

Office of  
Inspector  
General

**Work  
Plan**

FISCAL YEAR  
**2009**



Department of Health and Human Services  
Office of Inspector General

# A Message from the Office of Inspector General

We are pleased to present the Office of Inspector General (OIG) Work Plan for fiscal year (FY) 2009. This publication describes activities that OIG plans to initiate or continue with respect to the programs and operations of the Department of Health and Human Services (HHS) in the next year. To place the Work Plan in context, we describe below our mission, work activities, organization, and work-planning process.

## Mission

Our mission, as mandated by the Inspector General Act of 1978, 5 U.S.C. App., is to conduct and supervise audits and investigations relating to the programs and operations of HHS; provide leadership and coordination and recommend policies for activities designed to promote economy, efficiency, and effectiveness in the administration of, and to prevent and detect fraud and abuse in, such programs and operations; and provide a means for keeping the Secretary of HHS and Congress informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for and progress of corrective action.

The operational mission statement we use for organizational purposes is to protect HHS program integrity and beneficiary well-being by detecting and preventing waste, fraud, and abuse; identifying to Congress, HHS, and the public opportunities to improve program economy, efficiency, and effectiveness; and holding accountable those who violate program requirements.

## Work Activities

We accomplish our mission by conducting audits, investigations, and inspections; by providing industry guidance; and, when appropriate, by imposing civil monetary penalties (CMP), assessments, and administrative sanctions. At all levels, we work in close cooperation with HHS and its Operating and Staff Divisions, the Department of Justice (DOJ), other agencies in the Executive Branch, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds.

## Organization

Four components carry out OIG's mission-related activities: the Office of Audit Services (OAS), Office of Investigations (OI), Office of Evaluation and Inspections (OEI), and Office of Counsel to the Inspector General (OCIG). We are headquartered in Washington, DC, and have a nationwide network of approximately 90 regional and field offices, with more than 80 percent of our staff working outside the Washington, DC, metropolitan area.

- OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

- 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, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.
- OI conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with DOJ and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, or CMPs.
- 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 the False Claims Act, program exclusion, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

### **Work-Planning Process**

Annually, OIG conducts a comprehensive work-planning process to identify the areas most worthy of attention in the coming year. The various factors we take into account include the following:

- requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress and HHS's management;
- significant management and performance challenges facing HHS, which we identify as part of HHS's annual agency financial report;
- work performed by HHS and other organizations, such as the Government Accountability Office and the Office of Management and Budget (OMB); and
- management's actions to implement OIG recommendations from previous reviews.

Prior to issuing our final plan, we provide a draft to HHS and OMB. Comments received assist us in refining our proposals and conceptualizing plans for future years.

OIG work planning does not end with the publication of this annual plan; rather, it is a dynamic process to ensure that we accommodate the changing nature of issues affecting HHS. We are continuously examining current events, emerging issues, and shifts in the priorities of Congress

and the Administration. As a result of this examination, we may add new activities and decide to delay or cancel lower-priority work.

We are frequently asked how we allocate our resources and select the areas to review. Generally, we direct our resources to reflect OIG's and HHS's budget and priorities and accommodate our specific budget mandates. Consequently, over the last several years, we have allocated about 80 percent of our resources to reviews and investigations of the Medicare and Medicaid programs and 20 percent to HHS's public health and human services programs.

This edition, effective as of September 2008, describes ongoing and planned assignments and provides for each assignment the subject and scope of the review and criteria related to the program being reviewed. We also provide review identification codes, the year in which we expect the report to be issued, and whether the work will be in progress at the start of the FY or will be a new start during the year. Usually, our ongoing work will result in FY 2009 reports. Work slated to begin in FY 2009 will result in FY 2009 or FY 2010 reports, depending upon when the assignments are initiated during the year and the complexity and scope of the examinations.

In this Work Plan, our ongoing and planned reviews are described in two parts:

- “Centers for Medicare & Medicaid Services” describes reviews related to Medicare, Medicaid, information systems controls, Gulf Coast hurricane response, State Children's Health Insurance Program (SCHIP), and related investigations and legal counsel to OIG.
- “Public Health and Human Services Programs and Departmentwide Issues” describes reviews related to agencies, such as the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the Administration for Children and Families, and the Administration on Aging. This part also describes departmentwide issues, such as financial accounting and information systems management.

The Work Plan is available on our Web site at <http://oig.hhs.gov/publications.html>. If you have questions about this publication, please contact OIG's Office of External Affairs at 202-619-1343.

You may report potential instances of waste, fraud, or abuse related to HHS's programs to the OIG Hotline at 1-800-HHS-TIPS (1-800-447-8477) or [HHSTips@oig.hhs.gov](mailto:HHSTips@oig.hhs.gov).



# Terms, Titles, Organizations, and Public Laws

## Terms and Titles

The list below is limited to terms and titles for which acronyms and abbreviations appear on more than one page of a major section of this publication.

AIDS	acquired immunodeficiency syndrome
AMP	average manufacturer price
ASC	ambulatory surgical center
ASP	average sales price
CAS	Cost Accounting Standards
CERT	Comprehensive Error Rate Testing program
CFR	Code of Federal Regulations
CMP	civil monetary penalty
CSE	child support enforcement
CWF	Common Working File
DME	durable medical equipment
DRG	diagnosis-related group
DSH	disproportionate share hospital
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment services
ESRD	end-stage renal disease
FAR	Federal Acquisition Regulation (Code of Federal Regulations, Title 48)
FFP	Federal financial participation
FI	fiscal intermediary
FUL	Federal upper limit
FY	fiscal year
HCBS	home- and community-based services
HCPCS	Healthcare Common Procedure Coding System
HHA	home health agency
HHSAR	HHS Acquisition Regulation (Code of Federal Regulations, Title 48)
HIV	human immunodeficiency virus
IMD	institution for mental diseases
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage organization
MEDIC	Medicare Drug Integrity Contractor
MFCU	Medicaid Fraud Control Unit
MPFS	Medicare Physician Fee Schedule
MSIS	Medicaid Statistical Information System
NCH	National Claims History
NPI	national provider identifiers
PBM	pharmacy benefit manager
PDE	prescription drug event
PDP	prescription drug plan
PERM	Payment Error Rate Measurement process
PPS	prospective payment system
SCHIP	State Children's Health Insurance Program
SNF	skilled nursing facility
TANF	Temporary Assistance for Needy Families program
TrOOP	true out-of-pocket costs for Part D
URA	unit rebate amount
UPL	upper payment limit
U.S.C.	United States Code
WAMP	widely available market price

## Organizations

The Work Plan refers to the following governmental organizations. (The acronym or abbreviation is used if there is more than one reference to the organization in a major section.)

