U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES ★ OFFICE OF INSPECTOR GENERAL

OIG Work Plan

2017

Introductory Message from the Office of Inspector General

The U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), Work Plan for fiscal year (FY) 2017 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.

Daniel R. Levinson
Inspector General

OIG's Responsibility

Our organization protects 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), Indian Health Service (IHS), and National Institutes of Health (NIH).

The amount of work conducted about particular programs is determined by the amount of funds available and the purpose limitations in the funding appropriated to OIG. OIG's funding that is directed toward oversight of the Medicare and Medicaid programs—including oversight of financial integrity and quality and safety of medical services—constitutes a significant portion of OIG's total funding (approximately 78 percent in FY 2016). The remaining share of OIG's efforts and resources are focused on other HHS programs and management processes, including key issues, such as efficient and effective operation of health insurance marketplaces and accuracy of related financial assistance payments; safety of the Nation's food and drug supply; security of national stockpiles of pharmaceuticals for use during emergencies; cybersecurity; 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 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, as well as outreach, compliance, and educational activities, conducted by personnel in the following components.

OAS

OEI

OI

OCIG

EM

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.

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; providing specialized expertise in cross-cutting issues; ensuring effective management of budget, finance, information technology (IT), human resources, and other operations; and serving as a liaison to HHS, Congress, and other stakeholders. EM plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies.

Some of the TMCs reflect **persistent and concerning vulnerabilities** that OIG has highlighted for HHS over many years.

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 those 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.

Top Management and 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 top management challenges 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. For more information on the Top Management and Performance Challenges facing HHS, please visit https://oig.hhs.gov/reports-and-publications/top-challenges/index.asp.

What This Document Contains

Work planning is an ongoing and evolving process, and the Work Plan is updated throughout the 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, revised, and removed and includes new items that have been started or planned since April 2016.

OIG posts its Work Plan online at http://oig.hhs.gov/reports-and-publications/workplan/index.asp. Because we make continual 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 our Work Plan, please contact us at public.affairs@oig.hhs.gov.

OIG on the web: http://www.oig.hhs.gov

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HHS OIG is the largest Inspector General's office in the Federal Government, with **approximately 1,600 dedicated to combating fraud, waste, and abuse and to improving the efficiency** of HHS programs.

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"OIG's mission is to **protect the integrity of HHS programs**, as well as the health and welfare of program beneficiaries. In fulfillment of this mission, we promote provider compliance, recommend program safeguards, and follow up on those recommendations ..."

— Inspector General Daniel R. Levinson

What's New

This Work Plan summarizes new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the current fiscal year and beyond. Specifically, this edition of the Work Plan removes items that have been completed, postponed, or canceled, and includes new items that have been started since April 2016. This Work Plan also indicates as "Revised" items where a substantial aspect of an ongoing review has changed since the April 2016 Work Plan Update. The list below reflects how our Work Plan has changed since it was last updated in April 2016 through September 2016.

CMS: Medicare Parts A and B

- **COMPLETED**: CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain (OEI-04-12-00380) – Issued June 2016
- **COMPLETED**: Adverse Events in Rehabilitation Hospitals: National Incidence among Medicare Beneficiaries (OEI-06-14-00110) – Issued July 2016
- **COMPLETED**: Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases (OEI-05-16-00031) – Issued June 2016
- **COMPLETED**: Medicare: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure (OEI-04-11-00591) – Issued May 2016
- **COMPLETED**: MACs Continue to Use Different Methods to Determine Drug Coverage (OEI-03-13-00450) – Issued August 2016
- **COMPLETED**: Comparison of ASP and AMP: Results for 4th Quarter 2015 (OEI-03-16-00230) – Issued May 2016
- **COMPLETED**: Comparison of ASP and AMP: Results for 1st Quarter 2016 (OEI-03-16-00250) – Issued August 2016
- **COMPLETED**: Medicare Benefit Integrity Contractors' Activities in 2012 and 2013: A Data Compendium (OEI-03-13-00620) – Issued May 2016
- **COMPLETED**: Recommendation Follow-up: CMS Should Address Medicare's Flawed Payment System for DME Infusion Drugs (OEI-12-16-00340) – Issued August 2016

- **COMPLETED**: Hospices Should Improve Their Election Statements and Certifications of Terminal Illness (OEI 02-10-00492) – Issued September 2016
- **COMPLETED**: Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress – Mandatory Review (OEI-09-16-00100) – Issued September 2016
- **COMPLETED**: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data – Mandatory Review (OEI-09-16-00040) – Issued September 2016
- **COMPLETED**: Escalating Medicare Billing for Ventilators Raises Concerns (OEI-12-15-00370) – Issued September 2016
- **COMPLETED**: Medicare Improperly Paid Millions of Dollars for Unlawfully Present Beneficiaries for 2013 and 2014 – Mandatory Report (A-07-15-01159) – Issued September 2016
- **COMPLETED**: Inpatient Claims for Mechanical Ventilation (A-09-14-02041) – Issued June 2016
- **NEW**: Hyperbaric Oxygen Therapy Services – Provider Reimbursement in Compliance with Federal Regulations
- **NEW**: Incorrect Medical Assistance Days Claimed by Hospitals
- **NEW**: Inpatient Psychiatric Facility Outlier Payments
- **NEW**: Case Review of Inpatient Rehabilitation Hospital Patients Not Suited for Intensive Therapy
- **NEW**: Nursing Home Complaint Investigation Data Brief
- **NEW**: Skilled Nursing Facilities – Unreported Incidents of Potential Abuse and Neglect
- **NEW**: Skilled Nursing Facility Reimbursement
- **NEW**: Skilled Nursing Facility Adverse Event Screening Tool
- **NEW**: Medicare Hospice Benefit Vulnerabilities and Recommendations for Improvement, A Portfolio
- **NEW**: Review of Hospices Compliance with Medicare Requirements
- **NEW**: Hospice Home Care — Frequency of Nurse On-site Visits to Assess Quality of Care and Services
- **NEW**: Comparing HHA Survey Documents to Medicare Claims Data
- **NEW**: Part B Services during Non-Part A Nursing Home Stays: Durable Medical Equipment
- **NEW**: Medicare Market Share of Mail-Order Diabetic Testing Strips: April 1–June 30, 2016 – Mandatory Review
- **NEW**: Positive Airway Pressure Device Supplies – Supplier Compliance with Documentation Requirements for Frequency and Medical Necessity

- **NEW**: Monitoring Medicare Payments for Clinical Diagnostic Laboratory Tests – Mandatory Review
- **NEW**: Medicare Payments for Transitional Care Management
- **NEW**: Medicare Payments for Chronic Care Management
- **NEW**: Data Brief on Financial Interests Reported under the Open Payments Program
- **NEW**: Power Mobility Devices Equipment – Portfolio Report on Medicare Part B Payments
- **NEW**: Drug Waste of Single Use Vial Drugs
- **NEW**: Potential Savings from Inflation-Based Rebates in Medicare Part B
- **NEW**: Medicare Payments for Service Dates After Individuals' Dates of Death
- **NEW**: Management Review: CMS's Implementation of the Quality Payment Program
- **REVISED**: Intensity-Modulated Radiation Therapy
- **REVISED**: National Background Checks for Long-Term-Care Employees – Mandatory Review
- **REVISED**: Ambulance Services – Supplier Compliance with Payment Requirements
- **REVISED**: Inpatient Rehabilitation Facility Payment System Requirements
- **REVISED**: Histocompatibility Laboratories – Supplier Compliance with Payment Requirements
- **REMOVED**: Diabetes Testing Supplies Effectiveness of System Edits to Prevent Inappropriate Payments for Blood Glucose Test Strips and Lancets to Multiple Suppliers
- **REMOVED**: Power Mobility Devices – Supplier Compliance with Payment Requirements
- **REMOVED**: Ambulatory Surgical Centers – Payment System
- **REMOVED**: CMS Management of the ICD-10 Implementation
- **REMOVED**: Hospital Cost Reports: Implications of Compensation on Medicare Reimbursement

CMS: Medicare Parts C and D

- **COMPLETED**: High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns (OEI-02-16-002900) – Issued June 2016
- **COMPLETED**: Memorandum Report: Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2016 (OEI-05-16-00090) – Issued June 2016

- **NEW**: Medicare Part C Payments for Service Dates After Individuals' Dates of Death
- **NEW**: Extent of Denied Care in Medicare Advantage and CMS Oversight
- **NEW**: Medicare Part D Rebates Related to Drugs Dispensed by 340B Pharmacies
- **NEW**: Questionable Billing for Compounded Topical Drugs in Part D
- **NEW**: Medicare Part D Payments for Service Dates After Individuals' Dates of Death
- **REVISED**: Medicare Part D Eligibility Verification Transactions
- **REMOVED**: Medicare Part D Beneficiaries' Exposure to Inappropriate Drug Pairs
- **REMOVED**: Generic Drug Price Increases in Medicare Part D

CMS: Medicaid

- **COMPLETED**: Medicaid: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure (OEI-04-11-00590) – Issued May 2016
- **COMPLETED**: Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented (OEI-05-13-00520) – Issued May 2016
- **COMPLETED**: Medicaid Fraud Control Units Fiscal Year 2015 Annual Report (OEI-07-16-00050) – Issued September 2016
- **COMPLETED**: Family Planning Services – Claims for Enhanced Federal Funding (multiple reports) – Issued FY 2016
- **COMPLETED**: State Reporting of Medicaid Collections (A-05-14-00018) – Issued May 2015
- **COMPLETED**: Medical Loss Ratio (multiple reports) – Issued FY 2016
- **NEW**: States' MCO Medicaid Drug Claims
- **NEW**: Data Brief on Fraud in Medicaid Personal Care Services
- **NEW**: Delivery System Reform Incentive Payments
- **NEW**: Accountable Care in Medicaid
- **NEW**: Third-Party Liability Payment Collections in Medicaid
- **NEW**: Medicaid Overpayment Reporting and Collections
- **NEW**: Overview of States' Risk Assignments for Medicaid-only Provider Types

- **NEW**: Health-Care-Related Taxes: Medicaid MCO Compliance with Hold-Harmless Requirement
- **NEW**: Health Care-Acquired Conditions – Medicaid Managed Care Organizations
- **REMOVED**: Manufacturer Compliance with AMP Reporting Requirements

CMS: Health Insurance Marketplaces

- **COMPLETED**: Consumer Operated and Oriented Plan Loan Program: CO-OP Conversion of Start-Up Loans and CMS Monitoring Activities (A-05-16-00019) – Issued August 2016
- **COMPLETED**: State-Based Marketplaces Information System Security Controls (multiple reports) – Issued May 2016 – September 2016
- **REVISED**: CMS Oversight and Issuer Compliance in Ensuring Data Integrity for the ACA Risk Adjustment Program
- **REVISED**: CMS Monitoring Activities for Consumer Operated and Oriented Plan Loan Program
- **REMOVED**: Risk Corridors: Insights from 2014 and 2015

CMS: Electronic Health Records

- **COMPLETED**: Medicaid Incentive Payments for Adopting Electronic Health Records (multiple reports) – Issued August–October 2016
- **COMPLETED**: Hospital Electronic Health Record Contingency Plans (OEI-01-14-00570) – Issued July 2016

PHR: Centers for Disease Control and Prevention

- **COMPLETED**: CDC – Award Process for the President's Emergency Plan for AIDS Relief Cooperative Agreements (A-04-15-04021) – Issued May 2016
- **COMPLETED**: CDC – Accountability for Property (A-04-14-03546) – Issued June 2016
- **REVISED**: CDC – Grantee's Use of President's Emergency Plan for AIDS Relief Funds

- **REVISED**: CDC – World Trade Center Health Program: Review of Administrative Costs – Mandatory Review

PHR: Food and Drug Administration

- **COMPLETED**: FDA is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist (OEI-01-14-00390) – Issued July 2016
- **NEW**: Hospital's Reliance on Drug Compounding Facilities
- **REVISED**: FDA's Review of Networked Medical Device Cybersecurity During the Premarket Process
- **REVISED**: FDA Response Planning for a Medical Device Compromise

PHR: Health Resources and Services Administration

- **COMPLETED**: State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (OEI-05-14-00430) – Issued June 2016

PHR: Indian Health Service

- **NEW**: Purchase Referred Care Program – IHS
- **NEW**: Review of Health Services Administered by a Federally Qualified Health Center – IHS
- **REMOVED**: Performance Improvements in IHS Hospitals – Application of Root Cause Analysis

PHR: National Institutes of Health

- **NEW**: Review of National Institutes of Health Data Controls to Ensure the Privacy and Protection of Volunteers in the Precision Medicine Initiative

HSR: Administration for Children and Families

- **COMPLETED**: More Effort is Needed to Protect the Integrity of the Child Care and Development Fund Block Grant Program (OEI-03-16-00150) – Issued July 2016
- **COMPLETED**: Head Start Grant Recompetition: Early Implementation Results Suggest Opportunities for Improvement (OEI-12-14-00650) – Issued August 2016
- **COMPLETED**: Superstorm Sandy Block Grants: Funds Benefited States' Reconstruction and Social Service Efforts, Though ACF's Guidance Could be Improved (OEI-09-15-00200) – Issued September 2016
- **NEW**: States' Accuracy of Reporting TANF Spending Information

HSR: Administration for Community Living

- **COMPLETED**: Memorandum Report: Performance Data for the Senior Medicare Patrol Projects: June 2016 Performance Report (OEI-02-16-00190) – Issued June 2016

HSR: Other HHS-Related Reviews

- **COMPLETED**: HHS Has Made Progress in Properly Classifying Documents; However, New Issues Should Be Addressed – Mandatory Review (OEI-07-16-00080) – Issued September 2016
- **NEW**: Review of CMS Action on CERT Data
- **NEW**: Compliance with the Digital Accountability and Transparency Act – Mandatory Review
- **NEW**: Audit of HHS Information System Security Controls to Track Prescription Drug Disbursements
- **REMOVED**: Requests for Audit Services

Acronyms and Abbreviations

Below is a list of acronyms and abbreviations frequently used in this document. The list below of Federal departments and agencies (noted with an asterisk: *), legislative and regulatory annotations (noted with a pound symbol: #), and frequently used terms (noted with a plus sign: +) are spelled out only on first reference. All other terms are spelled out in every section or narrative in which they appear and are therefore not included in this section.

ACA# . . . . . Patient Protection and Affordable Care Act

ACF* . . . . . Administration for Children and Families

ACL* . . . . . Administration for Community Living

ACO+ . . . . . accountable care organization

ASPR* . . . . Assistant Secretary for Preparedness and Response

CDC* . . . . . Centers for Disease Control and Prevention

CHIP+ . . . . . Children's Health Insurance Program

CMS* . . . . . Centers for Medicare & 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

FAR# . . . . . Federal Acquisition Regulation

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

IT+ . . . . . Information Technology

HRSA* . . . . Health Resources and Services Administration

MA+ . . . . . Medicare Advantage

MACRA[#] . . . Medicare Access and CHIP [Children's Health Insurance Plan] Reauthorization Act of 2015

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

PCS[+] . . . . . personal care services

PHR[+] . . . . . Public Health Reviews

Recovery Act[#] . . . American Recovery and Reinvestment Act

SAMHSA* . . . Substance Abuse and Mental Health Services Administration

SNF[+] . . . . . skilled nursing facility

SSA[#] . . . . . Social Security Act

USDA* . . . . U.S. Department of Agriculture

Centers for Medicare & Medicaid Services (CMS)

Enrollment in Medicaid and CHIP **has grown by 16 million people since October 2013** to a total of **72.9 million individuals** enrolled as of January 2016.

In FY 2016, Medicare's budget was $595 billion

$595 billion

CMS, which include Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), account for more than 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 Patient Protection and Affordable Care Act (ACA).

Total Federal program spending for Medicare, Medicaid, and CHIP was $986 billion for FY 2016.[1] The amount spent on Medicare for this time period was approximately $595 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 electronic health records (EHRs).[2] Enrollment in Medicaid and CHIP has grown by 16 million people since October 2013 to a total of 72.9 million individuals enrolled as of January 2016.[3]

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) 2015, Medicare Parts A and B served more than 37 million people and provided approximately $371 billion in program payments.[4] Medicare expended over $85 billion in Part D benefit payments in CY 2015, serving over 41 million beneficiaries.[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 certification surveys and hospice-worker licensure requirements; oversight of SNFs' compliance with patient admission requirements; and evaluation of CMS's Fraud Prevention System.

