Medicare Part C offers Medicare beneficiaries a managed care option through 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. 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.

Medicare Part D, also called the Medicare prescription drug benefit, is a Federal program to subsidize the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries. Medicare expended over \$77 billion in Part D benefit payments in CY 2014, serving over 37 million beneficiaries.⁷ Part D administration depends on 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

⁷ Cms.gov/fastfacts

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. HHS faces numerous challenges in managing its Part D program, including oversight, drug abuse and diversion, and questionable and inappropriate utilization.

Part C – Medicare Advantage

Medicare Advantage Organization Practices in Puerto Rico

We will determine whether 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 § 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 § 1852 (c)(1)(A) and (C).

OAS: W-00-15-35734. Expected to be issued in FY 2016

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 to be issued in 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. In general, MA organizations receive higher payments for sicker patients. 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. (SSA, §§ 1853(a)(1)(C) and (a)(3).)

OAS: W-00-14-35078; W-00-15-35078; various reviews. Expected to be issued in FY 2016

Part D – Prescription Drug Program

NEW: Generic Drug Price Increases in Medicare Part D

We will review the average rate of increase in prices for drugs covered under Medicare Part D from 2010 – 2015 and the percentage of generic drugs decreased/increased in price. We will also determine whether certain generic manufacturers are more likely to increase their prices and the effect of increased generic prices on beneficiaries. CMS estimates that Part D spending totaled \$69 billion in 2013. Although brand-name drugs accounted for the majority of Part D expenditures, due to their higher cost, the top 10 most prescribed drugs that year were all generics. In fact, 22 generic drugs accounted for 69 percent of the total number of claims, but only 15 percent of spending, for the costliest 100 Part D drugs.

OEI: 12-16-00130. Expected to be issued in FY 2017

NEW: Part D Data Brief Update

In 2015, OIG released a data brief, entitled *Questionable Billing and Geographic Hotspots Point to Fraud and Abuse in Medicare Part D (OEI-02-15-00190)*. It found that, between 2006 and 2014, Medicare spending for commonly abused opioids grew faster than spending for all Part D drugs. The purpose of this data brief is to provide updated data on Part D billing trends. In addition to focusing on commonly abused opioids, it will also examine billing trends for compounded drugs.

OEI-02-16-00290. Expected to be issued in FY 2016

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 2011 and 2015 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 8 times greater than the general inflation rate for the same year.

OEI: 03-15-00080. Expected to be issued in 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 how much Medicare paid for drugs and medical supplies ordered by physicians who had financial relationships with manufacturers and group purchasing organizations (GPOs) reported in the Open Payments system. Further, we will determine the

extent to which data in the open payments system is missing or inaccurate and the extent to which CMS oversees manufacturers' and GPOs' compliance with data reporting requirements and whether the required data for physician and teaching hospital payments are valid. Manufacturers are required to disclose to CMS payments made to physicians and teaching hospitals (ACA § 6002). 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 to be issued in FY 2017

REVISED: Federal Payments for Part D Catastrophic Coverage

We will analyze trends in Federal Government reinsurance subsidy payments to Medicare Part D plan sponsors between 2010 and 2014. We will also analyze trends in prescription drug events for drugs dispensed to beneficiaries who have entered the catastrophic coverage portion of their Part D benefit. A beneficiary enters catastrophic coverage when their drug spending exceeds a certain threshold that is determined annually. The Federal Government's reinsurance subsidy covers 80 percent of catastrophic drug costs. (SSA, § 1860D-15.)

OEI: 02-16-4-00270. Expected to be issued in FY 2017

REVISED: Medicare Part D Eligibility Verification Transactions

We will review CMS' oversight of E1 transactions processed by contractors and whether the E1 transactions were created and used for intended purposes. Also, we will review E1 transactions to assess the validity of the data. An E1 transaction is a Medicare Eligibility Verification transaction that the pharmacy submits to the TrOOP (True Out-of-Pocket) facilitator to determine beneficiary's eligibility to the Part D program and Part D insurance coverage information. The TrOOP facilitator returns information to the pharmacy that is needed to submit the prescription drug event (PDE). 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 to be issued in FY 2017

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. Exposure to inappropriate drug pairs could result in harm to patients.

OAS: W-00-15-35750. Expected to be issued in FY 2017

Part D Pharmacy Enrollment

We will review CMS's ability to oversee pharmacies that bill for Part D drugs. 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. Currently, CMS must rely on Part D plan sponsors to follow up and take action against problematic pharmacies. Unlike Medicare fee-for-service providers, Part D pharmacies are not required to enroll in Medicare. However, they may enroll for other reasons. For example, pharmacies that bill Medicare for durable medical equipment under Medicare Part B must enroll in Medicare fee-for-service. As a result, CMS screens these pharmacies to ensure that they meet the requirements to be a Medicare provider. CMS also has the authority to revoke their enrollment. We will determine the extent to which pharmacies that bill for Part D drugs, especially those identified as high risk, are enrolled in Medicare fee-for-service.

OEI: OEI-02-15-00440. Expected to be issued in FY 2017

Ensuring Dual Eligibles' Access to Drugs under Part D – Mandatory Review

We will review the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries, as required. Dual-eligible beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as Part D plans meet certain limitations outlined in 42 CFR § 423.120, they have discretion to include different Part D drugs and drug utilization tools in their formularies. The ACA, § 3313, requires OIG to conduct this review annually.

OEI: 05-16-00090. Expected to be issued in FY 2016

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. Prior OIG work 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 to be issued in FY 2016

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 prescription drug event 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 of HHS to determine payments to the plans. (SSA, § 1860D-15(f)(1).)