Administration for Children and Families (ACF)  
Administration on Aging (AoA)  
Agency for Healthcare Research and Quality (AHRQ)  
Centers for Disease Control and Prevention (CDC)  
Centers for Medicare & Medicaid Services (CMS)  
Congressional Budget Office (CBO)  
Department of Commerce (DOC)  
Department of Agriculture (USDA)  
Department of Defense (DOD)  
Department of Health and Human Services (HHS)  
Department of the Treasury (Treasury)  
Department of Transportation (DOT)  
Department of Justice (DOJ)  
Drug Enforcement Administration (DEA)  
Food and Drug Administration (FDA)  
General Services Administration (GSA)  
Government Accountability Office (GAO)  
Health Resources and Services Administration (HRSA)  
Indian Health Service (IHS)  
Medicare Payment Advisory Commission (MedPAC)  
National Institutes of Health (NIH)  
Office for Civil Rights (OCR)  
Office of Acquisition and Grants Management (OAGM)  
Office of Audit Services (OAS)  
Office of Child Support Enforcement (OCSE)  
Office of Counsel to the Inspector General (OCIG)  
Office of Evaluation and Inspections (OEI)  
Office of Human Research Protections (OHRP)  
Office of Inspector General (OIG)  
Office of Investigations (OI)  
Office of Management and Budget (OMB)  
Office of National Drug Control Policy (ONDCP)  
Office of the Assistant Secretary for Preparedness and Response (ASPR)  
Office of the Secretary (OS)  
Substance Abuse and Mental Health Services Administration (SAMHSA)

## Public Laws

The Work Plan refers to the following Public Laws (P.L.). (The acronym or abbreviation for a law is used when there is more than one reference to the law in a major section.)

Anti-Deficiency Act of 1950, P.L. No. 82-414 (“Anti-Deficiency Act”)

Balanced Budget Act of 1997, P.L. No. 105-33 (BBA)

Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000,  
P.L. No. 106-554 (BIPA)

Chief Financial Officers Act of 1990, P.L. No. 101-576 (CFO Act)

Comprehensive Environmental Response, Compensation, and Liability Act of 1980, P.L. No. 96-510  
(CERCLA)

Deficit Reduction Act of 2005, P.L. No. 109-171 (DRA)

Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272 (EMTALA)

Export Administration Act of 1979, P.L. No. 96-72 (EAA)

False Claims Amendments Act of 1986, P.L. No. 99-562 (FCA)

Federal Information Security Management Act of 2002, Title III, E-Government Act of 2002, P.L. No. 107-347 (FISMA)

Food and Drug Administration Modernization Act of 1997, P.L. No. 105-115 (FDAMA)

Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717 (FDCA)

Government Management Reform Act of 1994, P.L. No. 103-356 (GMRA)

Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191 (HIPAA)

Improper Payments Information Act of 2002, P.L. No. 107-300 (IPIA)

Indian Health Care Improvement Act of 1976, P.L. No. 94-437 (IHCIA)

Inspector General Act of 1978, 5 U.S.C. App., P.L. No. 95-452 (IG Act)

Intergovernmental Cooperation Act of 1968, P.L. No. 90-577 (ICA)

Medicare Improvements for Patients and Providers Act of 2008, P.L. 110-275 (MIPPA)

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 (MMA)

Older Americans Act of 1965, P.L. No. 89-73 (OAA)

Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508 (OBRA 1990)

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. No. 107-188 (Bioterrorism Act)

Public Health Service Act of 1944 (PHS Act)

Ryan White Comprehensive AIDS Resources Emergency Act of 1990, P.L. No. 101-381 (Ryan White CARE Act)

Ryan White HIV/AIDS Treatment Modernization Act of 2006, P.L. No. 109-415 (Ryan White HIV/AIDS Program)

Social Security Act of 1935, P.L. No. 74-271 (Social Security Act)

Supplemental Appropriations Act of 2008, P.L. No. 110-252 (not abbreviated)

Tax Equity and Fiscal Responsibility Act of 1982, P.L. No. 97-248 (TEFRA)

Tax Relief and Health Care Act of 2006, P.L. No. 109-432 (TRHCA)