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[1] www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/index.html
[2] Ibid
[3] http://kff.org/medicaid/issue-brief/two-year-trends-in-medicaid-and-chip-enrollment-data-findings-from-the-cms-performance-indicator-project
[4] www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-07-28.html
[5] www.hhs.gov/about/budget/fy2015/budget-in-brief/cms/medicare/index.html

Medicare Parts A and B

- Hospitals
- Nursing Homes
- Hospices
- Home Health Services
- Medical Equipment & Supplies
- Other Providers & Suppliers
- Prescription Drugs
- Part A & B Contractors
- Other Part A and B Management Issues

Medicare Parts C and D

Medicaid

Health Insurance Marketplaces

Electronic Health Records

Related Legal and Investigative Activities

Hospitals

Hyperbaric Oxygen Therapy Services—Provider Reimbursement in Compliance with Federal Regulations

Hyperbaric oxygen (HBO) therapy involves giving a beneficiary high concentrations of oxygen within a pressurized chamber in which the beneficiary intermittently breathes 100 percent oxygen. HBO therapy is primarily an adjunctive treatment for the management of select nonhealing wounds. In accordance with CMS Publication 100-03, National Coverage Determinations Manual, Ch. 20, § 20.29(A), a beneficiary must meet 1 of 15 covered conditions for providers to receive HBO reimbursement. Prior OIG reviews expressed concerns that: (1) beneficiaries received treatments for noncovered conditions, (2) medical documentation did not adequately support HBO treatments, and (3) beneficiaries received more treatments than were considered medically necessary. We will determine whether Medicare payments related to HBO outpatient claims were reimbursed in accordance with Federal requirements.

OAS: W-00-16-35780; various reviews • Expected Issue Date: FY 2017

Incorrect Medical Assistance Days Claimed by Hospitals

The Medicare program, like the Medicaid program, includes provisions under which Medicare-participating hospitals that serve a disproportionate share of low-income patients may receive disproportionate share hospital payments. In Medicare, disproportionate share hospital payments to providers are based on Medicaid patient days that the hospitals furnish. Providers report these Medicaid patient days on the Medicare cost reports that Medicare administrative contractors review and settle. Because Medicare disproportionate share hospital payments are the result of calculations to which a number of sometimes complex factors and variables contribute, they are at risk of overpayment. We will determine whether, with respect to Medicaid patient days, Medicare administrative contractors properly settled Medicare cost reports for Medicare disproportionate share hospital payments in accordance with Federal requirements.

OAS: W-00-16-35782 • Expected Issue Date: FY 2017

Inpatient Psychiatric Facility Outlier Payments

Inpatient Psychiatric Facilities, either freestanding hospitals or specialized hospital-based units, provide active psychiatric treatment to meet the urgent needs of those experiencing an acute mental health crisis, which may involve mental illnesses or alcohol- or drug-related problems. From FY 2014 to FY 2015, the number of claims with outlier payments increased by 28 percent, and total Medicare payments for stays that resulted in outlier payments increased from $450.2 million to $534.6 million (19 percent). We will determine whether Inpatient Psychiatric Facilities nationwide

Medicare Parts A and B

- Hospitals
- Nursing Homes
- Hospices
- Home Health Services
- Medical Equipment & Supplies
- Other Providers & Suppliers
- Prescription Drugs
- Part A & B Contractors
- Other Part A and B Management Issues

Medicare Parts C and D

Medicaid

Health Insurance Marketplaces

Electronic Health Records

Related Legal and Investigative Activities

complied with Medicare documentation, coverage, and coding requirements for stays that resulted in outlier payments.

OAS: W-00-16-35778 • Expected Issue Date: FY 2017

Case Review of Inpatient Rehabilitation Hospital Patients Not Suited for Intensive Therapy

Inpatient rehabilitation (rehab) hospitals are freestanding facilities that specialize in providing intensive rehab therapy to patients recovering from illness, injury, or surgery. In conducting a medical review for a separate evaluation to identify adverse events in inpatient rehab hospitals, physician reviewers found a small number of cases in which the patients appeared to be unsuited for intensive therapy. The purpose of this study is to assess a sample of rehabilitation hospital admissions to determine whether the patients participated in and benefited from intensive therapy. For patients who were not suitable candidates, we will identify reasons they were not able to participate and benefit from therapy.

OEI: 06-16-00360 • Expected Issue Date: FY 2017

Intensity-Modulated Radiation Therapy

Intensity-modulated radiation therapy (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. 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. Prior OIG reviews identified hospitals that incorrectly billed for IMRT services. We will review Medicare outpatient payments for IMRT to determine whether the payments were made in accordance with Federal requirements.

OAS: W 00 16 35733; W-00-16-35740; various reviews • Expected Issue Date: FY 2017

Outpatient Outlier Payments for Short-Stay Claims

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. We will determine the extent of potential Medicare savings if hospital outpatient stays were ineligible for an outlier payment.

OAS: W-00-16-35775 • Expected Issue Date: FY 2017

Medicare Parts A and B

- Hospitals
- Nursing Homes
- Hospices
- Home Health Services
- Medical Equipment & Supplies
- Other Providers & Suppliers
- Prescription Drugs
- Part A & B Contractors
- Other Part A and B Management Issues

Medicare Parts C and D

Medicaid

Health Insurance Marketplaces

Electronic Health Records

Related Legal and Investigative Activities

Comparison of Provider-Based and Freestanding Clinics

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). 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.

OAS: W-00-17-30026 • Expected Issue Date: FY 2017

Reconciliations of Outlier Payments

Outliers are additional payments that Medicare provides to hospitals for beneficiaries who incur unusually high costs. The original outlier payments are based on the cost-to-charge ratio from the most recently settled cost report. The actual cost-to-charge ratio for the year in which the service was provided is available only at the time of cost report settlement for that year. CMS performs outlier reconciliations at the time of cost report settlement. 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 review Medicare outlier payments to hospitals to determine whether CMS performed necessary reconciliations in a timely manner to enable Medicare contractors to perform final settlement of the hospitals' associated cost reports. We will also determine whether the Medicare contractors referred all hospitals that meet the criteria for outlier reconciliations to CMS.

OAS: W-00-16-35451; various reviews • Expected Issue Date: FY 2017

Hospitals' Use of Outpatient and Inpatient Stays Under Medicare's Two-Midnight Rule

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 inpatient payment is generally appropriate if physicians expect beneficiaries' care to last at least two midnights; otherwise, outpatient payment is generally appropriate. This rule represents a change to the criteria used to determine the appropriateness of payment for inpatient admissions. 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.

OEI: 02-15-00020 • Expected Issue Date: FY 2017

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Medicare Costs Associated with Defective Medical Devices

According to FDA, recalls of medical devices nearly doubled from 2003 through 2012. CMS has expressed concerns about the impact of the cost of replacement devices, including ancillary cost, on Medicare payments for inpatient and outpatient services. We will review Medicare claims to identify the costs to Medicare resulting from additional use of medical services associated with defective or recalled medical devices.

OAS: W-00-15-35516; various reviews • Expected Issue Date: FY 2017

Payment Credits for Replaced Medical Devices That Were Implanted

Certain medical devices are implanted during an inpatient or 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 that are due to recalls or failures (42 CFR §§ 412.89 and 419.45). Prior OIG reviews have determined that Medicare Administrative Contractors made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices. We will determine whether Medicare payments for replaced medical devices were made in accordance with Medicare requirements.

OAS: W-00-16-35745; various reviews • Expected Issue Date: FY 2017

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

Overlapping claims can happen when a beneficiary is an inpatient of one hospital and then sent to another hospital to obtain outpatient services that are not available at the originating hospital. 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. 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.

OAS: W-00-16-35752 • Expected Issue Date: FY 2017

Selected Inpatient and Outpatient Billing Requirements

This review is part of a series of hospital compliance reviews that focus on hospitals with claims that may be at risk for overpayments. Prior OIG reviews and investigations have identified areas at risk for noncompliance with Medicare billing requirements. We will review Medicare payments to acute care hospitals to determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments. Our review will focus on those hospitals with claims that may be at risk for overpayments.

OAS: W-00-16-35538; various reviews • Expected Issue Date: FY 2017

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Duplicate Graduate Medical Education Payments

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)). To ensure that this incorrect counting does not occur, CMS created the Intern and Resident Information System (IRIS). Prior OIG reviews determined that hospitals received duplicate reimbursement for DGME costs. We will review provider data from IRIS to determine whether hospitals received duplicate or excessive DGME payments. We will also assess the effectiveness of IRIS in preventing duplicate payments for DGME costs. If duplicate payments were claimed, we will determine which payment was appropriate.

OAS: W-00-15-35432; various reviews • Expected Issue Date: FY 2017

Indirect Medical Education Payments

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 indirect medical education (IME) adjustments, are calculated using the hospital's ratio of resident full-time equivalents to available beds. Prior OIG reviews determined that hospitals received excess reimbursement for IME costs. We will review provider data to determine whether hospitals' IME payments were made in accordance with Federal requirements. We will also determine whether the IME payments were calculated properly.

OAS: W-00-15-35722 • Expected Issue Date: FY 2017

Outpatient Dental Claims

With few exceptions, dental services are generally excluded from Medicare coverage (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). OIG audits have found that hospitals received Medicare reimbursement for noncovered dental services, resulting in significant overpayments. We will roll up the results of our audits of Medicare hospital outpatient payments for dental services to provide CMS with cumulative results and make recommendations for any appropriate changes to the program.

OAS: W-00-16-35603 • Expected Issue Date: FY 2017

Nationwide Review of Cardiac Catheterizations and Endomyocardial Biopsies

Medicare payments for endomyocardial biopsies are generally intended to cover right heart catheterizations (RHC) when they are performed during the same outpatient encounter. However, under certain circumstances, a hospital may bill

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and receive payment for both procedures by including a modifier 59 on the claim to indicate that the RHC is "separate and distinct" (e.g., different session or patient encounter) from the endomyocardial biopsy. Prior OIG reviews found that some hospitals did not comply with Medicare billing requirements because they included modifier 59 in instances when the procedures performed were not separate and distinct. We will review Medicare payments to hospitals nationwide for outpatient RHCs and endomyocardial biopsies performed during the same patient encounter.

OAS: W-00-15-35721; various reviews • Expected Issue Date: FY 2017

Payments for Patients Diagnosed with Kwashiorkor

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. A diagnosis of kwashiorkor on a claim substantially increases the hospitals' reimbursement from Medicare. Prior OIG reviews have identified inappropriate payments to hospitals for claims with a kwashiorkor diagnosis. 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. We will roll up the results of our audits of Medicare hospital payments for kwashiorkor to provide CMS with cumulative results and make recommendations for any appropriate changes to the program.

OAS: W-00-15-35715; various reviews • Expected Issue Date: FY 2017

Review of Hospital Wage Data Used to Calculate Medicare Payments

Hospitals report wage data annually to CMS, which is then used to calculate wage index rates to account for different geographic area labor market costs. 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. We will review hospital controls over the reporting of wage data used to calculate wage indexes for Medicare payments (SSA §§ 1886(d)(3) and 1886(d)(3)(E)).

OAS: W-00-15-35725; W-00-16-35452; various reviews • Expected Issue Date: FY 2017

CMS Validation of Hospital-Submitted Quality Reporting Data

CMS's hospital inpatient quality reporting program requires Medicare acute-care hospitals to submit certain quality data, or they will receive a payment reduction. CMS is required to establish a process to conduct validation of this program (SSA § 1886(b)(3)(B)(viii)(XI)). CMS uses validated hospital inpatient quality reporting data for the hospital value-based purchasing program and the hospital acquired condition reduction program. We will determine the extent to which CMS-validated hospital inpatient quality reporting data are accurate and complete. This study will also describe the actions that CMS has taken as a result of its validation.

OEI: 01-15-00320 • Expected Issue Date: FY 2017

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Long-Term-Care Hospitals – Adverse Events in Postacute Care for Medicare Beneficiaries

Long-term-care hospitals (LTCHs) are inpatient hospitals that provide long-term care to clinically complex patients, such as those with multiple acute or chronic conditions. Medicare beneficiaries typically enter LTCHs following an acute-care hospital stay to receive intensive rehabilitation and medical care. LTCHs are the third most common type of postacute care facility after SNFs and inpatient rehabilitation facilities. LTCHs account for nearly 11 percent of Medicare costs for postacute care ($5.4 billion in FY 2011). We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving care in LTCHs. We will also identify factors contributing to these events and determine the extent to which the events were preventable.

OEI: 06-14-00530 • Expected Issue Date: FY 2017

Hospital Preparedness and Response to Emerging Infectious Diseases

Several HHS agencies, including CMS, CDC, and Office of the Assistant Secretary for Preparedness and Response (ASPR) provide resources, i.e., guidance and support, for hospitals as they prepare for emerging infectious disease threats. 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). We will describe hospitals' efforts to prepare for the possibility of public health emergencies resulting from emerging infectious disease threats. Additionally, we will determine hospitals' 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.

OEI: 06-15-00230 • Expected Issue Date: FY 2017

Nursing Homes

NEW Nursing Home Complaint Investigation Data Brief

All nursing home complaints categorized as immediate jeopardy and actual harm must be investigated within a 2- and 10-day timeframe, respectively. A 2006 OIG report found that State agencies did not investigate some of the most serious complaints within these required timeframes. We will determine to what extent State agencies investigate the most serious nursing home complaints within the required timeframes. This work will provide an update from our previous review.

OEI: 01-16-00330 • Expected Issue Date: FY 2017

NEW Skilled Nursing Facilities – Unreported Incidents of Potential Abuse and Neglect

SNFs are institutions that provide skilled nursing care, including rehabilitation and various medical and nursing procedures. Ongoing OIG reviews at other settings indicate the potential for unreported instances of abuse and neglect. We will assess the incidence of abuse and neglect of Medicare beneficiaries receiving treatment in SNFs and

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determine whether these incidents were properly reported and investigated in accordance with applicable Federal and State requirements. We will also interview State officials to determine if each sampled incident was reported, if required, and whether each reportable incident was investigated and subsequently prosecuted by the State, if appropriate.

OAS: W-00-16-35779 • Expected Issue Date: FY 2017

NEW Skilled Nursing Facility Reimbursement

Some SNF patients require total assistance with their activities of daily living and have complex nursing and physical, speech, and occupational therapy needs. SNFs are required to periodically assess their patients using a tool called the Minimum Data Set that helps classify each patient into a resource utilization group for payment. Medicare payment for SNF services varies based on the activities of daily living score and the therapy minutes received by the beneficiary and reported on the Minimum Data Set. The more care and therapy the patient requires, the higher the Medicare payment. Previous OIG work found that SNFs are billing for higher levels of therapy than were provided or were reasonable or necessary. We will review the documentation at selected SNFs to determine if it meets the requirements for each particular resource utilization group.

OAS: W-00-16-35784 • Expected Issue Date: FY 2017

NEW Skilled Nursing Facility Adverse Event Screening Tool

OIG developed the SNF adverse event trigger tool as part of its study, "Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries" (OEI-06-11-00370), released in February 2014. The tool was developed with assistance from clinicians at the Institute for Healthcare Improvement (IHI), which also published the tool for industry use. This product will describe the purpose, use, and benefits of the SNF adverse event trigger tool and the guidance document released by IHI, including the methodology for developing the instrument and the instrument's use in developing the February 2014 report findings. The product will also describe the contributions of OIG and IHI. The goal of this product is to disseminate practical information about the tool for use by those involved with the skilled nursing industry.

OEI: 06-16-00370 • Expected Issue Date: FY 2017

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

The ACA provides grants to States, through CMS, to implement background check programs of prospective long-term-care employees and providers. The ACA requires that OIG conduct an evaluation of this grant program, known as the National Background Check Program, after its completion (ACA § 6201). For States that closed their grants in the preceding year, we will review the procedures

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States implemented for long-term-care facilities and providers to conduct background checks on prospective employees who would have direct access to patients. We will determine the outcomes of the States' programs and whether the checks led to any unintended consequences.

OEI: 07-16-00160 • Expected Issue Date: FY 2017

Skilled Nursing Facility Prospective Payment System Requirements

Medicare requires a beneficiary to be an inpatient of a hospital for at least 3 consecutive days before being discharged from the hospital to be eligible for SNF services (SSA § 1861(i)). If the beneficiary is subsequently admitted to an 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. We will review compliance with the SNF prospective payment system requirement related to a 3-day qualifying inpatient hospital stay.