OAS: W-00-14-35411; W-00-15-35411; various reviews. Expected to be issued in 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. HHS is required 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. (SSA, § 1860D14A, 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 to be issued in FY 2016

Medicaid Program

The Federal Government and States jointly fund Medicaid, which provides medical assistance to certain low-income individuals and individuals with disabilities. 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 payment and delivery models; Medicaid managed care, including 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. In addition, OIG plans to expand its examination of the quality and safety of care provided in a variety of home- and community-based settings, including Medicaid personal care services.

Medicaid Prescription Drug Reviews

NEW: Physician-Administered Drugs for Dual Eligible Enrollees

We will determine whether Medicare requirements for processing physician-administered drug claims impact State Medicaid agencies' ability to correctly invoice Medicaid drug rebates for dual eligible enrollees. Dual eligible describes individuals who are enrolled in both Medicare and Medicaid. States

are required to collect rebates on physician-administered drugs. To collect these rebates, State agencies must submit to the manufacturers the National Drug Codes for all single-source drugs and for the top 20 multiple-source physician-administered drugs. For dual eligible enrollees, covered Medicare Part B prescription drugs received in a hospital outpatient setting (which include physician-administered drugs) require a copayment, which Medicaid is generally responsible for paying. If a State agency paid any portion of a drug claim to the provider, the State agency must then invoice the eligible drugs for rebate and the manufacturer would thus be liable for payment of the rebate.

OAS: W-00-16-31512. Expected to be issued in FY 2017

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 to be issued in FY 2017

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 will also review State oversight of and coordination with MCO's 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 must 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 to be issued in FY 2016

Manufacturer Compliance with AMP Reporting Requirements

We will determine manufacturer compliance with average manufacturer price (AMP) reporting requirements and identify actions that CMS has taken to improve compliance with those requirements. Manufacturer-reported AMPs – which are used to calculate Medicaid rebates, 340B prices, and in Part B price substitutions – play a critical role in Federal cost containment strategies for prescription drugs. Certain drug manufacturers must report AMP data to CMS on a quarterly and monthly basis. (SSA

§ 1927(b)(3); 42 CFR § 447.510(a) & (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 to be issued in 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. (SSA, § 1927(a).)

OAS: W-00-14-31400; W-00-16-31400; various reviews. Expected to be issued in FY 2016

States' Collection of Rebates for Drugs Dispensed to Medicaid MCO Enrollees

We will determine whether 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 to be issued in FY 2016

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 ACA 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 to be issued in FY 2017

Treatment of Authorized Generic Drugs

We will review drug manufacturers' treatment of sales of authorized generics in their calculation of average manufacturer price (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 the AMP, and consequently, a lower rebate would be paid to the State.

OAS: W-00-15-31499. Expected to be issued in FY 2016

State Claims for Federal Reimbursement

Medicaid Payments for Multiuse Vials of Herceptin

We will review States' claims for the Federal share of Medicaid payments for the drug Herceptin, which is used to treat breast cancer, to determine whether providers properly billed the States for the drug. We will determine whether providers' claims to States were complete and accurate and were billed in accordance with the regulations of the selected States. Prior OIG audits of Herceptin have shown provider noncompliance with Medicare billing requirements. Similar issues may occur in Medicaid.

OAS: W-00-15-31476; various reviews. Expected to be issued in FY 2016

Home Health Services and Other Community-Based Care

NEW: Oversight and Effectiveness of Medicaid Waivers

We will determine the extent to which selected States made use of Medicaid waivers and if costs associated with the waivers are efficient, economic, and do not inflate Federal costs. We will also look at oversight of State Medicaid waivers. More States are using waivers to alter their Medicaid program in significant ways. Oversight of State waiver programs present challenges to ensure that payments made under the waivers are consistent with efficiency, economy, and quality of care and do not inflate Federal costs.

OAS: W-00-16-31513. Expected to be issued in FY 2017

Adult Day Health Care Services

We will review Medicaid payments by States for adult day health 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 waivers. (SSA, § 1915, and 42 CFR § 440.180.) Prior OIG work shows that these payments do not always comply with Federal and State requirements.

OAS: W-00-16-31386; various reviews. Expected to be issued in FY 2017

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 home- and community-based services (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).) 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-00-16-31465; various reviews. Expected to be issued in FY 2017

Other Medicaid Services, Equipment, and Supplies

Express Lane Eligibility – Mandatory Review

We will determine the extent to which selected States made inaccurate eligibility determinations using the Express Lane Option for Medicaid and 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 and challenges of such use, and the efforts and barriers to employing and extending ELE to renewal and adult applications.

OAS: W-00-15-31485; OEI: 06-15-00410; various reviews. Expected to be issued in FY 2016

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; W-00-16-31121; various reviews. Expected to be issued in FY 2017

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. (SSA, § 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; W-00-16-31452; various reviews. Expected to be issued in FY 2017

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. (SSA, §§ 1905(a)(4)(B) and 1905(r).) Federal regulations define “dental services” as diagnostic, preventative, or corrective procedures provided by or under the supervision of a dentist. (42 CFR § 440.100.) Services include the treatment of teeth and the associated structure of the oral cavity and disease, injury, or impairment that may affect the oral cavity or general health of the recipient.

OAS: W-00-13-31135; W-00-15-31135; W-00-16-31135. Expected to be issued in FY 2017

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. (SSA, § 1903(a)(5).)

OAS: W-00-15-31078; various reviews. Expected to be issued in 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. Section 2401 of the ACA added section 1915(k) to the SSA, 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-00-16-31495. Expected to be issued in FY 2017

Payments to States under the Balancing Incentive Program

We will review expenditures that 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 non-institutional LTSS. The States must also use the additional Federal funding for the purposes of providing new or expanded offerings of non-institutional LTSS.

OAS: W-00-15-31482; W-00-16-31482; various reviews. Expected to be issued in FY 2017

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-00-15-31502; W-00-16-31502; various reviews. Expected to be issued in FY 2017

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.