# Table of Contents

<b>A Message from the Office of Inspector General .....</b>	<b>i</b>
Mission.....	i
Work Activities.....	i
Organization.....	i
Work-Planning Process.....	ii
<b>Terms, Titles, Organizations, and Public Laws .....</b>	<b>v</b>
Terms and Titles.....	v
Organizations .....	vi
Public Laws.....	vi
<b>Table of Contents.....</b>	<b>ix</b>
<b>Centers for Medicare &amp; Medicaid Services .....</b>	<b>1</b>
<b>Medicare Program.....</b>	<b>2</b>
<b>Medicare Part A and Part B .....</b>	<b>3</b>
<b>Hospitals.....</b>	<b>3</b>
Part A Hospital Capital Payments.....	3
Additional Part A Medicare Capital Payments for Extraordinary Circumstances .....	3
Provider-Based Status for Inpatient and Outpatient Facilities .....	4
Hospital Ownership of Physician Practices.....	4
Part A Inpatient Prospective Payment System Wage Indices .....	4
Payments to Organ Procurement Organizations .....	5
Inpatient Hospital Payments for New Technologies .....	5
Inpatient Rehabilitation Facility Payments .....	5
Critical Access Hospitals .....	5
Medicare Disproportionate Share Payments .....	6
Inpatient Psychiatric Facility Emergency Department Adjustments.....	6
Interrupted Stays at Inpatient Psychiatric Facilities Payments.....	6
Provider Bad Debts .....	6
Medicare Secondary Payer.....	6
Reliability of Hospital-Reported Quality Measure Data .....	7
Payments for Diagnostic X Rays in Hospital Emergency Departments.....	7
Oversight of Hospitals’ Compliance With the Emergency Medical Treatment and Labor Act.....	7
Coding and Documentation Changes Under the Medicare Severity Diagnosis Related Group System .....	8
Serious Medical Errors (“Never Events”).....	8
Financial Status of Hospitals in the New Orleans Area .....	8
<b>Home Health Agencies.....</b>	<b>9</b>
Part B Therapy Payments for Home Health Beneficiaries .....	9
Accuracy of Coding and Claims for Medicare Home Health Resource Groups .....	9
Physician Referrals for Home Health Agency Services.....	9
Medicare Home Health Payments for Insulin Injections .....	9
Comprehensive Error Rate Testing Program: Fiscal Year 2008 Home Health Agency Claims Error Rate.....	10
<b>Nursing Homes .....</b>	<b>10</b>
Skilled Nursing Facility Consolidated Billing .....	10
Accuracy of Coding for Medicare Skilled Nursing Facility Resource Utilization Groups’ Claims.....	10
Part B Services in Nursing Homes: Mental Health Needs and Psychotherapy Services.....	11
Calculation of Medicare Benefit Days .....	11

Oversight of Nursing Home Minimum Data Set Data .....	11
Nursing Home Residents Aged 65 or Older Who Received Antipsychotic Drugs .....	12
<b>Hospice Care .....</b>	<b>12</b>
Medicare Hospice Care for Nursing Home Residents: Services and Appropriate Payments.....	12
Physician Billing for Medicare Hospice Beneficiaries .....	12
Trends in Medicare Hospice Utilization .....	13
<b>Physicians and Other Health Professionals .....</b>	<b>13</b>
Place of Service Errors.....	13
Evaluation and Management Services During Global Surgery Periods.....	13
Medicare Practice Expenses Incurred by Selected Physician Specialties .....	13
Services Performed by Clinical Social Workers .....	14
Outpatient Physical Therapy Services Provided by Independent Therapists .....	14
Medicare Payments for Colonoscopy Services .....	14
Physicians' Medicare Services Performed by Nonphysicians .....	14
Appropriateness of Medicare Payments for Polysomnography .....	15
Long-Distance Physician Claims Requiring a Face-to-Face Visit .....	15
Geographic Areas With a High Density of Independent Diagnostic Testing Facilities .....	15
Patterns Related to High Utilization of Ultrasound Services .....	15
Medicare Payments for Chiropractic Services Billed With the Acute Treatment Modifier .....	16
Physician Reassignment of Benefits .....	16
Medicare Payments for Unlisted Procedure Codes.....	16
Laboratory Test Unbundling by Clinical Laboratories .....	16
Variation of Laboratory Pricing .....	17
Clotting Factor Furnishing Fee .....	17
Medicare Billings With Modifier GY .....	17
<b>Durable Medical Equipment and Supplies .....</b>	<b>18</b>
Durable Medical Equipment Payments for Beneficiaries Receiving Home Health Services.....	18
Medicare Payments for Various Categories of Durable Medical Equipment .....	18
Medicare Payments for Durable Medical Equipment Claims With Modifiers .....	18
Medicare Payments for Continuous Positive Airway Pressure Devices .....	18
Comprehensive Error Rate Testing Program: Fiscal Year 2009 Durable Medical Equipment Error Rate .....	19
Comprehensive Error Rate Testing Program: Durable Medical Equipment Corrective Actions .....	19
Part B Services in Nursing Homes: Overview .....	19
Part B Services in Nursing Homes: Enteral Nutrition Therapy.....	20
Part B Pricing of Enteral Nutrients for Nursing Homes.....	20
Medicare Pricing for Parenteral Nutrition.....	20
Part B Services in Nursing Homes: Durable Medical Equipment.....	21
Medicare Part B Payments for Home Blood-Glucose-Testing Supplies.....	21
Duplicate Payments to Durable Medical Equipment Suppliers With Multiple National Provider Identifiers .....	21
Payments to Medical Suppliers and Home Health Agencies Associated With "Currently Not Collectible" Overpayments .....	21
Appropriateness of Medicare Reimbursement for Pressure-Reducing Support Surfaces .....	22
Comparison of Prices for the Negative Pressure Wound Therapy Pump.....	22
Medicare Payments for Power Wheelchairs .....	22
Supplier Purchase Prices for Power Wheelchairs in the Medicare Program.....	22
Repair and Servicing of Capped Rental Durable Medical Equipment .....	23
Appropriateness of Durable Medical Equipment Categorization.....	23
<b>Part B Payments for Prescription Drugs .....</b>	<b>23</b>
Payments to Dialysis Facilities for Epogen.....	23
Medicare Payment for Chemotherapy Drug Administration Services .....	24
Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Widely Available Market Prices .....	24
Monitoring Part B Drug Prices: Comparing Average Sales Prices to Average Manufacturer Prices .....	24
Aberrant Claim Patterns for Inhalation Drugs in South Florida.....	24
Oversight of Manufacturers' Average Sales Price Data Submissions.....	24
Utilization of Albuterol and Levalbuterol Among Medicare Beneficiaries .....	25
<b>Other Reviews Related to Part A and Part B.....</b>	<b>25</b>