OAS: W-00-16-30014 • Expected Issue Date: FY 2017

Potentially Avoidable Hospitalizations of Medicare- and Medicaid-Eligible Nursing Facility Residents

High occurrences of patient transfers from nursing facilities to hospitals for potentially preventable conditions could indicate poor quality of care. Prior OIG work identified a nursing facility with a high rate of Medicaid recipient transfers to hospitals for a urinary tract infection (UTI), a condition that is often preventable and treatable in the nursing facility setting without requiring hospitalization. The audit disclosed that the nursing facility often did not provide UTI prevention and detection services in accordance with its residents' care plans, increasing the residents' risk for infection and hospitalization. We will review nursing homes with high rates of patient transfers to hospitals for potentially preventable conditions and determine whether the nursing homes provided services to residents in accordance with their care plans (42 CFR § 483.25(d)).

OAS: W-00-17-35792 • Expected Issue Date: FY 2017

Hospices

NEW Medicare Hospice Benefit Vulnerabilities and Recommendations for Improvement: A Portfolio

The Medicare hospice program is an important benefit for beneficiaries and their families at the end of life. However, OIG and others have identified vulnerabilities in payment, compliance, and oversight as well as quality-of-care concerns, which can have significant consequences both for beneficiaries and for the program. We will summarize OIG evaluations, audits, and investigative work on Medicare hospices and highlight key recommendations for protecting beneficiaries and improving the program.

OEI: 02-16-00570 • Expected Issue Date: FY 2017

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Review of Hospices' Compliance with Medicare Requirements

Hospice provides palliative care for terminally ill beneficiaries and supports family and other caregivers. When a beneficiary elects hospice care, the hospice agency assumes the responsibility for medical care related to the beneficiary's terminal illness and related conditions. Federal regulations address Medicare conditions of and limitations on payment for hospice services (42 CFR Part 418, Subpart G). We will review hospice medical records and billing documentation to determine whether Medicare payments for hospice services were made in accordance with Medicare requirements.

OAS: W-00-16-35783; various reviews • Expected Issue Date: FY 2017

Hospice Home Care — Frequency of Nurse On-Site Visits to Assess Quality of Care and Services

In 2013, more than 1.3 million Medicare beneficiaries received hospice services from more than 3,900 hospice providers, and Medicare hospice expenditures totaled $15.1 billion. Hospices are required to comply with all Federal, State, and local laws and regulations related to the health and safety of patients (42 CFR § 418.116). Medicare requires that a registered nurse make an on-site visit to the patient's home at least once every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs (42 CFR § 418.76(h)(1)(i)). We will determine whether registered nurses made required on-site visits to the homes of Medicare beneficiaries who were in hospice care.

OAS: W-00-16-35777 • Expected Issue Date: FY 2017

Home Health Services

Comparing HHA Survey Documents to Medicare Claims Data

Through the survey and certification process, CMS and State agencies may identify potentially unqualified or fraudulent providers because of their direct contact with these providers. Home Health Agencies (HHAs) supply patient information (i.e., rosters and schedules) to State agencies during the recertification survey process, but State agencies do not have access to Medicare claims data to verify this information. Therefore, fraudulent HHAs might intentionally omit certain patients from information supplied to State agencies to avoid scrutiny. Previous OIG work has shown that the home health program is prone to fraud, waste, and abuse. We will determine whether HHAs are accurately providing patient information to State agencies for recertification surveys.

OEI: 05-16-00510 • Expected Issue Date: FY 2018

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Home Health Compliance with Medicare Requirements

The Medicare home health benefit covers intermittent skilled nursing care, physical therapy, speech-language pathology services, continued occupational services, medical social worker services, and home health aide services. For CY 2014, Medicare paid home health agencies (HHAs) about $18 billion for home health services. CMS's Comprehensive Error Rate Testing (CERT) program determined that the 2014 improper payment error rate for home health claims was 51.4 percent, or about $9.4 billion. Recent OIG reports have similarly disclosed high error rates at individual HHAs. Improper payments identified in these OIG reports consisted primarily of beneficiaries who were not homebound or who did not require skilled services. We will review compliance with various aspects of the home health prospective payment system and include medical review of 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.

OAS: W-00-16-35712; W-00-16-35501; various reviews • Expected Issue Date: FY 2017

Medical Equipment and Supplies

NEW Part B Services During Non-Part A Nursing Home Stays: Durable Medical Equipment

If a beneficiary continues to reside in a SNF after 100 days, Medicare Part B may provide coverage for certain therapy and supplies (non-Part A stay). A July 2009 OIG report found that Medicare Part B allowed inappropriate payments of $30 million in 2006 for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) provided during non-Part A stays in SNFs. This study will determine the extent of inappropriate Medicare Part B payments for DMEPOS provided to nursing home residents during non-Part A stays in 2015. We will also determine whether CMS has a system in place to identify inappropriate payments for DMEPOS and recoup payments from suppliers.

OEI: 06-16-00380 • Expected Issue Date: FY 2017

NEW Medicare Market Share of Mail-Order Diabetic Testing Strips: April 1 through June 30, 2016 – Mandatory Review

OIG is required to report the market share of diabetic testing strips (DTS) before each subsequent round of the competitive bidding program pursuant to section 1847(b)(I0)(B) of the SSA. This first data brief in a series of three will determine the market share of DTS for the 3-month period immediately preceding the implementation of the National Mail Order Recompete on July 1, 2016 (i.e., April through June 2016). The second report will be for the 3-month period immediately after implementation (i.e., July through September 2016). The third report will be for a similar time frame 6 months after implementation (October through December 2016). These data will help CMS determine how the National Mail Order Recompete may impact shifts in the market. This is the second time we will conduct this series of three DTS market share reports.

OEI: 04-16-00470 • Expected Issue Date: FY 2017

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Positive Airway Pressure Device Supplies — Supplier Compliance with Documentation Requirements for Frequency and Medical Necessity

Beneficiaries receiving continuous positive airway pressure or respiratory assist device therapy (PAP) require replacement of the device's supplies (e.g. mask, tubing, headgear, and filters) when they wear out or are exhausted. Medicare payments for these supplies in 2014 and 2015 were approximately $953 million. Prior OIG work found that suppliers automatically shipped PAP device supplies when no physician orders for refills were in effect. For supplies and accessories used periodically, orders or certificates of medical necessity must specify the type of supplies needed and the frequency with which they must be replaced, used, or consumed (CMS's Medicare Program Integrity Manual, Pub. 100-08, Ch. 5, §§ 5.2.3 and 5.9). Beneficiaries or their caregivers must specifically request refills of repetitive services and/or supplies before suppliers dispense them (CMS's Medicare Claims Processing Manual, Pub. 100-04, Ch. 20, § 200). We will review claims for frequently replaced PAP device supplies to determine whether documentation requirements for medical necessity, frequency of replacement, and other Medicare requirements are met.

OAS: W-00-16-35240; W-00-17-35787 • Expected Issue Date: FY 2017

Orthotic Braces – Reasonableness of Medicare Payments Compared to Amounts Paid by Other Payers

Since 2009, Medicare payments for orthotic braces, including back and knee, have more than doubled and almost tripled for certain types of knee braces. 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-00-17-35756; various reviews • Expected Issue Date: FY 2017

Osteogenesis Stimulators – Lump-Sum Purchase Versus Rental

Osteogenesis stimulators, 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. We will determine whether potential savings can be achieved by Medicare and its beneficiaries if osteogenesis stimulators are rented over a 13-month period

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(the period of consecutive months of rental at which the Medicare payment is capped) rather than acquired through a lump-sum purchase.

OAS: W-00-17-35747; various reviews • Expected Issue Date: FY 2017

Power Mobility Devices – Lump-Sum Purchase Versus Rental

Power-operated vehicles (also known as scooters) and power wheelchairs are collectively classified as power mobility devices (PMDs) and covered under the Medicare Part B DMEPOS benefit. CMS defines a PMD as a covered DMEPOS 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 power wheelchairs. For PMDs not affected by ACA, the beneficiary has the option of either purchasing or renting the PMD. We will determine whether potential savings can be achieved by Medicare if certain PMDs 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.

OAS: W-00-17-35223; various reviews • Expected Issue Date: FY 2017

Competitive Bidding for Medical Equipment Items and Services – Mandatory Review

Federal law requires OIG to conduct postaward audits to assess CMS's competitive bidding program. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(1)(E)). 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.

OAS: W-00-14-35241; various reviews • Expected Issue Date: FY 2017

Orthotic Braces – Supplier Compliance with Payment Requirements

Medicare requires that suppliers' claims for DMEPOS 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. 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. We will review Medicare Part B payments for orthotic braces to determine whether they were medically necessary and were supported in accordance with Medicare requirements.

OAS: W-00-17-35749 • Expected Issue Date: FY 2017

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Nebulizer Machines and Related Drugs – Supplier Compliance with Payment Requirements

A nebulizer machine changes medication from a liquid to a mist so that it can be more easily inhaled into the lungs. For CY 2014, Medicare paid approximately $632.8 million for inhalation drugs. Medicare requires that claims for nebulizer machines and related drugs 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. A preliminary OIG review identified that at least 50 percent of claims reviewed were not paid in accordance with Medicare 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.

OAS: W-00-15-35465 • Expected Issue Date: FY 2017

Access to Durable Medical Equipment in Competitive Bidding Areas

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. We will determine the effects of the competitive bidding program on Medicare beneficiaries' access to certain types of DMEPOS subject to competitive bidding.

OEI: 01-15-00040; various reviews • Expected Issue Date: FY 2017

Other Providers and Suppliers

NEW Monitoring Medicare Payments for Clinical Diagnostic Laboratory Tests – Mandatory Review

Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to replace its current system of determining payment rates for Medicare Part B clinical diagnostic laboratory tests with a new market-based system that will use rates paid to laboratories by private payers. Pursuant to PAMA, OIG is required to conduct an annual analysis of the top 25 laboratory tests by Medicare payments and analyze the implementation and effect of the new payment system. We will analyze Medicare payments for clinical diagnostic laboratory tests performed in 2016 and monitor CMS's implementation of the new Medicare payment system for these tests. This work will build upon our previous analyses of Medicare Part B laboratory test payments in 2014 and 2015 and our review of CMS's progress toward implementing the new Medicare payment system.

OEI: 00-00-00000; 00-00-00000 • Expected Issue Date: FY 2017

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Medicare Payments for Transitional Care Management

Transitional Care Management (TCM) includes services provided to a patient whose medical and/or psychosocial problems require moderate or high-complexity medical decision-making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospital, observation status in a hospital, or skilled nursing facility/nursing facility, to the patient's community setting (home, domicile, rest home, or assisted living). Beginning January 1, 2013, Medicare covered TCM services and paid for them under the Medicare Physician Fee Schedule. Medicare-covered services, including chronic care management, end-stage renal disease, and prolonged services without direct patient contact, cannot be billed during the same service period as TCM. We will determine whether payments for TCM services were in accordance with Medicare requirements.

OAS: W-00-17-35786 • Expected Issue Date: FY 2017

Medicare Payments for Chronic Care Management

Chronic Care Management (CCM) is defined as the non-face-to-face services provided to Medicare beneficiaries who have multiple (two or more), significant chronic conditions (Alzheimer's disease, arthritis, cancer, diabetes, etc.) that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. These significant chronic conditions are expected to last at least 12 months or until the death of the patient. CCM cannot be billed during the same service period as transitional care management, home health care supervision/hospice care, or certain end-stage renal disease services. Beginning January 1, 2015, Medicare paid separately for CCM under the Medicare Physician Fee Schedule and under the American Medical Association Current Procedural Terminology. We will determine whether payments for CCM services were in accordance with Medicare requirements.

OAS: W-00-17-35785 • Expected Issue Date: FY 2017

Data Brief on Financial Interests Reported Under the Open Payments Program

The Physician Payments Sunshine Act (from the ACA § 6002) requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals. Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. We will analyze 2015 data extracted from the Open Payments website to determine the number and nature of financial interests. We will also determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations. We will determine the volume and total dollar amount associated with drugs

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and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.

OEI: 03-16-00420 • Expected Issue Date: FY 2017

Power Mobility Devices Equipment – Portfolio Report on Medicare Part B Payments

Previous OIG work identified inappropriate payments for power mobility devices (PMDs) that were medically unnecessary, were not documented in accordance with Medicare requirements, cheaper to rent instead of purchase, or were fraudulent. We will compile the results of prior OIG audits, evaluations, and investigations of PMD equipment paid by Medicare to identify trends in payment, compliance, and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities. This planned work will offer recommendations to reduce Medicare PMD vulnerabilities that were detected in prior OIG work.

OIG: W-00-17-35791 • Expected Issue Date: FY 2017

Ambulance Services – Supplier Compliance with Payment Requirements

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)).

Prior OIG work found that Medicare made inappropriate payments for advanced life support emergency transports. We will determine whether Medicare payments for ambulance services were made in accordance with Medicare requirements.

OAS: W-00-17-35574; various reviews • Expected Issue Date: FY 2017

Inpatient Rehabilitation Facility Payment System Requirements

Inpatient rehabilitation facilities (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, specific medical record documentation, at the time of IRF admission, must support a reasonable expectation that the patient needs multiple intensive therapies, one of which must be physical or occupational therapy; is able to actively participate and demonstrate measurable improvement; and requires supervision by a rehabilitation physician to assess and modify the course of treatment as needed to maximize the benefit from the rehabilitation process. Our prior reviews of individual IRFs have identified substantial Medicare overpayments. We will determine whether IRFs nationwide billed claims in compliance with Medicare documentation and coverage requirements.

OAS: W-00-15-35730 • Expected to be issued in FY 2017

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Histocompatibility Laboratories – Supplier Compliance with Payment Requirements

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Histocompatibility laboratories typically provide testing required for bone marrow and solid organ transplantation services. Cost information for these laboratories must be accurate and in sufficient detail to support payments made for services provided (42 CFR § 413.24(a) and (c)). Costs claimed in the cost report must be related to the care of beneficiaries; reasonable, necessary, and proper; and allowable under Medicare regulations (42 CFR § 413.9(a), (b), and (c)(3)). From March 31, 2013, through September 30, 2014, histocompatibility laboratories reported $131 million in reimbursable costs on their most recent cost reports. We will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements.

OAS: W-00-16-35742 • Expected Issue Date: FY 2017

Review of Financial Interests Reported Under the Open Payments Program

Manufacturers are required to disclose to CMS payments made to physicians and teaching hospitals (ACA § 6002). Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. The Open Payments Program provides public transparency about provider-industry relationships. We will determine the extent to which data in the open payments system is missing or inaccurate, the extent to which CMS oversees manufacturers' and group purchasing organizations' compliance with data reporting requirements, and whether the required data for physician and teaching hospital payments are valid.

OEI: 03-15-00220 • Expected Issue Date: FY 2017

Ambulatory Surgical Centers – Quality Oversight

Medicare sets minimum health and safety requirements for ambulatory surgical centers (ASCs) through the conditions for coverage (SSA § 1832(a)(2)(F)(i)). CMS requires that ASCs become Medicare certified to show they meet these conditions (SSA § 1865 and 42 CFR Part 416). 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. We will review the frequency of Medicare's certification surveys for ASCs.

OEI: 01-15-00400 • Expected Issue Date: FY 2017

Payments for Medicare Services, Supplies, and DMEPOS Referred or Ordered by Physicians –Compliance

CMS requires that physicians and nonphysician practitioners who order certain services, supplies, and/or DMEPOS be Medicare-enrolled physicians or nonphysician practitioners and be legally eligible to refer and order services, supplies, and DMEPOS (ACA § 6405). If the referring or ordering physician or nonphysician practitioner is not eligible to order or refer, then Medicare claims should not be paid.

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We will review select Medicare services, supplies, and DMEPOS referred or ordered by physicians and nonphysician practitioners to determine whether the payments were made in accordance with Medicare requirements.

OAS: W-00-17-35748 • Expected Issue Date: FY 2017

Anesthesia Services – Noncovered Services

Medicare Part B covers anesthesia services provided by a hospital for an outpatient or by a freestanding ambulatory surgical center for a patient. 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.

OAS: W-00-17-35753 • Expected Issue Date: FY 2017

Anesthesia Services – Payments for Personally Performed Services

Physicians must 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)). 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.