OAS: W-00-14-31040; W-00-16-31040; various reviews. Expected to be issued in FY 2017

State Management of Medicaid

NEW: States' Compliance with Requirements for Treatment of Health Care-Related Taxes on Medicaid Managed Care Organizations

We will review whether States are in compliance with the requirements for health care-related taxes. Specifically, CMS issued a letter to State health officials on July 25, 2014 (SHO 14-001). The letter clarified the correct treatment of health care-related taxes on Medicaid MCOs. Our work will focus on those States identified by CMS that, at one time, taxed only Medicaid MCOs. Federal regulations define and set forth the standard for permissible health care-related taxes. (42 CFR §§ 433.55 and 433.68.)

OAS: W-00-16-31511. Expected to be issued in FY 2017

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-00-16-31455; various reviews. Expected to be issued in 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-00-15-31110; various reviews. Expected to be issued in FY 2017

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 A87, Cost Principles for State, Local, and Indian Tribal Governments, Attachment A, §C.1.j.) A State must claim Federal financial participation for costs associated with a program only in accordance with its approved cost allocation plan (45 CFR § 95.517(a)).

OAS: W-00-13-31467; W-00-14-31467; W-00-15-31467; various reviews. Expected to be issued in FY 2017

Enhanced Federal Medical Assistance Percentage (FMAP)

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, §1202, 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; W-00-16-31480; various reviews. Expected to be issued in FY 2017

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; W-00-16-31140; OEI: 06-14-00330; various reviews. Expected to be issued in FY 2017

State Reporting of Medicaid Collections

We will determine whether States accurately captured Medicaid collections and returned the correct Federal share related to those collections. Previous OIG work revealed multiple errors in compiling collection amounts, 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; W-00-16-31457; various reviews. Expected to be issued in FY 2017

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. We reviewed the claim adjustments 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. (SSA, § 1903(a)(1).)

OAS: W-00-14-31460; W-00-15-31460; various reviews. Expected to be issued in FY 2017

State Oversight of Provider Ownership Information

We will determine the extent to which States collect required ownership information for provider entities enrolled in Medicaid, and we will describe the extent to which they verify the collected information. We will also determine whether States 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 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. Expected to be issued in FY 2016

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. 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 to be issued in FY 2016

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. Federal financial participation 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. (SSA, §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 only partial payment. (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-00-13-31473; W-00-14-31473; W-00-16-31473; OEI: 09-14-00020; various reviews. Expected to be issued in FY 2016

OIG Oversight of State Medicaid Fraud Control Units

NEW: State Medicaid Fraud Control Unit FY 2015 Annual Report

We will analyze the statistical information that was self-reported by the MFCUs for FY 2015, describing in the aggregate the outcomes of MFCU criminal and civil cases. We will identify common themes from onsite reviews of the 50 MFCUs that were published from FY 2011 through FY 2015. We will identify the potential costs and benefits of creating MFCUs in jurisdictions that currently do not have a Unit.

OEI: 07-16-00050. Expected to be issued in FY 2016

Reviews of State Medicaid Fraud Control Units

OIG provides oversight and administers a Federal grant award for the 50 State MFCUs, which investigate and prosecute Medicaid provider fraud as well as complaints of patient abuse or neglect in Medicaid-funded facilities and in board and care facilities. 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 to be issued in FY 2016

Medicaid Information System Controls and Security**NEW: State Medicaid Agency Breach Protections and Responses**

We will examine breach notification procedures of State Medicaid agencies and their contractors, as well as their responses to past breaches of unsecured patient health information. State Medicaid agencies and contractors are required to comply with the Breach Notification Rule (45 CFR §§ 164.400-414). The Breach Notification Rule outlines requirements for health information safeguards and for notifications after the discovery of a breach of unsecured health information. The potential for a breach of unsecured patient health information, including data held by State Medicaid agencies and their contractors, is a major concern for health care providers and consumers.

OEI: 09-16-00210. Expected to be issued in FY 2017

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-00-15-31374; W-00-16-31374; various reviews. Expected to be issued in FY 2017

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. CMS is responsible for ensuring that appropriate security controls have been implemented.

OAS: W-00-15-40019; W-00-15-41015; W-00-16-41015; various reviews. Expected to be issued in FY 2016, FY 2017

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 to be issued in FY 2016

Medicaid Managed Care

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

REVISED: Medical Loss Ratio

We will review selected States and MCOs that do not use contract provisions that require a minimum percentage of total costs to be expended for medical services (medical loss ratio). A medical loss ratio is a tool that can help ensure that the majority of capitated payments are used to deliver services to beneficiaries. For States that do not use medical loss ratio provisions in their contracts with MCOs, we will calculate a medical loss ratio for selected organizations. We will also determine the extent of potential Medicaid program savings if MCOs were required to pay rebates for not meeting medical loss ratio provisions. The ACA established minimum medical loss ratio standards for certain commercial health insurers and Medicare Advantage plans. While these standards do not apply to Medicaid, we will use them as a basis for our calculations after making adjustments to reflect Medicaid specific programs and populations.

OAS: W-00-15-31372; W-00-16-31372; various reviews. Expected to be issued in FY 2016

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. We will determine whether the Federal share of recoveries of MCO payments that States received through profit-limiting methodologies is returned to the Federal Government. CMS reimburses each State at the FMAP for the quarter in which the expenditure was

made (SSA § 1903(a)(1)). When a State recovers a prior expenditure, it must refund the Federal share by reporting the recovery to CMS at the FMAP used to calculate the amount it had originally received (SSA § 1903(d)(2); CMS State Medicaid Manual, § 2500.6(B)).

OAS: W-00-16-31508. Expected to be issued in FY 2017

Review of States' Methodologies for Assigning Managed Care Organization Payments to Different Medicaid FMAPs

We will review methodologies for assigning MCO payments to different Medicaid FMAPs (e.g., the regular FMAP, the family planning FMAP, the Indian Health Services (IHS) FMAP, etc.). The Federal Government pays its share of a State's medical assistance expenditures under Medicaid on the basis of the FMAP, which varies depending on the State's relative per capita income (SSA § 1905(b)).