Separately Billable Laboratory Services Under the End Stage Renal Disease Program.....	25
Ambulance Services Used To Transport End Stage Renal Disease Beneficiaries .....	25
Ambulatory Surgical Center Payment System.....	26
Medical Identity Theft in Medicare .....	26
Comprehensive Error Rate Testing Program: FY 2008 Transportation Claims Error Rate .....	26
<b>Medicare Part A and Part B Contractor Operations .....</b>	<b>27</b>
Preaward Reviews of Contract Proposals .....	27
Contractors' Administrative Costs .....	27
Contracting Operations .....	27
Pension Segmentation .....	27
Pension Costs Claimed.....	27
Unfunded Pension Costs .....	27
Pension Segment Closing.....	28
Postretirement Benefits and Supplemental Employee Retirement Plan Costs .....	28
Medicare Summary Notice .....	28
Medicare and Medicaid Data Match Project.....	28
Accuracy and Completeness of the National Provider Identifier .....	29
Recovery Audit Contractors: Reducing Medicare Improper Payments .....	29
Medicare Contractors' Use of Payment Suspensions and Other Administrative Sanctions.....	29
Collection of Medicare Overpayments Referred by Program Safeguard Contractors .....	29
Handling of Complaints Referred by the 1-800-HHS-TIPS Hotline .....	30
Validation of National Claims History File .....	30
Medicare Payments for Medical Equipment and Supply Claims With Invalid or Inactive Physician Identifiers .....	30
<b>Medicare Part C (Medicare Advantage) .....</b>	<b>30</b>
Stabilization Fund .....	31
Managed Care Encounter Data .....	31
Payments to Medicare Advantage Plans for Deceased Enrollees .....	31
Enhanced Payments for Certain Beneficiary Types.....	31
Medicare Advantage Payments to Critical Access Hospitals.....	32
Administrative Costs Included in Medicare Advantage Bid Submissions .....	32
Graduate Medical Education Payments Included in Payments to Medicare Advantage Plans .....	32
Investment Income Earned by Medicare Advantage Plans .....	32
Disenrollments From Medicare Advantage Plans.....	33
Medicare Advantage Rebate Benefits .....	33
Medicare Advantage Risk Adjustment Validation.....	33
Beneficiary Appeals in the Medicare Advantage Program .....	33
Comparing Special Needs Plan Beneficiaries to Other Medicare Advantage Prescription Drug Plan Beneficiaries .....	34
<b>Medicare Part D Prescription Drug Program .....</b>	<b>34</b>
Part D Dual-Eligible Demonstration Project.....	34
Duplicate Drug Claims for Hospice Beneficiaries .....	35
Medicare Part D Duplicate Payments .....	35
Duplicate Medicare Part A and Part B Claims Included With Part D Claims.....	35
Coordination and Oversight of Medicare Parts B and D To Avoid Duplicate Payments.....	36
Payments for Drugs Under Medicare Part D During Part A Skilled Nursing Stays .....	36
Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse.....	36
Medicare Drug Integrity Contractors' Adherence to Contractual Arrangements.....	36
Medicare Prescription Drug Integrity Contractors' Detection of Fraud and Abuse.....	36
Accuracy of Drug Prices on the Medicare Prescription Drug Plan Finder.....	37
Medicare Part D Reconciliation Calculations .....	37
Medicare Part D Data Submitted by Sponsors for Reconciliations.....	37
Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2007 .....	37
Retiree Drug Subsidy Program: Eligibility of Plans and Individuals.....	38

Allowable Costs Under the Retiree Drug Subsidy Program .....	38
Medication Therapy Management Program.....	38
Less-Than-Effective and Terminated Drugs in Part D.....	38
Aberrant Part D Claims.....	39
Part D Catastrophic Coverage.....	39
True Out-of-Pocket Costs for Part D.....	39
Bid Submission by Part D Sponsors .....	39
Part D Sponsors’ Audits of Pharmacies .....	40
Disenrollment of Deceased Beneficiaries .....	40
Part D Negotiated Drug Prices and Price Concessions .....	40
Comparing Pharmacy Reimbursement Amounts: Medicare Part D to Medicaid.....	41
Medicare Part D Coverage Gap .....	41
E-Prescribing in Part D .....	41
Oversight of Pharmacy Benefit Managers .....	41
Impact of Rebates on Long Term Care Pharmacies.....	41
Medicare Prescription Drug Plans Formulary Changes .....	42
<b>Medicaid Program .....</b>	<b>42</b>
<b>Medicaid Hospitals .....</b>	<b>42</b>
Hospital Outlier Payments .....	42
States’ Disproportionate Share Hospital Payments for Care of Individuals in Institutions for Mental Diseases.....	43
Provider Eligibility for Medicaid Reimbursement.....	43
Medicaid Disproportionate Share Hospital Payment Distribution .....	43
Supplemental Payments to Private Hospitals.....	43
Potentially Excessive Medicaid Payments for Inpatient and Outpatient Services .....	44
<b>Medicaid Home, Community, and Nursing Home Care .....</b>	<b>44</b>
Community Residence Rehabilitation Services .....	44
Targeted Case Management.....	44
Medicaid Payments to Continuing Day Treatment Providers.....	45
Medicaid Payments to Nursing Homes While Dual-Eligible Beneficiaries Received Covered Medicare Part A Services .....	45
Transparency Within Nursing Facility Ownership.....	45
Medicaid Home Health Agency Claims.....	45
Medicaid Payments for Personal Care Services.....	46
Medicaid Payments for Medicare-Covered Home Health Services .....	46
Compliance With States’ Requirements for Medicaid-Funded Personal Care Service Attendants .....	46
State and Federal Oversight of Home- and Community-Based Services Provided in Assisted Living Facilities.....	46
State and Federal Oversight of Home- and Community-Based Services.....	47
Medicaid Adult Day Health Service Payments for Ineligible and Absent Beneficiaries .....	47
Community Transition Services Provided to Medicaid Home- and Community- Based Services Waiver Beneficiaries .....	47
Plans of Care: Addressing Minimum Data Set and Resident Assessment Protocols Through Provided Services .....	48
States’ Use of Civil Monetary Penalty Funds .....	48
Payments for “Bed Holds” .....	48
<b>Medicaid Prescription Drugs .....</b>	<b>48</b>
Timely Submission of Average Manufacturer Price Data.....	48
Manufacturer Submissions of Outlier Average Manufacturer Prices.....	49
Calculation of Average Manufacturer Prices .....	49
States’ Medicaid Drug Claims .....	49
Medicaid Payments for Drugs Not Approved for Use by Children .....	50
Family Planning Access and Care and Treatment Adjustments.....	50
Alien Emergency Drug Claims .....	50
Medicaid Third-Party Liability for Prescription Drug Payments.....	50
Compound Drugs.....	51