OAS: W-00-17-35706; various reviews • Expected Issue Date: FY 2017

Physician Home Visits – Reasonableness of Services

A home visit is when a physician provides evaluation and management (E/M) services in a beneficiary's home. From January 2013 through December 2015, Medicare provided $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)). We will determine whether Medicare payments to physicians for E/M home visits were reasonable and made in accordance with Medicare requirements.

OAS: W-00-17-35754 • Expected Issue Date: FY 2017

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Prolonged Services – Reasonableness of Services

Prolonged services are for additional care provided to a beneficiary after an evaluation and management (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 Processing Manual includes requirements that must be met in order to bill for a prolonged E/M service code (Medicare Claims Processing Manual, Pub. 100-04, Ch. 12, § 30.6.15.1). We will determine whether Medicare payments to physicians for prolonged E/M services were reasonable and made in accordance with Medicare requirements.

OAS: W-00-17-35755 • Expected Issue Date: FY 2017

Chiropractic Services – Part B Payments for Noncovered 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). Prior OIG work identified inappropriate payments for chiropractic services. Medicare will not pay for items or services that are not "reasonable and necessary" (SSA § 1862(a)(1)(A)). We will review Medicare Part B payments for chiropractic services to determine whether such payments were claimed in accordance with Medicare requirements.

OAS: W-00-16-35606; various reviews • Expected Issue Date: FY 2017

Chiropractic Services – Portfolio Report on Medicare Part B Payments

Previous OIG work identified inappropriate payments for chiropractic services that were medically unnecessary, were not documented in accordance with Medicare requirements, or were fraudulent. 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. This planned work will offer recommendations to reduce Medicare chiropractic vulnerabilities that were detected in prior OIG work.

OAS: W-00-17-35770; OIG-12-14-03 • Expected Issue Date: FY 2017

Selected Independent Clinical Laboratory Billing Requirements

An independent clinical laboratory is one that is independent both of an attending or consulting physician's office and of a hospital. Previous 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

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the provider has and furnishes upon request the information necessary to determine the amounts due (SSA § 1833(e)). We will review Medicare payments to independent clinical laboratories to determine laboratories' compliance with selected billing requirements. We will focus on independent clinical laboratories with claims that may be at risk for overpayments. We will use the results of these reviews to identify clinical laboratories that routinely submit improper claims, and we will recommend recovery of overpayments.

OAS: W-00-17-35726; various reviews • Expected Issue Date: FY 2017

Physical Therapists – High Use of Outpatient Physical Therapy Services

Previous OIG work found that claims for therapy services provided by independent physical therapists were not reasonable, were not properly documented, or the therapy services were not medically necessary. Medicare will not pay for items or services that are not "reasonable and necessary" (SSA § 1862(a)(1)(A)). We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. Our focus is on independent therapists who have a high utilization rate for outpatient physical therapy services. Documentation requirements for therapy services can be found in CMS's Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 15, § 220.3.

OAS: W-00-16-35220; various reviews • Expected Issue Date: FY 2017

Portable X-ray Equipment – Supplier Compliance with Transportation and Setup Fee Requirements

Portable x-ray suppliers provide diagnostic imaging services at patients' locations – most often residences including private homes and group living facilities, such as nursing homes – rather than in a traditional clinical setting, such as a doctor's office or hospital. Medicare generally reimburses for portable x-ray services if the conditions for coverage are met (42 CFR §§ 486.100–486.110). However, previous 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. 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.

OAS: W-00-16-35464 • Expected Issue Date: FY 2017

Sleep Disorder Clinics – High Use of Sleep-Testing Procedures

An OIG analysis of CY 2010 Medicare payments for Current Procedural Terminology[6] codes 95810 and 95811, which totaled approximately $415 million,

[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.

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showed high utilization associated with these sleep-testing procedures. 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. Medicare will not pay for items or services that are not "reasonable and necessary" (SSA § 1862(a)(1)(A)). 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. Requirements for coverage of sleep tests under Part B are located in CMS's Medicare Benefit Policy Manual, Pub. No. 100 02, Ch. 15, § 70.

OAS: W-00-17-35521; various reviews • Expected Issue Date: FY 2017

Prescription Drugs

Drug Waste of Single-Use Vial Drugs

The FDA approves vial sizes for single use submitted by manufacturers but does not control the vial sizes submitted for approval. Savings might be realized if single vial sizes currently available in other countries were available in the United States and if manufacturers were to market these smaller vials at lower prices. The Medicare Claims Processing Manual, Pub. 100-04, Ch. 17, § 40 provides policy on the use of the "JW" modifier for discarded Part B drugs and biologicals to track the amount of reimbursed waste in single-use vials effective January 1, 2017. We will determine the amount of waste for the 20 single-use-vial drugs with the highest amount paid for waste as identified by the JW modifier and provide specific examples of where a different size vial could significantly reduce waste.

OAS: W-00-17-35788 • Expected Issue Date: FY 2017

Potential Savings from Inflation-Based Rebates in Medicare Part B

Each year, statutorily mandated rebates enable Medicaid to recoup a substantial portion of the billions spent by the program on prescription drugs. In contrast, Medicare Part B also spends billions annually on prescription drugs; however, no similar rebate authority exists for Part B to reduce the costs of drugs to the program. OIG will examine the amount the Federal Government could potentially collect from pharmaceutical manufacturers if inflation-indexed rebates were required under Medicare Part B, which builds upon earlier OIG work examining existing inflation-based rebates in Medicaid and potential rebates in Medicare Part B. The study will select a sample of 50–100 Part B drugs. We will calculate the amount covering the difference between the existing rebate policy in 2015 and a scenario where an inflation-based rebate methodology similar to Medicaid had been in place for drugs covered under Medicare Part B and in absence of industry adjustments to such rebate agreement.

OEI: 12-16-00560 • Expected Issue Date: FY 2017

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

In 2005, Medicare began paying for most Part B drugs using a new methodology based on the average sales prices (ASP). The enabling law required that OIG compare ASPs with average manufacturer prices (AMP) (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 threshold (5 percent), OIG notifies the HHS Secretary, who may disregard the ASP for the drug when setting reimbursement amounts, e.g., apply a price substitution policy. We will review Medicare Part B drug prices by comparing ASPs to AMPs and identify drug prices that exceed a designated threshold.

OEI: 03-16-00540; 03-16-00580; 00-00-0000 • Expected Issue Date: FY 2017

Payments for Immunosuppressive Drug Claims with "KX" Modifiers

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). Prior OIG reports found that Medicare claims for immunosuppressive drugs reported with the "KX" modifier may not always meet documentation requirements for payment under Part B. We will determine whether Part B payments for immunosuppressive drugs that were billed with a service code modifier "KX" met Medicare documentation requirements.

OAS: W-00-15-35707; various reviews • Expected Issue Date: FY 2017

Part A and B Contractors

Administrative Costs Claimed by Medicare Contractors

CMS administers the Medicare program through contractors. Contracts between CMS and the Medicare contractors define the functions to be performed and provide the reimbursement of allowable administrative costs incurred in the processing of Medicare claims. 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 Federal Acquisition Regulation (FAR) at 48 CFR Part 31.

OAS: W-00-17-35005; various reviews • Expected Issue Date: FY 2017

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Contractor Pension Cost Requirements

Medicare contractors are eligible to be reimbursed a portion of their pension costs and are required to separately account for the Medicare segment pension plan assets based on the requirements of their Medicare contracts and Cost Accounting Standards. 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 contractors 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 412 and 413; and the Medicare contract, Appendix B, § XVI.

OAS: W-00-17-35067; W-00-17-35094; various reviews • Expected Issue Date: FY 2017

Contractor Postretirement Benefits and Supplemental Employee Retirement Plan Costs

CMS reimburses a portion of its contractors' postretirement health benefits costs and the supplemental employee retirement plans costs. The reimbursement is determined by the cost reimbursement principles contained in the FAR, Cost Accounting Standards as required by the Medicare contracts. We will review the postretirement health benefit costs and the supplemental employee retirement plans of Medicare contractors 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-00-17-35095; various reviews • Expected Issue Date: FY 2017

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

Federal law requires independent evaluations of the security programs of Medicare Administrative Contractors and requires OIG to assess such evaluations and report the results of its assessments to Congress (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 912). We will review independent evaluations of information systems security programs of Medicare Administrative Contractors. We will report to Congress on our assessment of the scope and sufficiency of the independent evaluations and summarize their results.

OAS: W-00-17-41010 • Expected Issue Date: FY 2017

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Collection Status of ZPIC and PSC – Identified Medicare Overpayments

OIG issued several reports regarding the tracking and collection of overpayments that Medicare's contractors have made to providers. In response, CMS stated that it added reporting requirements that would improve overpayment tracking among the claims processors and Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs). ZPICs and PSCs are required to detect and deter fraud and abuse in Medicare Part A and 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. We will determine the total amount of overpayments that ZPICs and PSCs identified and referred to claims processors in 2014 and the amount of these overpayments that claims processors collected. We will also review the procedures for tracking collections of overpayments identified by ZPICs and PSCs.

OEI: 03-13-00630 • Expected Issue Date: FY 2017

Other Part A and B Program Management Issues

Delivery System Reform

Accountable Care Organizations: Beneficiary Assignment and Shared Savings Payments

The Medicare Shared Savings Program (MSSP), established by section 3022 of ACA, introduced accountable care organizations (ACOs) into the Medicare program to promote accountability of hospitals, physicians, and other providers for a patient population, coordinate items and services, and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. We will review the MSSP to determine whether beneficiary assignment to 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-00-17-35774; various reviews • Expected Issue Date: FY 2017

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Accountable Care Organizations: Savings, Quality, and Promising Practices

The MSSP, established by section 3022 of ACA, introduced ACOs into the Medicare program to promote accountability of hospitals, physicians, and other providers for a patient population, coordinate items and services, and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. We will review ACOs that participate in the MSSP and describe their performance on quality measures and cost savings over the first 3 years of the program. In addition, we will describe the characteristics of the ACOs that performed well on measures and achieved savings and analyze their spending and utilization of services over time. We will also identify these ACOs' strategies for and challenges to achieving quality and cost savings.

OEI: 02-15-00450 • Expected Issue Date: FY 2017

Use of Electronic Health Records to Support Care Coordination through ACOs

The MSSP, established by section 3022 of ACA, introduced ACOs into the Medicare program to promote accountability of hospitals, physicians, and other providers for a patient population, coordinate items and services, and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. We will review the extent to which providers participating in ACOs in the 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.

OEI: 01-16-00180 • Expected Issue Date: FY 2017

Billing and Payments

NEW Medicare Payments for Service Dates After Individuals' Dates of Death

Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to establish policies and implement claim edits to ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals. Prior reviews have identified Medicare payments for services ostensibly rendered to deceased individuals. We will review CMS's policies and procedures that ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals.

OAS: W-00-17-35771 • Expected Issue Date: FY 2017

NEW Management Review: CMS's Implementation of the Quality Payment Program

MACRA establishes a new Medicare physician payment system, known as the Quality Payment Program, which is intended to control Medicare expenditures and promote high-value, high-quality care. Under the Quality Payment Program, clinicians may receive positive or negative Medicare payment

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adjustments depending on their performance across a range of measures; alternatively, clinicians can opt to participate in an Advanced Alternative Payment Model, which offers other quality and payment incentives. We will review CMS's planning and early implementation of the Quality Payment Program. These payment reforms are a significant shift in how Medicare calculates compensation for clinicians and entails the development of a complex system for measuring, reporting, and scoring the value and quality of care. Additionally, MACRA mandates that final regulations must be issued by November 1, 2016, with the first performance year beginning January 1, 2017. We will describe the timelines and key milestones CMS has established for implementing the Quality Payment Program provisions of MACRA and will identify the key challenges and potential vulnerabilities CMS is facing during implementation.

OEI: 12-16-00400 • Expected Issue Date: FY 2017

Medicare Payments for Incarcerated Beneficiaries – Mandatory Review

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 MACRA requires the HHS Secretary 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).) We will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to incarcerated beneficiaries.

OAS: W-00-16-35624; various reviews • Expected Issue Date: 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.

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Part D–Prescription Drug Program

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Medicare expended over $77 billion in Part D benefit payments in CY 2014, serving more than 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 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 Part C Payments for Service Dates After Individuals' Dates of Death

CMS pays MA organizations for Part C benefits prospectively. A prior OIG review of deceased beneficiaries (OEI-04-12-00130) determined that Medicare improperly made $23 million in payments in 2011, of which $20 million was directly related to Medicare Part C payments that were made that year after beneficiaries' deaths. Federal regulations require that MA organizations disenroll a beneficiary from its MA plan on the death of the individual, which is effective the first day of the calendar month following the month of death. We will determine whether prospective payments made after a beneficiaries' date of death were in accordance with Medicare requirements.

OAS: W-00-17-35772 • Expected Issue Date: FY 2017

Extent of Denied Care in Medicare Advantage and CMS Oversight

Capitated payment systems are based on a payment per person rather than a payment per service provided. Capitated payment systems, such as those used by CMS to pay MA plans, may create financial incentives for plans to underserve beneficiaries. We will examine national trends and oversight by CMS of denied care within MA. We will determine the extent to which services were denied, appealed, and overturned in MA from 2013 to 2015. We will also compare rates of denials, appeals, and overturns across MA plans and evaluate CMS's efforts to monitor and prevent inappropriate denial of care in MA. Future work in this area may include medical record reviews to examine whether denials are appropriate.

OEI: 09-16-00410 • Expected Issue Date: FY 2018

Integrity of Medicare Advantage 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. Previous CMS and OIG audits have indicated vulnerabilities in the accuracy of data reported by MA organizations. Realizing the potential benefits of

[7] CMS.gov/fastfacts

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the MA encounter data for payment and program integrity oversight is contingent upon the data's completeness, validity, and timeliness. 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.

OEI: 03-15-00060 • Expected Issue Date: FY 2017

Risk Adjustment Data – Sufficiency of Documentation Supporting Diagnoses

Payments to MA organizations are risk adjusted on the basis of the health status of each beneficiary. MA organizations are required to submit risk adjustment data to CMS in accordance with CMS instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause CMS to pay MA organizations improper amounts (SSA §§ 1853(a)(1)(C) and (a)(3)). In general, MA organizations receive higher payments for sicker patients. CMS estimates that 9.5 percent of payments to MA organizations are improper, mainly due to unsupported diagnoses submitted by MA organizations. Prior OIG reviews have shown that medical record documentation does not always support the diagnoses submitted to CMS by MA organizations. 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.

OAS: W-00-16-35078; various reviews • Expected Issue Date: FY 2018

Part D – Prescription Drug Program

Medicare Part D Rebates Related to Drugs Dispensed by 340B Pharmacies

Drug manufacturer rebates reduce the cost of the Part D program to beneficiaries and the Government. Manufacturers frequently do not pay rebates for Part D prescriptions filled at 340B covered entities and contract pharmacies since they are already providing a discount on the purchase of the drug. The Medicare Part D program does not share in the purchase discounts. Savings could be realized if requirements similar to those of the Medicaid Drug Rebate Program that require manufacturers to pay rebates were adopted by the Medicare Part D program. We will determine the upper bound of what could be saved if pharmaceutical manufacturers paid rebates for drugs dispensed through the Medicare Part D program at 340B covered entities and contract pharmacies.

OAS: W-00-17-35789 • Expected Issue Date: FY 2017

Questionable Billing for Compounded Topical Drugs in Part D

Part D spending for compounded topical drugs grew by more than 3,400 percent between 2006 and 2015, reaching $224 million. This growth in spending, combined with an increase in the number of OIG investigative cases involving compounded drugs, suggests the emergence of a fraud risk. This review will describe billing for topical compounded drugs under Part D and

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identify pharmacies with questionable Part D billing for these drugs and any associated prescribers.

OEI: 02-16-00440 • Expected Issue Date: FY 2017

Medicare Part D Payments for Service Dates After Individuals' Dates of Death

Under Medicare Part D, individuals entitled to Medicare benefits under Part A or enrolled in Part B and who live in the service area of a Part D plan may obtain prescription drug coverage. CMS contracts with private prescription drug plans and MA plans (collectively known as sponsors) to offer prescription drug benefits to eligible individuals. A prior OIG review of deceased beneficiaries (OEI-04-12-00130) determined that Medicare improperly made $23 million in payments in 2011, of which $1 million was directly related to Medicare Part D payments that were made that year after beneficiaries' deaths. CMS pays prescription drug plan organizations for Part D benefits prospectively. A Part D sponsor must disenroll a beneficiary from its prescription drug plan on the death of the individual, which is effective the first day of the calendar month following the month of death. We will determine whether prospective payments made after a beneficiaries' date of death were in accordance with Medicare requirements.