Additionally, certain Medicaid services receive a higher FMAP, including family planning services (90 percent) and services provided through an IHS 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-00-16-31509. Expected to be issued in FY 2017

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 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-00-16-31510. Expected to be issued in FY 2017

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).) We will also 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 GAO found that CMS's oversight of States' rate-setting required improvement and that States may not audit or independently verify the MCO-reported data used to set rates. (GAO-10-810.)

OAS: W-00-15-31471; W-00-16-31471; various reviews. Expected to be issued in FY 2017

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; W-00-16-31497. Expected to be issued in FY 2017

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 to be issued in FY 2017

Health Insurance Marketplace Reviews

OIG works to oversee proper expenditure of taxpayer funds and the efficient and effective operation of the health insurance marketplaces and related programs, such as financial assistance payments and the premium stabilization programs. 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. In particular, implementation, operation, and oversight of the marketplaces are among the most significant challenges for the Department. Key focus areas for our marketplace oversight include payment accuracy, eligibility, management and administration, and security.

Payments

NEW: CMS Oversight of Risk Adjustment Data: Timeliness, Validity, and Completeness

The ACA mandates a risk adjustment program to stabilize premiums and prevent risk selection among individual and small group issuers by redistributing the costs of providing care for sicker patients with healthier patients. We will review summary reports produced by the ACA risk adjustment data collection system (i.e., the EDGE server) as well as CMS and issuer reports to determine the extent of any data discrepancies. We will determine what actions were taken by issuers to review and resubmit data as well as the extent to which issuers appealed risk adjustment changes.

OEI: 00-00-00000. Expected to be issued in FY 2017

NEW: Risk Corridors: Insights from 2014 and 2015

The ACA mandates a temporary risk corridors program to stabilize premiums and protect qualified health plans in the individual and small group markets against uncertainty in claims costs. We will assess the difference in reported risk corridors data from benefit years 2014 and 2015. We will also review the guidance and tools that CMS used to ensure the accuracy of reported risk corridors data for the 2 benefit years.

OEI: 00-00-00000. Expected to be issued in FY 2017

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 to be issued in FY 2017

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 – Advance Premium Tax Credit (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 issuers are responsible for terminating coverage, returning APTC payments, and reporting this information to CMS. We also plan to conduct work on CMS's automated policy-based payments system at the Federal marketplace by potentially looking at the accuracy of the determination of financial assistance payments and the use of enrollment and payment data.

OAS: W-00-15-59018; various reviews. Expected to be issued in FY 2017

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; W-00-15-59034; W-00-16-59034; various reviews. Expected to be issued in FY 2016

Eligibility

REVISED: CMS Oversight of Eligibility Determinations at State-Based Marketplaces

We will assess CMS's oversight activities of seven State-based marketplaces (SBMs) to ensure that individuals were determined eligible for qualified health plans (QHPs) and insurance affordability programs according to Federal requirements. As part of this review, we will: (1) summarize the results of our reviews of seven SBMs, which determined whether SBM internal controls were effective in ensuring that individuals were enrolled in QHPs according to Federal requirements; (2) assess CMS's efforts to address the deficiencies identified in our audit reports; (3) assess CMS's various review processes of the SBMs; and (4) contact the 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 to be issued in FY 2017

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 OIG 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 to be issued in FY 2016 (Additional work examining Medicaid eligibility systems is described in the "Medicaid Reviews" section.)

Management and Administration

REVISED: Consumer Operated and Oriented Plan Loan Program: CO-OP Conversion of Start-Up Loans 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 review the CO-OPs' conversion of start-up loans to surplus notes to determine compliance with program requirements and accounting principles. We will also reassess the CO-OPs financial condition to determine whether any improvements were made in 2015 and monitor actions by CMS to address underperforming CO-OPs. ACA §1322 directs the Secretary of

HHS to establish the CO-OP program by providing loans to assist the awardees with startup costs and State solvency requirements; 45 CFR part 156 implements section 1322.

OAS: W-00-16-59019; various reviews. Expected to be issued in FY 2016

Review of Funding to Establish the Federally Facilitated Marketplace

We will identify the source and amount of funding used to establish the Federally facilitated marketplace (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 the amount that the Department and CMS identified as FFM funding was accurate and complete.

OAS: W-00-16-55000. Expected to be issued in FY 2017

Security

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, modification, 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 to be issued in 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 websites. Additional information about consumer protection can be found at: <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Electronic Health Records

The Health Information Technology for Economic and Clinical Health Act, enacted as part of the Recovery Act, P.L. No. 111-5, established Medicare and Medicaid EHR incentive programs to promote the adoption of EHRs. 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. To improve the quality and value of American health care, the Federal Government promotes the use of

certified EHR technology by health care professionals and hospitals. As an incentive for using EHRs, the Federal Government is making payments to providers that attest to the “meaningful use” of EHRs.

The Congressional Budget Office estimates that from 2011 through 2019, spending on the Medicare and Medicaid EHR incentive programs will total \$30 billion; the Medicaid EHR incentive program will account for more than one-third of that amount. GAO has identified improper incentive payments as the primary risk to the EHR incentive programs. These programs may be at greater risk of improper payments than other programs because they are new and have complex requirements.