Medicaid Reimbursement for Unapproved Drugs .....	51
Zero Dollar Unit Rebate Amounts .....	51
States' Accountability Over Medicaid Drug Rebate Programs.....	51
Additional Rebates of Brand-Name Drugs .....	52
Assessing the Accuracy of Drug Type Classification in the Medicaid Drug Rebate Initiative File.....	52
Comparison of Medicaid Federal Upper Limit Amounts to Wholesale, Retail, and Medicare Pricing .....	52
<b>Other Medicaid Services .....</b>	<b>53</b>
Medicaid Dental Services .....	53
Family Planning Services.....	53
Medicaid Payments for Transportation Services.....	53
State Policies To Safeguard Medicaid Nonemergency Transportation Services .....	53
Medical Equipment .....	54
Early and Periodic Screening, Diagnostic, and Treatment Services .....	54
Providers Billing More Time Than Is Feasible in a Day.....	54
Rehabilitative Services.....	54
Enhanced Reimbursement to States for Indian Health Service Claims.....	54
Reimbursement Rates for Services Provided by Indian Health Service Facilities .....	55
Medical Services for Undocumented Aliens.....	55
Medicaid Payments for Laboratory Services for Dual-Eligible Beneficiaries .....	55
<b>Medicaid Administration .....</b>	<b>55</b>
Contingency Fee Payment Arrangements .....	55
Medicaid Payments for Services Provided Under Section 1115 Demonstration Projects.....	56
Medicaid Waiver Safety Net Care Pools.....	56
Medicaid Payments for Services Provided Under Section 1915(b) Managed Care/Freedom of Choice Waivers.....	56
Sections 1915(b) and (c) Concurrent Waivers .....	56
Medicaid Payments for Services Provided Under Section 1915(c) Home- and Community-Based Service Waivers .....	57
Enrollment of Excluded Medicaid Providers .....	57
Medicaid Transformation Grants .....	57
Medicaid Provider Tax Issues.....	57
Medicaid Eligibility in Multiple States .....	58
Duplicate Medicaid Payments to Providers on Behalf of Hurricane Evacuees.....	58
State Agencies' Redeterminations of Medicaid Eligibility .....	58
Use of Public Assistance Reporting To Reduce Improper Medicaid Payments by Multiple States .....	58
Medicaid Administrative Costs .....	59
Medicare/Medicaid Credit Balances .....	59
Medicaid Management Information System Costs .....	59
Medicaid Statistical Information System Data Reporting .....	59
Medicaid Managed Care Encounter Data: Reporting and Utilization.....	60
State Buy-In of Medicare Coverage.....	60
Medicaid Services to Incarcerated Juveniles.....	60
Early Implementation of the Medicaid Transfer of Asset Rules .....	60
Medicaid's All-Inclusive Rate for Reimbursement to the Indian Health Service .....	61
States' Subsidies of Employer-Sponsored Insurance Premium Assistance Programs .....	61
<b>Medicare and Medicaid Information Systems and Data Security .....</b>	<b>61</b>
Medicare: Annual Reports to Congress on Contractor Information Systems Security Programs .....	61
Medicare: Assessment of Claims Bypassing the Common Working File and the Impact on the National Claims History File.....	61
Medicare Contractor Information Technology Closeout Audits .....	62
Medicare Part D Selected General and Application Controls for Systems That Track True Out-of-Pocket Costs.....	62
Medicare Part D: Implementation of Supporting Systems at Small- and Medium-Size Plans and Plans New to Medicare .....	62
Medicare and Medicaid: Security of Portable Devices Containing Personal Health Information at Contractors and Hospitals.....	63

Medicare and Medicaid Health Information Data Security and Privacy .....	63
Medicaid Management Information Systems—Business Associate Agreements .....	63
Medicaid: Security Controls Over State Web-Based Applications .....	64
Medicaid: Security Controls at the Mainframe Data Center That Processes States' Claims Data .....	64
<b>State Children's Health Insurance Program .....</b>	<b>64</b>
Medicaid and State Children's Health Insurance Program Citizenship Requirements .....	64
State Children's Health Insurance Program Payments for Residents in Institutions for Mental Diseases .....	65
State Children's Health Insurance Program Administrative Costs .....	65
Dually Enrolled Beneficiaries in a State .....	65
Medicaid and State Children's Health Insurance Program Payment Error Rate Measurement .....	65
Medicaid and State Children's Health Insurance Program Payment Error Rate for One State's Managed Care Program .....	66
<b>Investigative and Legal Activities Related to Centers for Medicare &amp; Medicaid Services Programs and Operations.....</b>	<b>66</b>
Health Care Fraud .....	67
Exclusions From Program Participation .....	68
Provider Self-Disclosure .....	68
Resolution of False Claims Act Cases and Negotiation of Corporate Integrity Agreements .....	69
Providers' Compliance With Corporate Integrity Agreements .....	69
Advisory Opinions, Fraud Alerts, and Other Industry Guidance .....	69
Civil Monetary Penalties.....	70
 <b>Public Health and Human Service Programs and Departmentwide Issues</b>	 <b>71</b>
<b>Public Health Programs.....</b>	<b>71</b>
<b>Centers for Disease Control and Prevention .....</b>	<b>72</b>
Centers for Disease Control and Prevention's Implementation of Select Agent Regulations.....	72
Select Agent Transfers .....	72
Deemed Exports .....	72
Contracting Procedures .....	73
Monitoring of Subrecipient Emergency Preparedness Expenditures .....	73
The CHEMPACK Project: Storage of Drugs To Treat Nerve Agent Exposure.....	73
State 24/7 Reporting Systems .....	74
Fraud and Abuse Safeguards for the Vaccines for Children Program.....	74
Community Health Center Adoption of Recommendations for Human Immunodeficiency Virus Testing in Health Care Settings .....	74
State and Local Preparedness for Pandemic Influenza: Mass Prophylaxis and Medical Surge .....	74
<b>Food and Drug Administration.....</b>	<b>75</b>
Food and Drug Administration's Implementation of Select Agent Regulations.....	75
Oversight of Food Safety Operations.....	75
Complaint Investigation Process.....	75
FDA's Oversight of Postmarketing Surveillance Studies of Medical Devices .....	76
Adverse Event Reporting for Medical Devices.....	76
Food Facility Inspections .....	76
Compliance With Food Registry Requirements.....	77
Traceability in the United States Food Supply Chain .....	77
Oversight of Human Cells, Tissues, and Cellular- and Tissue-Based Products Establishments .....	77
Foreign Clinical Trials .....	77
Management of Information Technology Contracts at the Center for Drug Evaluation and Research.....	78
Renal Dialysis Facilities' Dosing Guidelines for Erythropoiesis Stimulating Agents .....	78
<b>Health Resources and Services Administration.....</b>	<b>78</b>