OAS: W-00-17-35773 • Expected Issue Date: FY 2017

Medicare Part D Eligibility Verification Transactions

An E1 transaction is a Medicare Eligibility Verification transaction that the pharmacy submits to the Part D transaction facilitator to determine a beneficiary's eligibility to the Part D program and other drug coverage information. The Part D transaction facilitator returns information to the pharmacy that is needed to submit the prescription drug event. E1 transactions are part of the real-time process of the Coordination of Benefits and calculating the True Out-of-Pocket balance (CMS, Medicare Prescription Drug Benefit Manual, Pub. No. 100-18, Ch. 14, § 30.4). We will review CMS's oversight of E1 transactions processed by contractors and whether the E1 transactions were created and used for intended purposes. We will also review E1 transactions to assess the validity of the data.

OAS: W-00-17-35751 • Expected Issue Date: FY 2017

Increase in Prices for Brand-Name Drugs Under Part D

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. 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

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brand-name drugs under Medicare Part D to the rate of inflation for the same period.

OEI: 03-15-00080 • Expected Issue Date: FY 2017

Federal Payments for Part D Catastrophic Coverage

A beneficiary enters catastrophic coverage when his or her annual drug spending exceeds a certain threshold. The Federal Government's reinsurance subsidy covers 80 percent of catastrophic drug costs (SSA § 1860D-15). 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.

OEI: 02-16-00270 • Expected Issue Date: FY 2017

Part D Pharmacy Enrollment

Since the inception of Part D, numerous OIG reports have raised concerns about CMS's oversight of or actions to address fraud in the Part D benefit. Recent law enforcement actions have highlighted the role pharmacies can play in prescription drug fraud. When problems occur, CMS must rely on Part D plan sponsors to follow up and take action against pharmacies. Currently, Part D pharmacies are not required to enroll in Medicare. However, they may enroll for other reasons. For example, pharmacies that bill Medicare for DMEPOS 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 review CMS's ability to oversee pharmacies that bill for Part D drugs and 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: 02-15-00440 • Expected Issue Date: FY 2017

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

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. We will review the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries, as required. The ACA, § 3313, requires OIG to conduct this review annually.

OEI: 00-10-00000 • Expected Issue Date: FY 2017

Recommendation Follow-Up – Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions

Medicare Part D Pharmacy and Therapeutics (P&T) committees make clinical decisions about which drugs are on a plan's list of prescription drugs. P&T committees are required to make prescription drug coverage decisions on the basis of scientific evidence and standards of practice. To comply

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In FY 2016, Medicaid's budget was $367 billion

$367 billion

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. We will determine what steps CMS and Part D sponsors have taken to improve oversight of P&T committee conflicts of interest.

OEI: 00-00-00000 • Expected Issue Date: FY 2019

Documentation of Pharmacies' Prescription Drug Event Data

Drug plan sponsors must submit prescription drug event records, which is a summary record of individual drug claim transactions at the pharmacy, for the HHS Secretary to determine payments to the plans (SSA § 1860D-15(f)(1)). 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. We will also conduct additional reviews of selected retail pharmacies identified in a prior OIG report as having questionable Part D billing.

OAS: W-00-17-35411; various reviews • Expected Issue Date: FY 2017

Quality of Sponsor Data Used in Calculating Coverage Gap Discounts

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. 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.

OAS: W-00-16-35611; W-00-17-35611; various reviews • Expected Issue Date: FY 2018

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.

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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 2017 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 (PCS).

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States' MCO Medicaid Drug Claims

Under the drug rebate program, CMS provides States with a quarterly Medicaid drug tape, which, in effect, lists all covered outpatient drugs and indicates a drug's termination date, if applicable. A drug manufacturer must have a rebate agreement with CMS to have its outpatient drugs covered under Medicaid (SSA § 1927(a)(1)). CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement. States contract with MCOs to provide Medicaid services, including covered outpatient drugs to enrollees if the MCO is contractually required to provide such drugs. We will determine whether MCO capitation payments included reimbursement for drugs that are not covered under the Medicaid program. MCOs have some flexibility in maintaining formularies of drugs regardless of whether the manufacturers of those drugs participate in the drug rebate program. State Medicaid agencies can establish requirements regarding MCOs' formularies.

OAS: W-00-17-31520 • Expected Issue Date: FY 2017

Physician-Administered Drugs for Dual Eligible Enrollees

The term "dual eligible" is used to describe 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. We will determine whether Medicare requirements for processing physician-administered drug claims

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impact State Medicaid agencies' ability to correctly invoice Medicaid drug rebates for dual-eligible enrollees.

OAS: W-00-16-31512 • Expected Issue Date: FY 2017

Specialty Drug Pricing and Reimbursement in Medicaid

Specialty pharmacies dispense prescription drugs that often require special handling or administration. These specialty drugs are often expensive and are used to treat complex 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. 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.

OEI: 00-00-00000 • Expected Issue Date: FY 2018

States' Actions Based on Medicaid Drug Utilization Reviews

States are required to establish drug utilization review (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). We will review the education and enforcement actions that States have taken on the basis of information generated by their DUR programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates.

OEI: 05-13-00550 • Expected Issue Date: FY 2017

States' Collection of Rebates on Physician Administered Drugs

States are required to collect rebates on covered outpatient drugs administered by physicians in order to be eligible for Federal matching funds (SSA § 1927(a)). Previous 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). 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.

OAS: W-00-17-31400; various reviews • Expected Issue Date: FY 2017

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

Medicaid MCOs are required to report enrollees' drug utilization to the State for the purpose of collecting rebates from manufacturers. Section 2501(c) of the ACA expanded the rebate requirement to include drugs dispensed to 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.

OAS: W-00-17-31483; various reviews • Expected Issue Date: FY 2017

Manufacturer Rebates – Federal Share of Rebates

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. 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.

OAS: W-00-17-31450; various reviews • Expected Issue Date: FY 2017

Treatment of Authorized Generic Drugs

An authorized generic drug is one that the manufacturer holding the title to the original new drug application 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 new drug application of the authorized generic drug must include the sales of this drug in its average manufacturer price (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. We will review drug manufacturers' treatment of sales of authorized generics in their calculation of AMP for the Medicaid drug rebate program. We will determine whether manufacturers included sales of authorized generics to secondary manufacturers in their AMP calculations.

OAS: W-00-17-31499 • Expected Issue Date: FY 2017

Medicaid Payments for Multiuse Vials of Herceptin

Previous OIG audits of Herceptin, a drug used to treat breast cancer, have shown provider noncompliance with Medicare billing requirements. Similar issues may occur in Medicaid. We will review States' claims for the Federal share of Medicaid payments for Herceptin 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

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billed in accordance with the regulations of the selected States.

OAS: W-00-17-31476; various reviews • Expected Issue Date: FY 2017

Home Health Services and Other Community-Based Care

Data Brief on Fraud in Medicaid Personal Care Services

OIG has conducted numerous audits, evaluations, and investigative work involving PCS. Much of this work is summarized in a November 2012 portfolio report to CMS entitled "Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement" (OIG-12-12-01). The portfolio report summarized the observations and findings of previous OIG evaluation and audit reports on Medicaid PCS and offered recommendations for improving program oversight. We will issue a data brief that provides, through data collected from the 50 State Medicaid Fraud Control Units (MFCUs, or Units) and OIG's Office of Investigations, an overview of PCS statistical data collected since the portfolio was issued in 2012. The data brief will provide information on State and Federal investigations, indictments, convictions, and recoveries involving fraud and patient abuse or neglect in Medicaid PCS. The data presented in this brief are intended to illustrate the prevalence and magnitude of fraud and patient abuse or neglect involving PCS. These data will be especially important for OIG's future work with CMS to combat these issues.

OEI: 12-16-00500 • Expected Issue Date: FY 2017

Oversight and Effectiveness of 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 regards to efficiency, economy, and quality of care and do not inflate Federal costs. 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 CMS's oversight of State Medicaid waivers.

OAS: W-00-17-31513 • Expected Issue Date: FY 2018

Adult Day Health Care Services

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. We will review Medicaid

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payments by States for adult day health care services to determine whether providers complied with Federal and State requirements.

OAS: W-00-16-31386; various reviews • Expected Issue Date: FY 2017

Room-and-Board Costs Associated with HCBS Waiver Program Payments

Medicaid covers the cost of home- and community-based services (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. We will determine whether selected States claimed Federal reimbursement for unallowable room-and-board costs associated with services provided under the terms and conditions of HCBS waiver programs. We will determine whether HCBS payments included the costs of room and board and identify the methods the States used to determine the amounts paid.

OAS: W-00-17-31465; various reviews • Expected Issue Date: FY 2017

Other Medicaid Services, Equipment, and Supplies

Express Lane Eligibility – Mandatory Review

The Express Lane Eligibility (ELE) option provides States with new avenues to ensure that children eligible for Medicaid or CHIP have a fast and simplified process for having their eligibility determined or renewed. The ELE option permits States to rely on eligibility findings made by other programs, such as Head Start and Temporary Assistance to Needy Families. MACRA, § 305, requires OIG to submit a report to Congress on the use of the ELE option under Medicaid and CHIP within 18 months of enactment. We will determine the extent to which selected States met Federal requirements in making Medicaid and CHIP eligibility determinations using the ELE option and developing eligibility error rates. We will also assess whether and how the selected States addressed issues that contributed to inaccurate determinations and the amount of payments associated with those determinations. An additional review will describe States' use of the different ELE models, the reported benefits and challenges of such use to States and low-income families, and the lessons learned by States in overcoming barriers to using ELE.

OEI: 06-15-00410; OAS: A-04-15-08043; A-04-15-08045 • Expected Issue Date: FY 2017

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Transportation Services – Compliance with Federal and State Requirements

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. We will determine the appropriateness of Medicaid payments by States to providers for transportation services.

OAS: W-00-17-31121; various reviews • Expected Issue Date: FY 2017

Health Care-Acquired Conditions – Prohibition on Federal Reimbursements

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). 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.

OAS: W-00-17-31452; various reviews • Expected Issue Date: FY 2017

State Claims for Federal Reimbursement

Dental Services for Children – Inappropriate Billing

Dental services are required for most Medicaid-eligible individuals under age 21 as a component of the Early and Periodic Screening, Diagnostic, and Treatment 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. Previous OIG work indicated that some dental providers may be inappropriately billing for services. We will review Medicaid payments by States for dental services to determine whether States have properly claimed Federal reimbursement.

OAS: W-00-17-31135 • Expected Issue Date: FY 2017

Community First Choice State Plan Option Under the Affordable Care Act

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 Community First Choice (CFC) services. To be eligible for CFC services, beneficiaries must

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otherwise require an institutional level of care and meet financial eligibility criteria. We will review CFC payments to determine whether the payments are proper and allowable.

OAS: W-00-17-31495 • Expected Issue Date: FY 2017

Payments to States Under the Balancing Incentive Program

Under the Balancing Incentive Program (BIP), eligible States can receive either a 2-percent or 5-percent increase in their FMAP for eligible Medicaid long-term services and support (LTSS) expenditures. Funding to States under the BIP cannot exceed $3 billion over the program's 4-year period (i.e., October 1, 2011, through September 30, 2015). To receive payments, participating States agree to make structural changes to increase access to noninstitutional LTSS. The States must also use the additional Federal funding for the purposes of providing new or expanded offerings of noninstitutional LTSS. We will review expenditures that States claimed under the BIP to ensure that they were for eligible Medicaid LTSS and determine whether the States used the additional enhanced Federal match in accordance with § 10202 of the ACA.

OAS: W-00-17-31482; various reviews • Expected Issue Date: FY 2017

State Agency Verification of Deficiency Corrections

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 on-site reviews or by obtaining other evidence of correction (State Operations Manual, Pub. No. 100-07, § 7300.3). A previous 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. We will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys.

OAS: W-00-17-31502; various reviews • Expected Issue Date: FY 2017

Medicaid Beneficiary Transfers from Group Homes and Nursing Facilities to Hospital Emergency Rooms

High occurrences of emergency transfers could indicate poor quality of care. Previous OIG work examined transfers to hospital emergency departments, raising concerns about the quality of care provided in some nursing facilities. We will review the rate of and reasons for transfer from group homes or nursing facilities to hospital emergency departments.

OAS: W-00-16-31040; various reviews • Expected Issue Date: FY 2017

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Delivery System Reform Incentive Payments

Delivery System Reform Incentive Payments are incentive payments made under Section 1115 waivers to hospitals and other providers that develop programs or strategies to enhance access to health care, increase the quality and cost-effectiveness of care, and increase the health of patients and families served. States must be able to demonstrate outcomes and ensure accountability for allocated funding. These incentive payments have significantly increased funding to providers for their efforts related to the quality of services. For example, one State made incentive payments totaling more than $6 billion in a 5-year period. We will ensure that select States adhered to applicable Federal and State requirements when they made incentive payments to providers.

OAS: W-00-17-31516; various reviews • Expected Issue Date: FY 2018

Accountable Care in Medicaid

The Medicaid program is experiencing a shift toward new models that promote accountability for the cost and quality of care delivered to patients and focus on better, more efficient coordination of care. Several delivery system reform initiatives in Medicaid, including, for example, medical homes and accountable care organizations, focus on accountable care and include elements such as implementing value-based payment structures, measuring quality improvement, and collecting and analyzing data. We will review selected accountable care models in Medicaid for compliance with relevant State and Federal requirements.

OAS: W-00-17-31518; various reviews • Expected Issue Date: FY 2018

State Management of Medicaid

Third-Party Liability Payment Collections in Medicaid

Medicaid beneficiaries may have additional health insurance through third-party sources. Previous OIG work described problems that State Medicaid agencies had in identifying and collecting third-party payments. States are to take all reasonable measures to ascertain the legal liabilities of third parties with respect to health care items and services (SSA § 1902(a)(25)). Medicaid is the payer of last resort and providers are to identify and refund overpayments received. We will determine if States have taken action to ensure that Medicaid is the payer of last resort by identifying whether a third-party payer exists and if the State correctly reports the third-party liability to CMS.

OAS: W-00-17-31517; A-05-17-00000 • Expected Issue Date: FY 2018

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NEW Medicaid Overpayment Reporting and Collections

Prior OIG audits identified Medicaid overpayments in various States and included recommendations for the collection of those overpayments. If a Federal audit indicates that a State has failed to identify an overpayment, CMS considers the overpayment as discovered on the date that the Federal official first notifies the State in writing of the overpayment and specifies a dollar amount subject to recovery (42 CFR § 433.316(e)). Federal regulations require that States report overpayments to CMS. For OIG audits in which CMS concurred with recommendations to collect overpayments, we will determine whether the overpayments have been recouped and properly reported to CMS.

OAS: W-00-17-31399; A-05-17-00000 • Expected Issue Date: FY 2018

NEW Overview of States' Risk Assessments for Medicaid-Only Provider Types

The ACA, § 6402, requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment, or revalidation in Medicare, Medicaid, and CHIP according to risk. In 2016, OIG found opportunities for improvement with enhanced provider screenings in Medicare and Medicaid. When only Medicaid recognizes a provider type (e.g., personal care attendants, nursing home providers, nonemergency transportation services), States are responsible for assessing the provider type's risk for fraud, waste, and abuse and assigning the risk category (42 CFR 455.450; 76 Fed. Reg. 5862 (February 2, 2011)). We will review States' assignment of Medicaid-only providers to the Federally-designated risk categories of high, moderate, and limited and any challenges States face in screening Medicaid-only provider types.

OEI: 05-16-00460 • Expected Issue Date: FY 2018

NEW Health-Care-Related Taxes: Medicaid MCO Compliance with Hold-Harmless Requirement

Many States finance a portion of their Medicaid spending by imposing taxes on health care providers. A health-care-related tax is permissible if the tax, among other standards, avoids hold-harmless arrangements which return collected taxes directly or indirectly to taxpayers. OIG currently is reviewing State tax programs for hospitals and nursing homes to test for compliance with the hold-harmless requirement. We will determine if health-care-related tax programs for MCOs meet Federal hold-harmless requirements in 42 CFR § 433.68 by examining the tax programs in large States that tax MCOs.