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. (American Recovery and Reinvestment Act (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 to be issued in FY 2016

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-00-13-31351; W-00-14-31351; W-00-15-31351; various reviews. Expected to be issued in FY 2017

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 EHR 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 to be issued in FY 2016

CMS-Related Legal and Investigative Activities

Legal Activities

OIG's resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalties (CMPs) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIAs) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the anti-kickback statute, and provides compliance program guidance (CPG). OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements and provides them with 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. (SSA § 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 2015, OIG excluded 4,112 individuals and entities from participation in Federal health care programs. Searchable exclusion lists are available on OIG's website 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 SSA, §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 SSA, §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 DOJ prosecutors to develop and pursue Federal false claims cases against individuals and entities that defraud the Federal 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 website at:

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

Advisory Opinions and Other Industry Guidance

To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the anti-kickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful 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 website at:

- Advisory Opinions: <http://oig.hhs.gov/fraud/advisoryopinions.asp>
- Fraud Alerts: <http://oig.hhs.gov/fraud/consumer-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 to OIG self-disclosures of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. 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 website 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_submission_form.pdf

Investigative Activities

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 ACF, the Administration for Community Living (ACL), Health Resources and Services Administration (HRSA), and IHS. OIG also investigates potential misuse of grants and contracts funds awarded by the CDC, NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), 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 Federal Bureau of Investigation (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). 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. HFPP was created as a voluntary public-private partnership, between the Federal Government, State officials, private health insurance organizations, and health care antifraud associations. NHCAA is the leading national nonprofit organization focused exclusively on combating health care fraud and abuse. NHCAA's 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 our Semiannual Report(s) to Congress, which are available on our website at: <http://oig.hhs.gov/publications.asp>.

See OIG's Consumer Alerts at: <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Health Care Fraud Strike Force Teams and Other Collaborations

OIG devotes significant resources to investigating Medicare and Medicaid fraud. We conduct investigations in conjunction with other law enforcement entities, such as the FBI, DEA, MFCUs, and other Federal and State law enforcement partners.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and DOJ to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. Using a collaborative model, Health Care Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud.

Strike Force teams are operating in nine major cities. The effectiveness of the Strike Force model is enhanced by interagency collaboration within HHS. For example, we refer credible allegations of fraud to CMS so it can suspend payments as appropriate. During Strike Force operations, OIG and CMS work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets. In support of Strike Force operations, OIG:

- investigates individuals, facilities, or entities that, for example, bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes to inflate reimbursement amounts, and false claims submitted to obtain program funds;
- investigates business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians; and
- examines quality-of-care and failure-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which Federal programs may have been billed for services that were medically unnecessary, were not rendered, or were not rendered as prescribed or in which the care was so deficient that it constituted “worthless services.”

Other areas of investigation include Medicare and Medicaid drug benefit issues and assisting CMS in identifying program vulnerabilities and schemes, such as prescription shorting (when a pharmacy dispenses fewer doses of a drug than prescribed, but charges the full amount).

Working with law enforcement partners at the Federal, State, and local levels, we investigate schemes that illegally market, obtain, and distribute prescription drugs. In doing so, we seek to protect Medicare and Medicaid from making improper payments, deter the illegal use of prescription drugs, and curb the danger associated with street distribution of highly addictive medications.

We assist MFCUs in investigating allegations of false claims submitted to Medicaid and will continue to strengthen coordination between OIG and organizations such as the National Association of Medicaid Fraud Control Units and the National Association for Medicaid Program Integrity. Highlights of recent enforcement actions to which OIG has contributed are posted to OIG’s website at <http://oig.hhs.gov/fraud/enforcement/criminal/>.

Public Health Reviews

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Our reviews of public health agencies within HHS generally include CDC, FDA, HRSA, IHS, and SAMHSA. 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 ensuring 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.

Centers for Disease Control and Prevention

CDC is the nation's leading public health agency, responsible for controlling disease outbreaks; making sure food and water are safe; helping people to avoid leading causes of death, such as heart disease, cancer, stroke, and diabetes; and working globally to reduce threats to the nation's health.

CDC – Oversight of the Select Agent Program

We will examine CDC's oversight of the Select Agent Program, including CDC's inspections of entities registered with the Program and CDC's oversight of entities' annual internal inspections. 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). Further, entities are required to conduct annual internal inspections (42 CFR § 73.9(a)(6)). Our first report will examine the number, frequency, and results of CDC inspections, as well as CDC's response to and follow up on noncompliance with regulatory requirements identified during inspections. Our second report will examine the extent that CDC ensures that entities comply with annual internal inspection requirements and that observations identified during these inspections are corrected.

OEI: 04-15-00430; 04-15-00431. Expected to be issued in FY 2017

CDC – World Trade Center Health Program: Review of Medical Claims – Mandatory Review

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 to be issued in FY 2016

CDC – Grants 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 program to ensure compliance with applicable laws, regulations, and departmental guidance. The review will include grants 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-00-14-58311. Expected to be issued in FY 2016

CDC – Grants Award Process for Ebola Preparedness and Response Funding

We will review CDC’s grants award 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 grants 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. This funding included \$1.771 billion, which was allocated to CDC to prevent, prepare for, and respond to Ebola domestically and internationally.

OAS: W-00-16-58300. Expected to be issued in FY 2017

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 to be issued in 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-00-16-58310. Expected to be issued in FY 2016

Food and Drug Administration

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA plays a role in the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. In addition, FDA regulates the manufacturing, marketing, and distribution of tobacco products.

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.

NEW: FDA – Review of Prescription Drug User Fees

We will review FDA policies and procedures and financial records related to prescription drug user fees to determine whether FDA appropriately expended user fee collections and accurately computed user

fee rates. The Prescription Drug User Fee Act (PDUFA) of 1992, Pub. L. 102-571, authorized FDA to collect fees from pharmaceutical and biotechnology companies that produce certain human drug and biological products to expedite the review of human drug applications. FDA is expected to use the user fees it collects under PDUFA to meet its goals for the timely review of human drug applications.

OAS: W-00-16-50003; various reviews. Expected to be issued in FY 2017

NEW: FDA's Review of Networked Medical Device Cybersecurity during the Device Approval Process

We will assess FDA's premarket review of the cybersecurity controls of medical devices that are wireless, Internet, and networked-connected (networked devices). Effective cybersecurity controls has become increasingly important as more medical devices use wireless and Internet technology intended to diagnose, cure, mitigate, treat, or prevent a disease or affect the function of the body. These networked devices are vulnerable to intentional and unintentional cybersecurity threats that may adversely affect the device's functionality and safety. Also, we will review premarket submissions to assess the extent to which FDA reviewed cybersecurity information of networked devices during the device approval phase.