Ryan White Care Act Payer of Last Resort Provision .....	78
Oversight of the Ryan White Core Medical Services Requirement .....	79
Oversight of Health Centers .....	79
Reporting Adverse Actions to the Healthcare Integrity and Protection Data Bank .....	79
<b>Indian Health Service.....</b>	<b>79</b>
Contract Health Services.....	79
Provision of Dialysis and Mental Health Services .....	80
Accounting for Medication Inventory.....	80
Background Investigations To Protect Indian Children .....	80
Indian Health Service Loan and Repayment Programs.....	80
<b>National Institutes of Health .....</b>	<b>81</b>
Superfund Financial Activities for Fiscal Year 2008 .....	81
National Institutes of Health’s Implementation of Select Agent Regulations.....	81
National Institute of Environmental Health Science’s Grant Process .....	81
Financial Conflicts of Interest in Research Funded by the National Institutes of Health.....	81
Colleges’ and Universities’ Compliance With Cost Principles.....	82
Use of Data and Safety Monitoring Boards in Clinical Trials .....	82
Clinical and Translational Science Awards.....	82
<b>Substance Abuse and Mental Health Services Administration .....</b>	<b>82</b>
Substance Abuse Prevention and Treatment Block Grants .....	82
<b>Cross-Cutting Public Health Activities .....</b>	<b>83</b>
Oversight of Federal Advisory Committee Special Government Employee Conflicts of Interest .....	83
Use of Public Health Preparedness and Response for Bioterrorism Program Funds in Gulf Coast States .....	83
Pandemic Influenza Expenditures.....	83
Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation .....	83
<b>Investigations.....</b>	<b>84</b>
Violations of Select Agent Requirements .....	84
<b>Legal Activities.....</b>	<b>84</b>
<b>Human Service Programs.....</b>	<b>84</b>
<b>Administration on Aging.....</b>	<b>85</b>
Aging Programs in One State.....	85
<b>Administration for Children and Families .....</b>	<b>85</b>
Foster Care and Adoption Assistance Training and Administrative Costs .....	85
Foster Care Per Diem Rates .....	85
Costs Billed by Child-Placing Agencies .....	85
Group Home and Foster Family Agency Rate Classification .....	86
Adoption Assistance Subsidies .....	86
Foster Care Claims for the Placement of Delinquent Children .....	86
Foster Care Preplacement/Candidacy Costs.....	86
Foster Children Over 19 Years Old.....	87
Oversight of System Design of Statewide Automated Child Welfare Information Systems .....	87
Foster Care Programs Collection and Reporting of Child Support Payments.....	87
Temporary Assistance for Needy Families Improper Payment Rate .....	87
Services for Recently Arrived Refugees .....	88
Head Start Matching Costs.....	88
Head Start Agencies’ Use of Grant Funds .....	88
Licensing Standards and Health and Safety Monitoring at Child Care Facilities .....	88
Use of Financial Institution Data Match To Collect Child Support .....	89
Federal Employers’ Payment Submissions to Child Support State Disbursement Units .....	89
Undistributable Child Support Collections .....	89
Child Support Incentive Payments.....	90
Interest Earned on Child Support Enforcement Funds.....	90
Increasing Child Support Collections .....	90
Followup to Noncustodial Parents’ Contributions Toward Medicaid Premiums.....	90
Investigations Under the Child Support Enforcement Task Force Model .....	90

<b>Departmentwide Issues .....</b>	<b>91</b>
<b>Financial Statement Audits.....</b>	<b>91</b>
Audits of Fiscal Years 2008 and 2009 Financial Statements .....	91
Fiscal Year 2009 Statement on Auditing Standards 70 Examinations .....	92
Fiscal Years 2008 and 2009 Financial-Related Reviews .....	92
<b>Other Financial Accounting Reviews .....</b>	<b>93</b>
Expired Appropriations .....	93
President’s Emergency Plan for Relief Funds.....	93
Public Welfare Cost Allocation Plan .....	93
Annual Accounting of Drug Control Funds .....	93
Use of Appropriated Funds in Program Support Center Contracting .....	94
Contracting Procedures .....	94
Non-Federal Audits.....	94
Reimbursable Audits.....	94
Requested Audit Services .....	95
<b>Automated Information Systems .....</b>	<b>95</b>
Information System Security Audits .....	95
Federal Information Security Management Act of 2002 and Critical Infrastructure Protection .....	95
<b>Other Departmental Issues .....</b>	<b>96</b>
Use of Discounted Airfares by Employees .....	96
State Protections for Persons With Disabilities in Residential Settings.....	96
Purchase Cards.....	96
Travel Cards.....	96

# Centers for Medicare & Medicaid Services

On average, the Office of Inspector General (OIG) allocates about 80 percent of its appropriations to work related to the Centers for Medicare & Medicaid Services (CMS), which administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

- Medicare, established under Title XVIII of the Social Security Act, provides health insurance for people 65 years old or older, people younger than 65 years old with certain disabilities, and people of any age with end-stage renal disease (ESRD). In fiscal year (FY) 2007, Medicare served an estimated 43.9 million enrollees at a cost of more than \$370.7 billion.
- Medicaid, established under Title XIX of the Social Security Act, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. For FY 2007, Medicaid enrollment was estimated at 49.1 million people, and total Federal and State outlays were \$333.2 billion, of which the Federal share was more than \$190.6 billion.
- SCHIP, established under Title XXI of the Social Security Act, is a matching grant to provide health insurance for low-income children who do not qualify for Medicaid but whose families are not able to afford private coverage. In FY 2007, SCHIP served an estimated 4.6 million beneficiaries at a cost of \$6 billion in Federal share.