OAS: W-00-17-31515; A-03-17-00000 • Expected Issue Date: FY 2018

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

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

OAS: W-00-17-31511 • Expected Issue Date: FY 2017

State Use of Provider Taxes to Generate Federal Funding

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). Previous OIG work raised concerns about States' use of health-care-related taxes. 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.

OAS: W-00-17-31455; various reviews • Expected Issue Date: FY 2017

State Compliance with Federal Certified Public Expenditures Regulations

Public entities (e.g., public hospitals) may certify that they spent funds on Medicaid items or services that are eligible for Federal matching funds. These funds are referred to as certified public expenditures (CPEs) and may be claimed as the State's share of Medicaid expenditures 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.) We will determine whether States comply with Federal regulations for claiming CPEs, which are normally generated by local governments as part of their contribution to the coverage of Medicaid services.

OAS: W-00-17-31110; various reviews • Expected Issue Date: FY 2017

State Cost Allocations That Deviate from Acceptable Practices

Previous OIG reviews of school- and community-based administrative claims found significant unallowable payments that were based on random moment sampling systems. Such systems must be documented 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).) We will review public assistance cost allocation plans and processes for selected States

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to determine whether the States claimed Medicaid costs that were supported and allocated on the basis of random moment sampling systems that deviated from acceptable statistical sampling practices.

OAS: W-00-17-31467; various reviews • Expected Issue Date: FY 2017

Enhanced Federal Medical Assistance Percentage

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. States can claim 100 percent FMAP for the difference between the Medicare rate and the States' Medicaid rate. We will review States' Medicaid claims to determine whether the States correctly applied enhanced FMAP payment provisions of the ACA.

OAS: W-00-17-31480; various reviews • Expected Issue Date: FY 2017

Medicaid Eligibility Determinations in Selected States

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. 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.

OAS: W-00-17-31140; OEI: 06-14-00330; various reviews • Expected Issue Date: FY 2017

State Use of Incorrect FMAP for Federal Share 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)). We previously reviewed the claim adjustments for one State and determined that it did not use the correct FMAP for the majority of adjustments. We will review States' Medicaid claims records to determine whether the States used the correct FMAP when processing claim adjustments.

OAS: W00-17-31460; various reviews • Expected Issue Date: FY 2017

Provider Payment Suspensions During Pending Investigations of Credible Fraud Allegations

Federal financial participation in Medicaid is not available for items or services furnished by an individual or entity when there is a credible allegation of fraud (SSA § 1903(i)(2), as amended by the ACA § 6402(h)(2)). Upon determinations

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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 MFCUs or to appropriate law enforcement agencies in States with no certified MFCUs (42 CFR § 455.23(d)). We will review States' use of payment suspensions as a program integrity tool.

OEI: 09-14-00020 • Expected Issue Date: FY 2017

OIG Oversight and Reviews of State Medicaid Fraud Control Units

OIG Oversight for State Medicaid Fraud Control Units

The 50 State MFCUs, located in 49 States and the District of Columbia, investigate and prosecute Medicaid provider fraud as well as complaints of patient abuse or neglect in Medicaid-funded facilities and board and care facilities. OIG provides oversight for the MFCUs and administers a Federal grant award that provides 75 percent of each MFCU's funding. As part of OIG's oversight, we provide guidance to the MFCUs; assess their adherence to Federal regulations, policy, and performance standards; and collect and analyze performance data. We also provide technical assistance and training and identify effective practices in MFCU management and operations. We will perform on-site reviews of a sample of MFCUs.

OEI: 00-00-00000; various reviews • Expected Issue Date: FY 2017

State Medicaid Fraud Control Units FY 2016 Annual Report

OIG provides guidance to the MFCUs, assesses compliance with Federal regulations and policy, and evaluates adherence to published performance standards. This annual report will analyze the statistical information that was reported by the MFCUs for FY 2016, describing in the aggregate the outcomes of MFCU criminal and civil cases. This report will also identify trends in MFCU case results and will report on significant developments for the MFCUs over the course of the year.

OEI: 00-00-00000 • Expected Issue Date: FY 2017

Medicaid Information System Controls and Security

State Medicaid Agency Breach Protections and Responses

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

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patient health information, including data held by State Medicaid agencies and their contractors, is a major concern for health care providers and consumers. 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).

OEI: 09-16-00210 • Expected Issue Date: FY 2017

Duplicate Payments for Beneficiaries with Multiple Medicaid Identification Numbers

During a preliminary data match, OIG 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. 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.

OAS: W-00-17-31374; various reviews • Expected Issue Date: FY 2017

CMS Oversight of States' Medicaid Information Systems Security Controls

CMS is responsible for ensuring that appropriate security controls have been implemented over States' Medicaid information systems. Prior OIG audits reported that States lack sufficient security features, potentially exposing Medicaid beneficiary health information to unauthorized access. We will determine whether the States safeguarded Medicaid data and supporting systems in accordance with Federal requirements. We will review general controls and use OIG's automated assessment tools to assess controls for their information system networks, databases, and web-facing applications.

OAS: W-00-17-41015; various reviews • Expected Issue Date: FY 2017

Completeness of Data in Transformed Medicaid Statistical Information System: Early Implementation

The Transformed Medicaid Statistical Information System (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. We will determine to what extent States' plans for submitting T-MSIS data will result in a complete national database.

OEI: 05-15-00050 • Expected Issue Date: FY 2017

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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.

NEW Health-Care-Acquired Conditions – Medicaid Managed Care Organizations

Previous OIG reviews found that some States continued to make Fee-for-Service Medicaid payments for hospital care associated with health-care-acquired conditions and provider preventable conditions. Provider preventable conditions are certain reasonably preventable conditions caused by medical accidents or errors in the health care setting. The ACA, § 2702, and implementing regulations at 42 CFR, § 447.26, prohibit Federal payments for provider preventable conditions. Because we found problems with States making fee-for-service payments associated with provider preventable conditions, we are expanding to managed care arrangements. We will also determine whether Medicaid MCOs have continued to make payments to providers for inpatient hospital services related to treating certain provider preventable conditions.

OAS: W-00-17-31519; various reviews • Expected Issue Date: FY 2018

Medical Loss Ratio – Recoveries of MCO Rebates from Profit-Limiting Arrangements

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)). In its final rule (81 Fed. Reg. 27498 (May 6, 2016)), CMS encouraged States to adopt provisions in contracts with managed care plans that would require remittances from the MCOs if a minimum medical loss ratio is not met. A medical loss ratio is a tool that can help ensure that the majority of capitated payments are used to deliver services to beneficiaries. Prior OIG reviews found that some States have adopted such remittance provisions. We will review States and managed care plans with contract provisions that require remittances 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)).

OAS: W-00-17-31508 • Expected Issue Date: FY 2017

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

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. We will review methodologies for assigning MCO payments to different Medicaid FMAPs, e.g., the regular FMAP, the family planning FMAP, and the IHS FMAP among others.

OAS: W-00-17-31509 • Expected Issue Date: FY 2017

Managed Long-Term-Care Reimbursements

Medicaid managed care plans are subject to Federal requirements (42 CFR Part 438). Some States contract with MCOs to provide long-term services. We will review States' reimbursements made to managed long-term-care plans to determine whether those reimbursements complied with certain Federal and State requirements.

OAS: W-00-17-31510 • Expected Issue Date: FY 2017

Medicaid Managed Care Reimbursement

States contract with MCOs to provide coverage for specific services to enrolled Medicaid beneficiaries. In return for covering those services, MCOs are paid a set monthly capitation payment. 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). 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 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)).

OAS: W-00-17-31471; various reviews • Expected Issue Date: FY 2017

MCO Payments for Services after Beneficiaries' Deaths

Previous OIG reports found that Medicare paid for services that purportedly started or continued after beneficiaries' dates of death. 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.

OAS: W-00-17-31497 • Expected Issue Date: FY 2017

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Medicaid Managed Care Entities' Identification of Fraud and Abuse

All MCOs are required to have processes to detect, correct, and prevent fraud, waste, and abuse. However, the Federal requirements surrounding these activities are general in nature (42 CFR §438.608), and MCOs vary widely in how they deter fraud, waste, and abuse. A previous 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. 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.

OEI: 02-15-00260 • Expected Issue Date: FY 2017

Health Insurance Marketplaces

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 health insurance marketplaces facilitate the purchase of private health insurance by consumers, as well as enrollment in subsidy programs for those who are eligible. In particular, implementation, operation, and oversight of the marketplaces are among the most significant challenges for HHS. Key focus areas for our marketplace oversight include payment accuracy, eligibility determinations, management and administration, and security of consumer information.

This section of the Work Plan outlines ongoing work in the areas of payment accuracy, eligibility, and management and administration. In addition, we continually assess IT security risks and will undertake additional reviews as appropriate. In conjunction with other law enforcement partners, OIG monitors reports of cybersecurity threats and consumer fraud. OIG 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.

Payments

CMS Oversight and Issuer Compliance in Ensuring Data Integrity for the ACA Risk Adjustment Program

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. The success of the risk adjustment program depends on issuers'

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submission of timely, valid, and complete data. Any incorrect or missing information could ultimately result in miscalculation of risk scores, payments, or charges for issuers. This study will examine the effectiveness of CMS oversight and issuer actions in ensuring the quality of data utilized for the risk adjustment program for the 2015 benefit year. We will review CMS's policies and procedures as well as CMS and issuer reports to determine the extent to which CMS ensured the submission of timely, valid, and complete data. We also will determine what actions were taken by issuers to review and resubmit data.

OEI: 03-16-00350 • Expected Issue Date: FY 2018

Allowability of Contract Expenditures

HHS awarded Establishment Grants to certain States to assist the States in setting up State-based marketplaces. 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. We will review the allowability of expenditures for contractor services claimed for Federal reimbursement by a State grantee funded under the Establishment Grants.

OAS: W-00-15-59034 • Expected Issue Date: FY 2017

Review of Affordable Care Act Establishment Grants for State Marketplaces

The ACA authorized Establishment Grants to States that elected to establish their own marketplaces. 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. For some of the reviews, 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-00-16-59034; various reviews • Expected Issue Date: FY 2017

Accuracy of Financial Assistance Payments for Individual Enrollees

Under the ACA an enrollee may be eligible for a premium tax credit. The tax credit lowers an individual's premiums for insurance purchased on a marketplace. An enrollee can choose to have the marketplace compute an estimated credit that is paid to the insurance company to lower the amount the enrollee pays in monthly premiums (advance payments of the premium tax credit, or APTC). For enrollees who receive APTCs but do not pay their portion of the premium for 3 consecutive months, qualified health plan issuers are responsible for terminating coverage, returning a portion of

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APTC payments, and reporting this information to CMS. In addition, cost-sharing reductions (CSRs) assist certain low-income enrollees with their out-of-pocket costs. The Federal Government makes monthly payments to qualified health plan issuers to cover their estimated CSR costs, and these payments are then periodically reconciled to actual CSR amounts that should have been paid to all plans for confirmed enrollees. We will determine whether CMS's internal controls were effective in ensuring the accuracy of financial assistance payments – APTC and CSRs – for individual enrollees. We will also 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 Issue Date: FY 2017

Eligibility

CMS Oversight of Eligibility Determinations at State-Based Marketplaces

CMS provides general oversight over States that elected to establish their own marketplaces. Prior OIG work identified issues with State-based marketplaces' internal controls involving eligibility and enrollment. Thus, we will assess CMS's oversight activities of seven State-based marketplaces (SBMs) to ensure that individuals were determined eligible for qualified health plans 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 qualified health plans 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.

OAS: W-00-15-42024 • Expected Issue Date: FY 2017

Inconsistencies in the Federally Facilitated Marketplace Applicant Data

In previous OIG work, CMS reported to OIG that the Federally Facilitated Marketplace (FFM) was unable to resolve 2.6 million out of 2.9 million inconsistencies that occurred in the 2013–2014 open enrollment period for the FFM because CMS's eligibility system was not fully operational. 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.

OEI: 01-14-00620 • Expected Issue Date: FY 2017

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Review of Funding to Establish the Federally Facilitated Marketplace

HHS operates the Federally Facilitated Marketplace (FFM) in each State that did not establish and does not operate its own State marketplace. CMS is accountable for the Federal funds involved in establishing the FFM. A previous OIG audit noted that CMS did not identify all FFM contract costs and did not properly validate the amounts to withhold for defect resolution. We will identify the source and amount of funding used to establish the FFM. We will determine whether HHS 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 HHS 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 HHS and CMS identified as FFM funding was accurate and complete.

OAS: W-00-16-55000 • Expected Issue Date: FY 2017

CMS Monitoring Activities for Consumer Operated and Oriented Plan Loan Program

The ACA, § 1322, directs the HHS Secretary to establish the Consumer Operated and Oriented Plan (CO-OP) program by providing loans to assist the awardees with startup costs and State solvency requirements; 45 CFR Part 156 implements section 1322. 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 CO-OP loan program. We will reassess the CO-OPs financial condition to determine whether any improvements were made in 2015 and 2016 and monitor actions by CMS to address underperforming CO-OPs.

OAS: W-00-16-59019 • Expected Issue Date: FY 2017

Electronic Health Records

The Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act (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 has made payments to providers that attest to the "meaningful use" of EHRs.

According to CMS, more than $30 billion in incentives have been paid through the Medicare and Medicaid EHR incentive programs. GAO has identified improper incentive payments as the primary risk to the EHR incentive programs. These programs may be at

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greater risk of improper payments than other programs because they have complex requirements.

Medicare Incentive Payments for Adopting Electronic Health Records

Medicare incentive payments are authorized over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology (Recovery Act, §§ 4101 and 4102). Incentive payments were scheduled to begin in 2011 and continue through 2016, with payment reductions to health care professionals who fail to become meaningful users of EHRs beginning in 2015 (§ 4101(b)). As of July 2015, Medicare EHR incentive payments totaled more than $20 billion. 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.

OAS: W 00 14 31352 • Expected Issue Date: FY 2017

Security of Certified Electronic Health Record Technology Under Meaningful Use

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) through (d)(9)). 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.

OAS: W-00-15-42002; various reviews • Expected Issue Date: FY 2017

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 and assessments. OIG also negotiates and monitors corporate integrity agreements 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. OIG encourages health care providers to promptly self-disclose conduct that

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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 2016, OIG excluded 3,635 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 cases involving civil monetary penalties, 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 civil monetary penalty 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 Corporate Integrity Agreements (CIA) 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 CIA. For example, we conduct site visits to entities that

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

Provider Self-Disclosure

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraud and abuse. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit 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

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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.pdf.

Investigative Activities

OIG investigates allegations of fraud, waste, and abuse in all of HHS'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, as well as 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 reviews allegations of gross mismanagement in HHS programs. OIG also investigates potential misuse of grant and contract funds awarded by 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.) OIG investigates potential fraud in connection with the health insurance marketplaces. 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 criminal violations by HHS employees and contractors.

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

CMS-Related Legal and Investigative Activities

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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. 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 anti-fraud associations.

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 Reports 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, Drug Enforcement Administration, 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 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

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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, Health Resources and Services Administration (HRSA), IHS, and SAMHSA. Issues related to public health are also addressed within the Office of the Secretary. For example, ASPR serves as the Secretary's principal advisor on matters related to Federal public health preparedness and response to public health emergencies. The functions of the Office of the Assistant Secretary for Health include overseeing the protection of volunteers involved in research.

Effective management of public health programs is essential to ensure that they achieve program goals and best serve the intended beneficiaries. In its future work planning activities, OIG may consider key risk areas surrounding the access to and quality of services, including the following: 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.

In its future work planning activities, OIG may **consider key risk** areas surrounding the **access** to and **quality of services**.

In FY 2016, CDC's budget was $7.6 billion

$7.6 billion

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Other Public Health-Related Reviews

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

President's Emergency Plan for AIDS Relief (PEPFAR) funds support international programs for acquired immunodeficiency syndrome (AIDS) prevention, treatment, and care. CDC received PEPFAR funds from the annual HHS appropriation and the Foreign Operations appropriation. In previous audits of foreign PEPFAR grantees, we identified unallowable expenditures and internal control weaknesses. We will review (1) whether CDC effectively accounted for and monitored PEPFAR funds and (2) whether selected foreign grantees managed PEPFAR funds received under the PEPFAR program in accordance with award requirements. In addition, we plan to prepare a report to summarize the findings for all foreign grantee audits and recommendations for CDC to take corrective action.