OEI: 09-16-00220. Expected to be issued in FY 2017

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 to be issued in FY 2017

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 to be issued in FY 2017

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 the Food Safety Modernization Act (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. FDA generally relies on firms to voluntarily cease distribution and recall harmful articles of food. Prior to 2011, FDA did not have the authority to require a firm to recall certain articles of food. However, the FSMA added section 423 to the FD&C Act, which gives FDA the authority to order a firm to recall certain articles of food after FDA determines that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals. 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 to be issued in FY 2016

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 with 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 to be issued in 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 to be issued in 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 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 to be issued in FY 2017

Health Resources and Services Administration

HRSA's programs provide health care to people who are geographically isolated or economically or medically vulnerable. This includes people living with HIV/AIDS, pregnant women, mothers, and their families and those in need of high quality primary health care. HRSA also supports the training of health professionals, the distribution of providers to areas where they are needed most, and improvements in health care delivery. HRSA oversees organ, bone marrow, and cord blood donation. It compensates individuals harmed by vaccination and maintains databases that protect against health care malpractice, waste, fraud, and abuse.

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 to be issued in FY 2016

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 5 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 ACF.

OAS: W-00-15-59000; various reviews. Expected to be issued in FY 2017

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 ACA provided community health centers with \$9.5 billion to support ongoing health center operations, create new health center sites, or expand preventive and primary health care services at existing health center sites. 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-00-15-59028; various reviews. Expected to be issued in FY 2016

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 to be issued in FY 2016

Indian Health Service

IHS is responsible for providing Federal health services to American Indians and Alaska Natives. The provision of health services to members of Federally-recognized tribes grew out of the special government-to-government relationship between the Federal government and Indian tribes. This relationship, established in 1787, is based on Article I, Section 8 of the Constitution, and has been given form and substance by numerous treaties, laws, Supreme Court decisions, and Executive Orders. IHS is the principal Federal health care provider and health advocate for Indian people, and its goal is to raise their health status to the highest possible level. IHS provides a comprehensive health service delivery system for approximately 1.9 million American Indians and Alaska Natives who belong to 567 Federally recognized tribes in 35 states.

NEW: Performance Improvement in IHS Hospitals: Application of Root Cause Analysis

We will evaluate IHS hospitals’ use of root cause analysis (RCA) in response to adverse events. RCAs are critical to hospital quality assessment and performance improvement (42 CFR §482.21). RCAs follow a protocol that begins with data collection and reconstruction of the event in question. A

multidisciplinary team analyzes the sequence of events leading to the error, with the goals of identifying how the event occurred and why the event occurred. Resulting action helps to prevent future harm.

OEI: 00-00-00000. Expected to be issued in FY 2017

NEW: Case Study of IHS Management of Poorly Performing Hospitals

We will identify management breakdowns, gaps, and lessons learned by IHS from its facilities' failures to meet the care needs of American Indians/Alaska Natives, e.g., evidenced by failure to operate some facilities in compliance with CMS conditions of participation. IHS directly operates 28 hospitals and a number of outpatient facilities with dispersed management. We will utilize interviews with senior management responsible for policies, practices, and resources that support care delivery in IHS facilities.

OEI: 06-16-00390. Expected to be issued in FY 2017

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 to be issued in FY 2016

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 to be issued in FY 2017

National Institutes of Health

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The goals of the agency are to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health; develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease; expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

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-00-16-51001; various reviews. Expected to be issued in FY 2017

NIH – Superfund Financial Activities for FY 2015 – Mandatory Review

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-00-16-59050. Expected to be issued in FY 2017

NIH – Colleges' and Universities' Compliance with Cost Principles

We will assess colleges' and universities' compliance with selected cost principles issued by OMB in Circular A21, 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 to be issued in FY 2016

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 bisphenol A (BPA) since 2000, as well as the roles that other Department programs and agencies (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, is also used in food and drink packaging and may leach into food or drink and be consumed by humans.

OEI: 01-15-00150. Expected to be issued in FY 2017

Substance Abuse and Mental Health Services Administration

SAMHSA leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. Congress established SAMHSA in 1992 to make substance use and mental disorder information, services, and research more accessible.

NEW: SAMHSA – Controls Over Opioid Treatment Programs

We will review State agencies' controls over Opioid Treatment Programs (OTP) funded under SAMHSA's Substance Abuse Prevention and Treatment Block Grant. Specifically, we will determine whether State agencies effectively monitor OTP services and medications in accordance with the Federal Guidelines for Opioid Treatment Programs established under 42 CFR Part 8. We will also ensure that program expenditures are allowable in accordance with Federal requirements outlined in 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

OAS: W-00-16-59035; various reviews. Expected to be issued in FY 2017

Other Public Health-Related Reviews

NEW: HHS Coordination of Roles and Responsibilities for Ebola Response Efforts

We will review the extent to which HHS planned and coordinated strategic decisions related to the Department's Ebola response efforts. We will also review how the Department's Ebola response activities were planned and coordinated with other U.S. Government agencies. Since the first cases of Ebola were reported in West Africa in March 2014, the United States has mounted a Governmentwide response to contain and eliminate the epidemic at its source, while also taking prudent measures to protect the American people. The HHS effort was launched encompassing many divisions, such as the CDC, ASPR, NIH, FDA, Office of Global Affairs, and U.S. Public Health Service Commissioned Corps.

OAS: W-00-16-58301; various reviews. Expected to be issued in FY 2017

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 that shipments are made and received in accordance with regulations cited above, at 42 CFR § 73.11(a) covering written security plans, and related supporting laboratory guidance or instruction.