OIG's emphasis on these health care programs reflects the spending of the Department of Health and Human Services (HHS). That is, CMS expenditures account for more than 80 percent of HHS's budget. OIG's resource allocation is also rooted in statutory mandates and funding sources, including the following:

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established the Health Care Fraud and Abuse Control program (HCFAC) under the direction of the Attorney General and the Secretary of HHS (the Secretary) to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a major portion of our annual operating budget and must be used for work related to Medicare and Medicaid.
- The Deficit Reduction Act of 2005 (DRA) provides our office \$25 million annually from FY 2006 through FY 2010 to undertake fraud and abuse control activities related to the Medicaid program.
- The Supplemental Appropriations Act of 2008 appropriated to OIG \$25 million for FY 2009 for purposes of reducing fraud and abuse in the Medicaid program and authorized to be appropriated to OIG \$25 million for FY 2010 and each subsequent FY.

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that we periodically compare average sales prices (ASP) to average manufacturer prices (AMP) and widely available market prices (WAMP) for drugs covered under Medicare Part B and notify the Secretary if the ASP for a drug exceeds the AMP or the WAMP by more than 5 percent. The MMA also requires that we report to Congress on annual evaluations of Medicare contractors' information security programs.

Through our previous reviews of CMS's management and programs, we identified several significant challenges, including oversight of Medicare Part D, Medicare integrity, Medicaid and SCHIP integrity, and quality of care. This Work Plan presents ongoing and proposed OIG work related to these challenges and other high-priority issues that we have identified during our work-planning process.

This part of the Work Plan is organized into the following areas: Medicare, Medicaid, and other CMS-related reviews and functions, including information systems controls, SCHIP, investigations, and legal counsel to OIG.

## Medicare Program

Medicare is the Nation's largest purchaser of health care (and, within that, of managed care). It accounts for approximately 14 percent of the Federal budget and processes over 1 billion fee-for-service claims a year. The Medicare program is funded through the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds and is composed of four parts:

- Medicare Part A helps pay for hospital, skilled nursing facility (SNF), home health, and hospice care for the aged and disabled. It is financed through the HI Trust Fund, which is primarily funded by payroll taxes paid by workers and employers. Medicare Part B helps pay for physician and outpatient hospital services, laboratory tests, medical equipment, and other items and services not covered by Part A. It is financed through the SMI Trust Fund, which is primarily funded by transfers from the general fund of the U.S. Treasury and by monthly premiums paid by beneficiaries.
- Medicare Part C, known as Medicare Advantage (MA), was established by the MMA to provide more health care coverage choices for Medicare beneficiaries through private health care companies that contract with Medicare to provide benefits. Part C is funded by both the HI and SMI trust funds.
- Medicare Part D, the prescription drug benefit program created by the MMA, provides subsidized access to drug insurance coverage on a voluntary basis for all beneficiaries and premium and cost-sharing subsidies for low-income enrollees. In general, coverage for this benefit is provided under private prescription drug plans (PDP) that offer only prescription drug coverage or through MA plans that integrate prescription drug coverage with the general health care coverage that they provide to Medicare beneficiaries. Part D is funded through the SMI account.

The size and scope of the Medicare program place it at high risk for payment errors. To ensure both the solvency of the Trust Funds and beneficiaries' continued access to quality services, correct and appropriate payments must be made for properly rendered services. Our targeted audits and evaluations continue to identify significant improper payments and problems in specific parts of the program. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments.

## Medicare Part A and Part B

The original Medicare program consisted of Part A and Part B and reflected a fee-for-service approach to health insurance. For Part A, our ongoing and new reviews in FY 2009 address hospitals, home health agencies (HHA), nursing homes, and hospice care. Our Part B-related reviews address payments to and services by physicians and other health professionals, durable medical equipment (DME) and supplies, and prescription drugs covered by Part B, followed by additional reviews that relate to both Part A and Part B and Medicare contractor operations.

Historically, Medicare contractors that are known as fiscal intermediaries (FI) and carriers ("carriers") have handled Medicare's claims administration activities, with the FIs processing claims for Medicare Parts A and B for certain facilities (including hospitals and SNFs) and the carriers processing claims for Medicare Part B (in particular for physician, laboratory, and other services). CMS also engages functional contractors that perform specific fee-for-service business functions. Pursuant to section 911 of the MMA, CMS is implementing a Medicare contracting reform initiative that will replace 23 FIs and 17 carriers with 15 Medicare Administrative Contractors (MAC) that will process both Part A and Part B workloads. Additionally, the reform plan includes four specialty MACs that will service suppliers of DME for a total of 19 MAC contracts.

Descriptions of our ongoing and planned reviews of Medicare Part A and Part B payments and services follow.

## Hospitals

### Part A Hospital Capital Payments

We will review Medicare inpatient capital payments. Capital payments reimburse a hospital's expenditures for assets, such as equipment and facilities. The basic methodology for determining capital prospective rates is found at 42 CFR § 412.308. We will determine whether capital payments to hospitals are appropriate. We will examine the methodology used to update capital rates and analyze the appropriateness of the payment level.