OAS: W-00-16-57300; various reviews • Expected Issue Date: FY 2017

CDC – World Trade Center Health Program: Review of Administrative Costs – Mandatory Review

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 World Trade Center Health Program (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)). Prior Federal audits found that CDC did not reliably estimate costs for monitoring and treating program beneficiaries. We will review 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 prevent excessive administrative payments in accordance with Federal contracting requirements.

OAS: W-00-16-59040 • Expected Issue Date: FY 2017

CDC – Oversight of the Select Agent Program

The Federal Select Agent Program oversees the possession, use, and transfer of biological select agents and toxins, which, if handled improperly, have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products. 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)). We will examine CDC's oversight of the Federal Select Agent Program, including CDC's inspections of entities registered with the program and CDC's oversight of entities' annual internal inspections. 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

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In FY 2016, FDA's budget was $2.7 billion

$2.7 billion

regulatory requirements identified during inspections. Our second report will examine the extent to which CDC ensures that sampled entities comply with annual internal inspection requirements and that observations identified during these inspections are corrected. The second report will also identify any differences and/or similarities between observations identified in CDC's and the entities' inspections for sampled entities.

OEI: 04-15-00430; 04-15-00431 • Expected Issue Date: FY 2017

CDC – Grant Award Process for Ebola Preparedness and Response Funding

The Consolidated and Further Continuing Appropriations Act of 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. The Grants Policy Directive, Part 2, § 04, specifies the process for competitive review, ranking applications, approval of applications, and award policy. Previous OIG reviews have found 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. 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.

OAS: W-00-16-58300 • Expected Issue Date: FY 2017

CDC – Oversight of Security of the Strategic National Stockpiles of Pharmaceuticals

The Strategic National Stockpile program, for which CDC and the Department of Homeland Security (DHS) share management responsibility, is designed to supplement and restock State and local public health agency pharmaceutical supplies in the event of a biological or chemical incident in the United States or its territories. 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. 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 DHS's Physical Security Manual to assess security risks at selected stockpiles.

OAS: W-00-16-58310 • Expected Issue Date: FY 2017

Food and Drug Administration

FDA is responsible for ensuring the safety, efficacy, and security of our Nation's food supply, drugs, biologics, and medical devices. FDA is also responsible for regulating tobacco products. Areas

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of particularly high risk include food safety, drug compounding, a complex drug supply chain, and improper marketing activities.

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

FDA – Hospitals' Reliance on Drug Compounding Facilities

Large-scale facilities that compound without a patient-specific prescription are regulated under section 503B of the Food, Drug and Cosmetic Act and referred to as outsourcing facilities. We will determine the extent to which hospitals obtain compounded sterile preparations from compounders, including outsourcing facilities that have registered with the FDA. We will also determine the extent to which compounders that produce compounded sterile preparations without a patient-specific prescription have registered with the FDA.

OEI: 00-00-00000 • Expected Issue Date: FY 2017

FDA's Review of Networked Medical Device Cybersecurity During the Premarket Process

Effective cybersecurity controls have become increasingly important as more medical devices are wireless, Internet, and network-connected (networked devices) and 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. We will examine FDA's premarket review of the cybersecurity controls of networked devices. We will also review FDA policies and other documents and interview FDA staff to examine FDA's approach to reviewing networked medical device cybersecurity in the premarket process.

OEI: 09-16-00220 • Expected Issue Date: FY 2017

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FDA Response Planning for a Networked Medical Device Compromise

Networked medical devices, including dialysis machines, pacemakers, radiology systems, and medication dispensing systems, pose a growing threat to the security and privacy of personal health information and the safety of patients. Such networked devices use hardware, software, and networks to monitor a patient's medical status, regulate bodily functions, and transmit and receive related data. The complexity and task performed by networked devices has increased exponentially over time. To meet the new demands within networked device functionality, wireless, Internet, and network connectivity has been introduced along with new cybersecurity vulnerabilities. FDA is responsible for ensuring and monitoring the safety and effectiveness of networked medical devices. We will examine the FDA's plans and processes for timely communicating and addressing a networked medical device cybersecurity compromise.

OAS: W-00-17-42020 • Expected Issue Date: FY 2017

FDA – Review of Prescription Drug User Fees

The Prescription Drug User Fee Act of 1992, Pub. L. 102-571, authorized FDA to collect fees from pharmaceutical and biotechnology companies seeking FDA approval of 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 the Act to meet its goals for the timely review of human drug applications. 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.

OAS: W-00-16-50003 • Expected Issue Date: FY 2017

FDA – Tobacco Establishment Compliance with the Family Smoking Prevention and Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act of 2009 requires owners and operators of tobacco establishments to register with FDA and submit product lists. A tobacco establishment is a facility that manufactures, prepares, compounds, or processes tobacco products. We will determine how many owners and operators of tobacco establishments have registered and submitted product lists to FDA. This evaluation will also assess the extent to which FDA has inspected and taken action against owners and operators of establishments that do not comply with the Tobacco Control Act.

OEI: 01-15-00300 • Expected Issue Date: FY 2017

FDA – Monitoring of Domestic and Imported Food Recalls

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 Food Safety Modernization Act (FSMA) added section 423 to the Food, Drug and

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Cosmetic 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. We will review FDA's monitoring of domestic and imported food recalls. The audit will determine the extent to which FDA has implemented the FSMA requirements related to 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.

OAS: W-00-15-50004 • Expected Issue Date: FY 2017

FDA – Inspections of Domestic 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. Additionally, FSMA established criteria for designating a domestic facility as high risk and mandated frequencies for FDA to complete inspections of domestic facilities designated high risk and non-high risk. We will review FDA's domestic inspection program and assess whether FDA is on track to meet the inspection frequencies required by FSMA.

OEI: 02-14-00420 • Expected Issue Date: FY 2017

FDA – Review of Information Exchange in the Drug Supply Chain

The drug supply chain is growing increasingly complex, with drugs often passing through numerous companies before ultimately reaching patients. This may make it difficult to track products to their sources in case of a recall and potentially complicate FDA's task of ensuring the integrity of products. 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 (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 Issue Date: FY 2017

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In FY 2016, HRSA's budget was $10.7 billion

$10.7 billion

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.

HRSA – Oversight of Vulnerable Health Center Grantees

Health centers provide preventive and primary health care to patients regardless of their ability to pay. Approximately 1 in 14 people in the United States relies on a HRSA-funded health center for medical care.[8] HRSA collects data on Health Center Program 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. We will determine the extent to which HRSA awarded grant money to Health Center Program grantees that have documented compliance or financial issues.

OEI: 05-14-00470 • Expected Issue Date: FY 2017

HRSA – Compliance with Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Requirements

The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program is designed to strengthen and improve the programs and activities carried out under Title V of the SSA, improve coordination of services for at-risk communities, and identify and provide comprehensive services to improve outcomes for families that reside in at-risk communities. The ACA, § 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. We will review compliance by States with terms and conditions of grants received under the MIECHV program. Specifically, we will determine 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.

OAS: W-00-15-59000; various reviews • Expected Issue Date: FY 2017

[8] http://bphc.hrsa.gov/about/what-is-a-health-center/index.html

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In FY 2016, IHS's budget was $4.9 billion

$4.9 billion

HRSA – Community Health Centers' Compliance with Grant Requirements of the Affordable Care Act

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. We will determine whether community health centers that received funds pursuant to the ACA, § 10503, are complying with Federal laws and regulations. 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 Issue Date: FY 2017

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 2.2 million American Indians and Alaska Natives who belong to 567 Federally recognized tribes in 35 States.

IHS – Purchased Referred Care Program

IHS provides Federal health services to 2.2 million American Indians and Alaska Natives in 567 Federally recognized tribes. IHS can provide health care directly or may fund tribes to independently deliver health care. When an IHS or tribal facility is not available, or does not provide the required care, patients are referred to the purchased/referred care (PRC) program, which coordinates needed services through private health care providers. PRC program funds grew 17.2 percent from $779.9 million in FY 2011 to $914.1 million in FY 2016. We are initiating this audit because of the significant magnitude and growth of PRC program funds and previous reports by GAO that highlighted problems with the program. This audit will focus on IHS-administered PRC program services, which totaled $333.7 million in FY 2016. We will determine whether IHS PRC program services were provided in compliance with the purpose, time, and amount requirements specified in appropriation statutes and IHS requirements.

OAS: W-00-16-51004 • Expected Issue Date: FY 2017

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IHS – Review of Health Services Administered by a Federally Qualified Health Center

IHS provides a comprehensive health service delivery system for approximately 2 million American Indians and Alaska Natives either by operating health facilities directly or by funding tribes through contracts or compacts to operate health facilities themselves. In certain cases, tribes may operate a facility known as a Federally Qualified Health Center (FQHC), which is certified by CMS to provide outpatient health services to rural areas or underserved populations. In addition to funding from IHS, the tribes may also receive health care funding from the Medicaid or Medicare programs. This report will build on OIG's body of work identifying longstanding challenges, including insufficient oversight and limited access to specialists, that likely impact the quality of health care services provided to American Indians and Alaska Natives. We will review a tribally operated FQHC that is funded by IHS, to determine whether health services delivered to American Indians and Alaska Natives met applicable Federal requirements.

OAS: W-00-17-59052 • Expected Issue Date: FY 2018

Management Review of IHS

IHS directly operates 28 hospitals, 62 health centers, and 25 health stations with dispersed management. We will examine the management of IHS, including assessing the organizational framework of IHS headquarters operations. This will include reviewing the fulfillment of roles and responsibilities, enforcement of policies and procedures, and strategies to address current and future challenges. We will conduct interviews with senior management responsible for policies, practices, and resources that support care delivery in IHS facilities.

OEI: 06-16-00390 • Expected Issue Date: FY 2017

IHS – Hospital Oversight

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. We will assess IHS's efforts to monitor and oversee its Federally operated hospitals and describe challenges that affect IHS hospitals and their ability to provide quality care and comply with Medicare standards.

OEI: 06-14-00010; 06-14-00011 • Expected Issue Date: FY 2017

IHS – Charge Card Program Review

Pursuant to the Charge Card Act, OIG performed a risk assessment of HHS's charge card program for FY 2013. We will review IHS's charge card programs (e.g., purchase and travel cards) to determine if the programs comply with Federal requirements. We used the results of the risk

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In FY 2016, NIH's budget was $31.5 billion

$31.5 billion

assessment to identify high-risk and high-impact areas warranting an audit.

OAS: W-00-16-51000; various reviews • Expected Issue Date: 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.

Review of National Institutes of Health Data Controls to Ensure the Privacy and Protection of Volunteers in the Precision Medicine Initiative

The FY 2016 budget provided $200 million to NIH to help develop the Precision Medicine Initiative. The Precision Medicine Initiative plans to have more than 1 million volunteers providing their personal health information to NIH so researchers, providers, and patients can work together toward the development of individualized care. Maintaining data security and privacy will be paramount to retaining the volunteers' trust and participation in the Precision Medicine Initiative. We will determine the controls NIH has developed to ensure privacy and protection of the volunteers' personal health information.

OAS: W-00-16-20009 • Expected Issue Date: FY 2017

NIH – Controls over Subcontracting of NIH Grant and Contract Work

Cost principles for Educational Institutions at 45 CFR Part 75 are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles will 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 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. We will conduct reviews

Substance Abuse and Mental Health

Other Public Health-Related Reviews

Centers for Disease Control and Prevention

Food and Drug Administration

Health Resources and Services Administration

Indian Health Service

National Institutes of Health

In FY 2016, SAMHSA's budget was $3.6 billion

$3.6 billion

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 Issue Date: FY 2017

NIH – Superfund Financial Activities for FY 2015 – Mandatory Review

NIH's National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. 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)). We will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

OAS: W-00-16-59050 • Expected Issue Date: FY 2017

Review of the National Institute of Environmental Health Sciences' Funding for Bisphenol A Safety Research

Bisphenol A (BPA) is a chemical primarily used in the production of polycarbonate plastics, but it is also used in food and drink packaging. BPA in packaging may leach into food or drink and be consumed by humans. We will determine the extent to which NIH's National Institute of Environmental Health Sciences (NIEHS) has conducted and funded research on the safety of BPA since 2000, as well as the roles that other HHS 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.

OEI: 01-15-00150 • Expected Issue Date: FY 2017

NIH – Colleges' and Universities' Compliance with Cost Principles

Cost principles for colleges and universities at 45 CFR Part 75 establish guidelines for charges to Federal grants. We will assess colleges' and universities' compliance with selected cost principles. We will conduct reviews at selected colleges and universities on the basis of the dollar value of Federal grants received and input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration.

OAS: W-00-13-50037; various reviews • Expected Issue Date: FY 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

Other Public Health-Related Reviews

Public Health Legal Activities

Centers for Disease Control and Prevention

Food and Drug Administration

Health Resources and Services Administration

Indian Health Service

National Institutes of Health

Substance Abuse and Mental Health

mental illness on America's communities. Congress established SAMHSA in 1992 to make substance use and mental disorder information, services, and research more accessible.

SAMHSA – Controls Over Opioid Treatment Programs

SAMHSA funds State agencies' Opioid Treatment Programs through its Substance Abuse Prevention and Treatment Block Grant. Opioid abuse is a compelling public health concern, and in the past OIG has recommended better security protocols to reduce thefts of opioids from hospitals and pharmacies. We will determine whether State agencies effectively monitor Opioid Treatment Programs' 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 Issue Date: FY 2017

Other Public Health-Related Reviews

HHS Coordination of Roles and Responsibilities for Ebola Response Efforts

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. We will review the extent to which HHS planned and coordinated strategic decisions related to HHS's Ebola response efforts. We will also review how HHS's Ebola response activities were planned and coordinated with other U.S. Government agencies.

OAS: W-00-16-58301; various reviews • Expected Issue Date: FY 2017

Controls Over the Preparation and Receipt of Select Agent Shipments

Pursuant to 42 U.S.C. 262a and 7 U.S.C. 8401, select agents and toxins are a subset of biological agents and toxins that HHS and the U.S. Department of Agriculture have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. Federal regulations at 42 CFR § 73.16 regulate the transfer of select agents. We will review NIH's and FDA's controls for preparing and receiving select agent shipments. 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 at 42 CFR § 73.11(a) covering written security plans and related supporting laboratory guidance or instruction.

OAS: W-00-16-52000; various reviews • Expected Issue Date: FY 2017

Other Public Health-Related Reviews

Public Health Legal Activities

Centers for Disease Control and Prevention

Food and Drug Administration

Health Resources and Services Administration

Indian Health Service

National Institutes of Health

Substance Abuse and Mental Health

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 to establish a compliance oversight process to review violations of HHS regulations protecting human research subjects. We will determine the extent to which the Office of Human Research Protections independently initiates, conducts, and makes determinations about compliance evaluations.

OEI: 01-15-00350 • Expected Issue Date: FY 2017

Audits of Superstorm Sandy Disaster Relief Act

The Disaster Relief Appropriations Act of 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-00-16-59052; various reviews • Expected Issue Date: FY 2017

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 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.

HHS funds and operates public health and human services programs to promote health and economic and social well-being.

In FY 2016, ACF's budget was $53.1 billion

$53.1 billion

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 the Administration for Community Living (ACL).

Administration for Children and Families

ACF operates more than 30 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.

Administration for Children and Families

Administration for Community Living

States' Accuracy of Reporting TANF Spending Information

The Temporary Assistance for Needy Families (TANF) program is designed to help needy families achieve self-sufficiency. States receive block grants ($16.5 billion annually) to design and operate programs that accomplish one of the four purposes of the TANF program. States must report expenditures to ACF on a quarterly basis. Effective FY 2015, States will report actual transfers, expenditures, and unliquidated obligations (henceforth referred to as expenditures) made with each open grant year award during a fiscal year on form ACF-196R. Each quarterly report will reflect expenditures cumulative through that quarter for the fiscal year, resulting in a fourth quarter report that reflects actual expenditures made with the grant year award funds for the fiscal year. States will no longer report expenditures cumulative through the current reporting period. We will determine the accuracy of States' reporting of TANF spending information using the new form ACF-196R.

OAS: W-00-17-25100 • Expected Issue Date: FY 2017

Head Start – Review of Single Audit Findings and Recommendations

Effective for awards made on or after December 26, 2014, all non-Federal entities that expend $750,000 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 (prior to December 26, 2014, the single audit threshold was $500,000). We will review the Office of Head Start's audit resolution of findings and recommendations contained in the single audit reports involving Head Start grantees for FYs 2013 to 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-00-16-20010; various reviews • Expected Issue Date: FY 2017

ORR – Unaccompanied Children Program Grantee Reviews

Under the Homeland Security Act of 2002, § 462, the Office of Refugee Resettlement (ORR) administers the Unaccompanied Children (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. The UC grant program totaled $911 million for FY 2014. We will review whether selected grantees met applicable grant terms and conditions of the 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.