OAS: W-00-16-51002; various reviews. Expected to be issued in FY 2017

Review of Office for Human Research Protections Compliance Evaluations to Ensure Human Subject Protection – Mandatory Review

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, scope, and trends of OHRPs' responses to allegations of noncompliance from 2000 to 2014. We will also determine the extent to which OHRP independently initiates, conducts, and makes determinations about compliance evaluations.

OEI: 01-15-00350. Expected to be issued in FY 2017

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: 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; W-00-16-59052; various reviews. Expected to be issued in FY 2016

Grantee's Use of President's Emergency Plan for AIDS Relief Funds

We will determine whether selected foreign grantees managed the 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; W-00-16-57300; various reviews. Expected to be issued in FY 2016

Public Health Legal Activities

OIG assists DOJ in resolving civil and administrative fraud cases and promoting compliance of HHS grantees. We assist DOJ in developing and pursuing Federal False Claims Act cases against institutions that receive grants from NIH and other public health service agencies. We also assist DOJ prosecutors in litigation and in settlement negotiations.

Violations of Select Agent Requirements

In 2005, HHS issued a final regulation on possession, use, and transfer of select (biological) agents and toxins that applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. ([70 Fed. Reg. 13294](#) (March 18, 2005, 42 CFR Part 73.)) The rule authorizes OIG to conduct investigations and to impose civil monetary penalties against individuals or entities for

violations of these requirements. We are continuing to coordinate efforts with CDC, FBI, and USDA to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

Human Services Reviews

HHS funds and operates public health and human services programs to promote health and economic and social well-being. Effective management is essential to ensure that these programs achieve their goals and best serve the programs' intended beneficiaries. HHS agencies that administer human services programs include ACF and ACL.

Administration for Children and Families

ACF operates programs that promote the economic and social well-being of children, families, and communities. These programs include the Temporary Assistance for Needy Families program; the national child support enforcement system; the Head Start program for preschool children; and assistance for childcare, foster care, and adoption services. ACF provides support to address a number of social areas, including homelessness, human trafficking, and community economic development.

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.

NEW: Review of States' CCDF Program Integrity Activities

We will review the program integrity activities that States have in place to protect the Child Care and Development Fund (CCDF) program. We will also describe the results of States' program integrity efforts. Total funding for the CCDF program from FY 2015 was approximately \$5 billion. Both the Department and OMB have identified the CCDF program as being susceptible to significant improper payments.

OEI: 03-16-00150. Expected to be issued in FY 2016

NEW: Head Start – Review of A-133 Audit Findings and Recommendations

We will review the Office of Head Start's audit resolution of findings and recommendations contained in A-133 audit reports involving Head Start grantees. All non-Federal entities that expend \$500,000 or more of Federal awards in a year are required to obtain an annual audit in accordance with the Single Audit Act Amendments of 1996 (pdf), OMB Circular A-133. Our audit will include a review of A-133 audits submitted by Head Start grantees for FYs 2013-2015. We will focus on grantees with repeat findings and review what action the Office of Head Start has taken to resolve the findings.

OAS: W-00-16-20009; various reviews. Expected to be issued in FY 2017

NEW: ORR – Unaccompanied Children Program Grantee Reviews

We will review whether selected grantees met applicable grant terms and conditions of the Unaccompanied Children (UC) program. Specifically, this work will determine whether a grantee: (1) used funding in accordance with Federal requirements, (2) adequately monitored the activities of its subcontractors, and (3) met certain safety standards applicable for the care of UC children in its custody. Under the Homeland Security Act of 2002, Section 462, the Office of Refugee Resettlement (ORR) administers the UC program. The UC program provides temporary shelter care and other related services to unaccompanied children in its custody. Before FY 2012, about 8,000 children were served annually in this program. In FY 2014, the number of children increased to over 57,500. UC grant program totaled \$911 million for FY 2014.

OAS: W-00-16-25060; various reviews. Expected to be issued in FY 2016

NEW: Recommendation Follow-Up: Office of Refugee Resettlement's Post-Placement Activities for Unaccompanied Children

The Office of Refugee Resettlement (ORR) is responsible for placing unaccompanied children in the custody of qualified sponsors who agree to provide for the child's well-being. In 2008, OIG found a lack of clarity between HHS and DHS about who is responsible for monitoring children who have been placed with sponsors and recommended that ORR establish a memorandum of understanding with DHS to clarify the roles and responsibilities of each Department. This recommendation has not been fully implemented; therefore, we will follow up on ORR's progress toward addressing the recommendation, examine any impediments encountered, as well as review ORR's efforts toward ensuring the well-being of children and that sponsors adhere to their sponsor agreements.

OEI: 09-16-00260. Expected to be issued in FY 2017

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: 12-16-00120. Expected to be issued in FY 2017

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. Psychotropic medications are drugs that affect brain activities associated with mental processes and behavior. Pursuant to Section 422(b)(15)(A) of the SSA (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 to be issued in FY 2017

Head Start – Implementation of Head Start Grant Recompensation

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 to be issued in FY 2016

Foster Care – Monitoring the Health and Safety of Children through the Complaint Resolution and Licensing Process

We will review whether 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 SSA are reported, investigated, and resolved in accordance with Federal and State requirements. We will also review States' oversight process to ensure that licensing requirements are met for foster care family homes. SSA Title IV-E Section 471(a)(9) and Title IV-E Section 472(c)(1).

OAS: W-00-15-25056; W-00-16-25056; various reviews. Expected to be issued in FY 2017

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 childcare services comparable to those provided to families not eligible" for CCDF subsidies. (45 CFR § 98.43)

OEI: 03-15-00170. Expected to be issued in FY 2018

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 to be issued in FY 2016

Administration for Community Living

ACL brings together the efforts and achievements of the Administration on Aging, the Administration on Intellectual and Developmental Disabilities, and the HHS Office on Disability to serve as the Federal agency responsible for increasing access to community supports, while focusing attention and resources on the unique needs of older Americans and people with disabilities across the lifespan.