OAS: W-00-16-25060; various reviews • Expected Issue Date: FY 2017

Administration for Children and Families

Administration for Community Living

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

Under the Homeland Security Act of 2002, § 462, the Office of Refugee Resettlement (ORR) administers the Unaccompanied Children (UC) program. The UC program provides temporary shelter, care, and other related services to unaccompanied children in its custody. In a 2008 report, OIG found that after ORR placed Unaccompanied Children (UC) with sponsors, it did not have methods to determine whether sponsors provided for UC's physical, mental, and financial well-being or that sponsors complied with their agreements with ORR. OIG recommended that ORR develop a formal agreement with DHS to delineate the roles and responsibilities of each Department, including each Department's specific responsibilities for gathering and exchanging information about children after placement, so as to ensure that children remain safe. This recommendation has not been fully implemented; therefore, we will follow up on ORR's progress toward addressing the recommendation, examine any impediments encountered, and review ORR's efforts toward ensuring the well-being of children.

OEI: 09-16-00260 • Expected Issue Date: FY 2017

States' Implementation of Guardian Ad Litem Requirements

Section 8 of the Child Abuse Prevention and Treatment Act requires that, as a condition of receiving Child Abuse Prevention and Treatment Act grant funding, States must ensure that every child involved in an abuse or neglect judicial proceeding is appointed an advocate, or guardian ad litem. The purpose of the guardian ad litem requirement is to ensure that the best interests of these vulnerable children are represented in the court by an individual who has a clear understanding of the situation and the child's needs. We will assess selected States' compliance with guardian ad litem requirements. We will also determine whether States ensure that guardians ad litem receive the required training appropriate to their role. We will further describe how children receive guardians ad litem representation in each State, including the number of times guardians ad litem met with children outside the court.

OEI: 12-16-00120 • Expected Issue Date: FY 2017

Foster Care – States' Protocols for the Use and Monitoring of Psychotropic Medications for Children in Foster Care

Psychotropic medications are used to treat mental health disorders such as schizophrenia, depression, bipolar disorder, anxiety disorders, and attention deficit/hyperactivity disorder. Pursuant to section 422(b)(15)(A) of the SSA, 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. We will describe States' protocols for the appropriate use and monitoring of psychotropic medications for children in foster care. For selected States, we

Administration for Children and Families

Administration for Community Living

will determine whether a sample of children in foster care enrolled in Medicaid received psychotropic medications in accordance with their State's protocols. Because ACF is responsible for the oversight of States' foster care programs, we will determine the extent to which the Agency ensures that children in foster care receive psychotropic drugs in accordance with States' protocols.

OEI: 07-15-00380 • Expected Issue Date: FY 2017

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

Under Title IV-E of the SSA, States must establish complaint procedures for handling allegations or referrals of abuse and noncompliance of health and safety requirements for foster care children. We will review whether complaints are recorded, investigated, and resolved in accordance with Federal and State requirements. We will also review States' oversight process to ensure they meet licensing requirements for foster care family homes (SSA Title IV-E § 471(a)(9) and Title IV-E § 472(c)(1)).

OAS: W-00-16-25056; various reviews • Expected Issue Date: FY 2017

States' CCDF Payment Rates and Access to Child Care Services

Reauthorized in the Child Care and Development Block Grant Act of 2014, the Child Care and Development Fund (CCDF) is the primary Federal funding source devoted to subsidizing the childcare expenses of low-income families. Each State sets payment rates for childcare providers, and ACF oversees payment rates. 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). We will assess whether States' payment rates under CCDF ensure access to childcare for low-income families. We will review States' processes for determining their payment rates as well as ACF's methods for determining whether States' CCDF payment rates are sufficient to ensure access to childcare services.

OEI: 03-15-00170 • Expected Issue Date: FY 2018

Administration for Community Living

Administration for Children and Families

In FY 2016, ACL's budget was $1.9 billion

$1.9 billion

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.

ACL – Senior Medicare Patrol Projects' Performance Data – Annual Review

In 1997, Senior Medicare Patrol (SMP) projects were established to recruit and train retired professionals and other senior citizens to prevent, recognize, and report health care fraud, errors, and abuse. The initiative stemmed from recommendations in a congressional committee report accompanying the Omnibus Consolidated Appropriations Act of 1997. OIG reports these performance data annually. We will review performance data and documentation relating to Medicare and Medicaid recoveries, savings, and cost avoidance for SMP projects. ACL requested this information, which will support its efforts to evaluate and improve the performance of its projects.

OEI: 00-00-00000 • Expected Issue Date: FY 2017

Other HHS-Related Reviews

OIG's work in progress and its planned work address departmentwide matters, such as **financial statements, financial accounting, information systems management**, and other departmental issues.

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 statements, financial accounting, information systems management, and other departmental issues. OIG's future planned work includes a holistic examination of HHS's 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 Chief Financial Officers Act of 1990 (CFO Act), as amended; the Government Management Reform Act of 1994 (GMRA); the Federal Financial Management Improvement Act of 1996; and information systems reviews required by the Federal Information Security Modernization Act of 2014. The CFO Act, as amended, 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 their components, including CMS.

The American health care system relies increasingly 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 HHS. 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
Financial Reviews
Information Security
Other HHS-Related Issues

Financial Statement Audits and Related Reviews

Audits of FYs 2016 and 2017 Consolidated HHS Financial Statements and Financial Related Reviews – Mandatory Review

The HHS financial statement audit determines whether the financial statements present fairly, in all material respects, the financial position of the audited entity for the specified time period. We will retain an independent external auditor and 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 financial statement audit is required by Chief Financial Officers Act of 1990, as amended by the Government Management Reform Act of 1994, and performed in accordance with Generally Accepted 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 15, 2016 and 2017, respectively. We plan to perform a number of ancillary financial-related reviews pertaining 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-00-17-40009; A-17-16-00001; A-17-17-00001 •
Expected Issue Dates: FY 2017 and FY 2018

FYs 2016 and 2017 Centers for Medicare & Medicaid Services' Financial Statements – Mandatory Review

The CMS financial statement audit determines whether the financial statements present fairly, in all material respects, the financial position of the audited entity for the specified time period (Chief Financial Officers Act of 1990, as amended; Government Management Reform Act of 1994; Federal Financial Management Improvement Act of 1996; Generally Accepted Government Auditing Standards; and OMB Bulletin 15-02, "Audit Requirements for Federal Financial Statements"). 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.

OAS: W-00-17-40008; A-17-16-02016; A-17-17-02017 •
Expected Issue Dates: FY 2017 and FY 2018

Financial Reviews

Review of CMS Action on CERT Data

Since 2003, CMS has utilized the Comprehensive Error Rate Testing (CERT) program to establish a national error rate for Medicare Fee-for-Service payments as mandated by the Improper Payments Information Act of 2002. We issued a report in 2010 identifying error-prone providers and recommended that CMS target these specific providers that contributed significantly to payment

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errors in the CERT program for provider-based reviews. Improper error rates and payments have not decreased in recent years. The FY 2015 reported national error rate for Medicare Fee-for-Service payments was approximately 12.1 percent, with improper payments estimated at $43.3 billion. We will determine if CMS took action on our previous recommendation to use CERT data to target error-prone providers and reduce payment errors. Additionally, we will analyze CERT data to identify errors and potential patterns where further interventions could reduce payment errors.

OAS: W-00-16-35788 • Expected Issue Date: FY 2017

Compliance with the Digital Accountability and Transparency Act (DATA Act) – Mandatory Review

On May 9, 2014, the President signed the DATA Act of 2014, which mandated the establishment of Governmentwide data standards for financial and payment data by May 2015, and agency reporting of consistent, reliable, and searchable financial and payment data by May 2017, to be displayed for taxpayers and policy makers on USASpending.gov. The DATA Act also requires OIG to review a statistically valid sampling of the spending data submitted under this Act by HHS and submit to Congress and make publically available a report assessing the completeness, timeliness, quality, and accuracy of the data sampled and the implementation and use of data standards by HHS. We will use the independent external auditor contracted to audit the annual CMS and HHS Financial Statement Audits to perform this work.

OAS: W-00-17-41021 • Expected Issue Dates: FY 2017 or FY 2018

Compliance with Reporting Requirements for Improper Payments – Mandatory Review

The Improper Payments Information Act of 2002 (IPIA), as amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) and the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA), requires the head of each Federal agency with programs or activities that may be susceptible to significant improper payments to report certain information to Congress. 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, HHS must report to Congress improper payment estimates, corrective action plans, and reduction targets. Pursuant to IPERA and OMB Circular A-123, Appendix C, "Requirements for Effective Estimation and Remediation of Improper Payments," OIG will review HHS compliance with IPIA, as amended, as well as how HHS assesses the programs it reports and the accuracy and completeness of the reporting in HHS's Agency Financial Report. We will make recommendations as needed.

OAS: W-00-17-40037; A-17-17-52000 • Expected Issue Date: FY 2017

Financial Reviews

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Other HHS-Related Issues

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

The Office of National Drug Control Policy Circular requires that agencies expending funds on National Drug Control Program activities submit 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 review HHS agencies' compliance with the circular. We will also submit the authentication with respect to HHS's FY 2016 annual accounting.

OAS: W-00-17-52312; various reviews • Expected Issue Date: FY 2017

HHS Contract Management Review

In its July 2011 Anti-deficiency Report to the President, HHS 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 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). We will review the controls that the HHS Program Support Center has in place to ensure compliance with requirements specified in appropriation 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.

OAS: W-00-13-52313 • Expected Issue Date: FY 2017

OIG Reviews of Non-Federal Audits

In accordance with the Uniform Grant Guidance at 2 CFR Part 200, 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. OIG reviews the audits and reports to ensure they meet applicable standards, identifies any follow-up work needed, and identifies issues that may require management attention. OIG also provides upfront technical assistance to non-Federal auditors to ensure 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. 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 the uniform grant guidance.

OAS: W-00-17-40005 • Expected Issue Date: FY 2017

Information Security

Financial Statement Audits and Related Reviews

Financial Reviews

Other HHS-Related Issues

OIG Reimbursable Audits 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. 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. We will conduct a series of audits as part of HHS's cognizant agency responsibility under the Uniform Grant Guidance, 2 CFR Part 200 that relates to Audits of States, Local Governments, and Nonprofit Organizations.

OAS: W-00-17-50012; various reviews • Expected Issue Date: FY 2017

Information Security

Audit of HHS Information System Security Controls to Track Prescription Drug Disbursements

HHS is responsible for implementing appropriate controls in NIH and IHS hospitals to track the disbursement of prescription drugs (including opioids and other Schedule II drugs) in accordance with Federal security requirements. Prior OIG audits reported that HHS lacks sufficient security controls, which potentially impact abuse of prescription drugs. We will determine whether HHS applications that track the disbursement of prescription drugs meet Federal information security standards. We will focus on access and physical controls. For selected NIH and IHS hospitals, we will review application controls and use OIG's automated assessment tools to assess the security of the networks, databases, and web-facing applications.

OAS: W-00-16-42020 • Expected Issue Date: FY 2017

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

The Federal Information Security Modernization Act (FISMA) and OMB Circular A-130, Managing Information as a Strategic Resource, 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. FISMA requires the Inspectors General to conduct an annual independent evaluation to determine the effectiveness of the information security program and practices of its agency. We will review HHS's and selected HHS operating divisions' compliance with FISMA.

OAS: W-00-17-40016; W-00-16-42001; various reviews • Expected Issue Date: FY 2017

Other HHS-Related Issues

Financial Statement Audits and Related Reviews

Financial Reviews

Information Security

Penetration Testing of HHS and Operating Division Networks

Penetration tests are used to identify methods of gaining access to a system by using tools and techniques known to be employed by hackers. Computer hacker groups are increasingly active in attempts to compromise government systems, release sensitive data to the public, or use such data to commit fraud. 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.

OAS: W-00-17-42020; W-00-17-42000; various reviews • Expected Issue Date: FY 2017

Other HHS-Related Issues

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

The Government Charge Card Abuse Prevention Act of 2012 (Charge Card Act) requires Inspectors General (IGs) to conduct periodic risk assessments of their agencies' charge card programs to analyze the risks of illegal, improper, or erroneous purchases. 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. OMB has instructed IGs to submit annual status reports on purchase and travel card audit recommendations beginning January 31, 2014, for compilation and transmission to Congress and GAO. 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. HHS's charge card programs enable cardholders to pay for commercial goods, services, and travel expenses.

OAS: W-00-16-59041 • Expected Issue Date: FY 2017

OIG's health care reform oversight strategy **focuses on the health insurance marketplaces**, reforms in the **Medicare and Medicaid** programs, and reforms in **public health care programs**.

Appendix: Health Care Reform

OIG's health care reform oversight strategy focuses on the health insurance marketplaces, reforms in the Medicare and Medicaid programs, and reforms in public health programs. Laws that implement parts of health reform, like ACA and MACRA, 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 and quality of care for patients and taxpayers. OIG is focused on reviewing the economy, efficiency, and effectiveness of the Department's health care reform programs.

This Appendix provides a consolidated list of planned work reviewing health care reform.

Health Insurance Marketplaces

The Federal and State-based health insurance marketplaces are used by consumers to purchase private health insurance and enroll in subsidy programs for which they are eligible. Related programs include the premium stabilization programs (i.e., the risk-adjustment, risk corridor, and reinsurance) and the CO-OP program.

The following reviews are described in more detail in the Health Insurance Marketplaces section of the Work Plan:

- CMS Oversight and Issuer Compliance in Ensuring Data Integrity for the ACA Risk Adjustment Program
- Allowability of Contract Expenditures
- Accuracy of Financial Assistance Payments for Individual Enrollees
- Review of Affordable Care Act Establishment Grants for State Marketplaces
- CMS Oversight of Eligibility Determinations at State-Based Marketplaces
- Inconsistencies in the Federally Facilitated Marketplace Applicant Data
- Review of Funding to Establish the Federally Facilitated Marketplace
- CMS Monitoring Activities for Consumer Operated and Oriented Plan Loan Program

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Medicare and Medicaid Reforms

Medicare Reviews

The ACA and MACRA introduced Medicare program changes designed to improve efficiency and quality of care and promote program integrity and transparency. The Medicare sections of the FY 2017 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 reform provisions related to the Medicare program and are described in more detail in the Medicare sections of the Work Plan:

- Accountable Care Organizations: Savings, Quality, 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
- Data Brief on Financial Interests Reported under the Open Payments Program
- Management Review: CMS's Implementation of the Quality Payment Program
- Medicare Payments for Transitional Care Management
- Medicare Payments for Chronic Care Management
- National Background Checks for Long-Term-Care Employees — Mandatory Review

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Medicaid Reviews

The Medicaid section of the Work Plan describes the range of FY 2017 reviews planned and those in progress to promote the effectiveness and efficiency of the growing Medicaid program. Focus areas include prescription drugs; home health services; other services, equipment, and supplies; State claims for Federal reimbursement; delivery system reform; State management of Medicaid; Medicaid information and security; and Medicaid managed care.

Reviews related to health reform include the following (these reviews are described more fully in the Medicaid section of the Work Plan):

- Enhanced Federal Medical Assistance Percentage
- States' Collection of Rebates for Drugs Dispensed to Medicaid MCO Enrollees
- Express Lane Eligibility – Mandatory Review
- Health-Care-Acquired Conditions – Prohibition on Federal Reimbursements
- Community First Choice State Plan Option Under the Affordable Care Act
- Payments to States Under the Balancing Incentive Program
- Delivery System Reform Incentive Payments
- Accountable Care in Medicaid
- Overview of States' Risk Assessments for Medicaid-only Provider Types
- Medicaid Eligibility Determinations in Selected States
- Provider Payment Suspensions during Pending Investigations of Credible Fraud Allegations
- Health-Care-Acquired Conditions – Medicaid Managed Care Organizations
- Manufacturer Rebates – Federal Share of Rebates

Other Programs

OIG work related to health reform in other programs 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
- NIH – Review of National Institutes of Health Data Controls to Ensure the Privacy and Protection of Volunteers in the Precision Medicine Initiative

U.S. Department of Health & Human Services

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