The Administration on Aging 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.

NEW: ACL – Senior Medicare Patrol Projects' Performance Data

We will review performance measures and documentation relating to Medicare and Medicaid recoveries, savings, and cost avoidance for Senior Medicare Patrol (SMP) projects. In 1997, SMP projects were established to recruit and train retired professionals and other senior citizens to recognize and report instances or patterns of health care fraud. The initiative stemmed from recommendations in a congressional committee report accompanying the Omnibus Consolidated Appropriations Act of 1997. OIG reports these performance data annually. The information was requested by the Administration on Aging, and will support ACL's efforts to evaluate and improve the performance of the projects.

OEI: 02-16-00190. Expected to be issued in FY 2017

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 Governmentwide 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 conducting financial statement audits 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 IT as a 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.

Financial Statement Audits and Related Reviews

REVISED: Audits of FYs 2015 and 2016 Consolidated HHS Financial Statements and Financial-Related Reviews – Mandatory Review

We will review the independent auditor's work papers 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 to be issued in FY 2016 and FY 2017

FYs 2015 and 2016 Centers for Medicare & Medicaid Services' Financial Statements – Mandatory Review

We will review the independent auditor's work papers to determine whether the financial statement audit of 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 to be issued in FY 2016 and FY 2017

Financial Reviews

REVISED: Compliance with Reporting Requirements for Improper Payments – Mandatory Review

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) [altogether, referred to as IPIA], 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 actions that it is taking to reduce those payments.

OAS: W-00-16-40037. Expected to be issued in 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 to be issued in FY 2016

HHS Agencies' Annual Accounting of Drug-Control Funds – Mandatory Review

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 2016 annual accounting.

OAS: W-00-16-52312; various reviews. Expected to be issued in FY 2017

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 Anti-deficiency 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 to be issued in FY 2016

OIG Reviews of Non-Federal Audits

We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with OMB Circular A133, 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 organization-wide 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. Expected to be issued in 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 A133, 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 that the entity receives.

OAS: W-00-15-50012; W-00-16-50012; various reviews. Expected to be issued in FY 2016

HHS Compliance with the Federal Information Security Modernization Act of 2014 – Mandatory Review

We will review various HHS operating divisions' compliance with FISMA. FISMA and OMB Circular A130, 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-00-16-40016; W-00-16-42001; various reviews. Expected to be issued in FY 2017

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-00-15-42000; W-00-15-42020; W-00-16-42020; various reviews. Expected to be issued in FY 2016

Other HHS-Related Issues

NEW: HHS Implementation of Recommendations Regarding its National Security Information Program – Mandatory Review

We will assess whether applicable classification policies have been adopted, effectively administered, and followed, based on our 2013 report. The Reducing Over-Classification Act of 2010 (the Act) requires that the Inspector General of each Federal department or agency with an officer or employee who is authorized to make original classification decisions conduct two evaluations. The second evaluation must review the progress made pursuant to the results of the first evaluation.

OEI: 07-16-00080. Expected to be issued in FY 2016

HHS Government Purchase, Travel, and Integrated Charge Card Programs – Mandatory Review

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-00-16-59041. Expected to be issued in FY 2017

Appendix: Affordable Care Act Reviews

OIG's Affordable Care Act oversight strategy focuses on the health insurance marketplaces, reforms in the Medicare and Medicaid programs, and public health programs. OIG is focused on reviewing the economy, efficiency, and effectiveness of programs across HHS that were implemented pursuant to the ACA. 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.

This Appendix provides a consolidated list of planned work reviewing ACA programs.

Health Insurance Marketplaces

- Allowability of Contract Expenditures
- Accuracy of Financial Assistance Payments for Individual Enrollees
- CMS Oversight of Risk Adjustment Data: Timeliness, Validity, and Completeness
- Risk Corridors: Insights from 2014 and 2015
- Review of Affordable Care Act Establishment Grants for State Marketplaces
- Consumer Operated and Oriented Plan Loan Program: CO-OP Conversion of Start-Up Loans and CMS Monitoring Activities
- Inconsistencies in the Federally Facilitated Marketplace Applicant Data
- Review of Funding to Establish the Federally Facilitated Marketplace
- CMS Oversight of Eligibility Determinations at State-Based Marketplaces
- State-Based Marketplaces Information System Security Controls

Medicaid and Medicare Reforms

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
- Medicaid Eligibility Determinations in Selected States
- Community First Choice State Plan Option under the Affordable Care Act
- States’ Experiences with Enhanced Provider Screening
- Provider Payment Suspensions during Pending Investigations of Credible Fraud Allegations
- Payments to States under the Balancing Incentive Program
- States’ Collection of Rebates for Drugs Dispensed to Medicaid Managed Care Organization Enrollees
- Health-Care-Acquired Conditions – Prohibition on Federal Reimbursements
- Manufacturer Rebates – Federal Share of Rebates

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 reforms provisions related to the Medicare program and are described in more detail in the “Medicare” sections of the Work Plan:

- Payments for Durable Medical Equipment Ordered by Physicians
- Accountable Care Organizations: Strategies and Promising Practices
- Accountable Care Organizations: Beneficiary Assignment and Shared Savings Payments
- CMS Validation of Hospital-Submitted Quality Reporting Data
- Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts
- Ensuring Dual Eligibles’ Access to Drugs under Part D
- Use of Electronic Health Records to Support Care Coordination through ACOs
- Review of Financial Interests Reported under the Open Payments Program

Other Programs

OIG work in this area includes:

- HRSA – Compliance with Maternal, Infant, and Early Childhood Home Visiting Requirements
- HRSA – Community Health Centers' Compliance with Grant Requirements of the Affordable Care Act
- HRSA – Duplicate Discounts for 340B-Purchased Drugs