*(OAS; W-00-08-35300; various reviews; expected issue date: FY 2009; work in progress)*

### Additional Part A Medicare Capital Payments for Extraordinary Circumstances

We will review additional Medicare capital payments made to hospitals for extraordinary circumstances. Pursuant to Federal regulations at 42 CFR § 412.348(f)(1), hospitals may request additional Medicare capital payments if they incur unanticipated capital expenditures in excess

of \$5 million (net of proceeds from other payment sources, such as insurance; litigation decisions; and other local, State, or Federal government funding programs) owing to extraordinary circumstances beyond their control (e.g., a flood, a fire, or an earthquake). We will determine whether the additional Medicare capital payments made to hospitals for extraordinary circumstances were in accordance with Federal requirements.  
(OAS; W-00-09-35216; various reviews; expected issue date: FY 2009; new start)

### **Provider-Based Status for Inpatient and Outpatient Facilities**

We will review cost reports of hospitals claiming provider-based status for inpatient and outpatient facilities. Since the beginning of the Medicare program, some hospitals have operated as single entities while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main hospital for Medicare purposes. Pursuant to 42 CFR § 413.65(d), CMS has the authority to grant provider-based status for facilities that are separate from the hospital, both on and off campus, that meet specific requirements. Hospitals with provider-based facilities may receive higher reimbursement when they include the costs of a provider-based entity on their cost reports. Freestanding facilities may also benefit from enhanced disproportionate share hospital (DSH) payments, upper payment limit (UPL) payments, or graduate medical education payments for which they would not normally be eligible. In addition, provider-based status for outpatient clinics may increase coinsurance liability for Medicare beneficiaries. We will determine the potential impact on both the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities.

(OAS; W-00-08-35424; various reviews; expected issue date: FY 2009; work in progress)

### **Hospital Ownership of Physician Practices**

We will review the appropriateness of Medicare reimbursement to hospital-owned physician practices that have the provider-based designation. In October 2005, CMS revised Federal regulations at 42 CFR § 413.65 to delineate requirements for hospitals to obtain provider-based designation for purchased physician practices. These requirements address such issues as the physical location of the entity, the patient population served, and the types of controls and governance exhibited by the hospital over the physician practice. Under the Hospital Outpatient Prospective Payment System (OPPS), hospitals may receive Medicare reimbursement for outpatient services in provider-based practices at amounts greater than CMS's Medicare Physician Fee Schedule (MPFS). We will determine whether hospitals have met the Federal requirements to obtain the provider-based designation and assess the impact of the increased cost to Medicare as a result of reimbursement under the OPPS for physician services in provider-based practices. We will also determine the extent to which hospital-owned physician practices without provider-based designation improperly received reimbursement under the OPPS.

(OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **Part A Inpatient Prospective Payment System Wage Indices**

We will review hospital and Medicare controls over the accuracy of the hospital wage data used to calculate wage indices for the IPPS. Hospitals must accurately report wage data for CMS to properly calculate the wage index in accordance with the Social Security Act, § 1886(d)(3). Our prior work found hundreds of millions of dollars in misreported wage data. We will determine whether hospitals have complied with Medicare requirements for reporting wage data and

determine the effect on the Medicare program of incorrect diagnosis-related group (DRG) reimbursement caused by inaccurate wage data. We will also examine the appropriateness of using hospital wage indices for other provider types.

*(OAS; W-00-07-35142; W-00-08-35142; various reviews; expected issue date: FY 2009; work in progress)*

### **Payments to Organ Procurement Organizations**

We will review Medicare payments made to organ procurement organizations (OPO). An OPO coordinates the retrieval, preservation, and transportation of organs for transplant and maintains a system to allocate available organs to prospective recipients. Medicare generally reimburses OPOs under 42 CFR § 413.200 in accordance with a cost basis method set out at 42 CFR § 413.24. We will determine whether payments made to OPOs are correct and supported.

*(OAS; W-00-08-35152; various reviews; expected issue date: FY 2009; work in progress)*

### **Inpatient Hospital Payments for New Technologies**

We will review payments made to hospitals for new services and technologies. Pursuant to the Social Security Act, §§ 1886(d)(5)(K) and (L), Medicare's new technology payments consist of payments for new medical services and technologies that qualify as new under 42 CFR § 412.87 and are demonstrated to be otherwise inadequately paid under the DRG system. We will determine whether hospitals have submitted claims in accordance with the criteria. We will also review CMS's calculation of the payments.

*(OAS; W-00-09-35191; various reviews; expected issue date: FY 2010; new start)*

### **Inpatient Rehabilitation Facility Payments**

We will review inpatient rehabilitation facilities' (IRF) claims for Medicare reimbursement in cases of transfers from IRFs to other IRFs, long term care hospitals (LTCH), acute inpatient hospitals, or nursing homes that accept payments under the Medicare or Medicaid programs. The Social Security Act, § 1886(j), established a prospective payment system (PPS) for IRFs. Federal regulations at 42 CFR § 412.624(f) provide for adjustment of the Federal prospective payment for patient transfers from IRFs to the specified provider types. Prior OIG reviews have identified improper IRF claims and reimbursement. Specifically, we will determine the extent to which coding errors for claims that should have been paid as transfers have resulted in IRFs submitting improper claims under the IRF PPS.

*(OAS; W-00-09-35217; various reviews; expected issue date: FY 2009; new start)*

### **Critical Access Hospitals**

We will review payments made to critical access hospitals (CAH). Pursuant to the Social Security Act, §§ 1814(l)(1) and 1834(g), CAHs are generally paid 101 percent of the reasonable costs of providing covered CAH services. We will determine whether CAHs have met the CAH designation criteria set forth in the Social Security Act, § 1820(c)(2)(B) and conditions of participation set forth at 42 CFR pt. 485, subpart F, and whether payments made to CAHs were made in accordance with Medicare requirements.

*(OAS; W-00-07-35101; W-00-08-35101; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare Disproportionate Share Payments**

We will review Medicare DSH payments made to hospitals. Under the Social Security Act, § 1886(d)(5)(F)(i)(I), Medicare makes additional payments to acute care hospitals that serve a significantly disproportionate number of low-income patients. Medicare DSH payments have been steadily increasing. We will determine whether these payments were made in accordance with Medicare methodology set forth in the Social Security Act, § 1886(d)(5)(F)(vii). We will review various components of the calculation methodology as set forth in the Social Security Act, § 1886(d)(5)(F)(v)-(vi), to determine whether the hospitals' classifications are appropriate, and examine the total amounts of uncompensated care costs that hospitals incur.

*(OAS; W-00-08-35402; various reviews; expected issue date: FY 2009; work in progress)*

### **Inpatient Psychiatric Facility Emergency Department Adjustments**

We will review payments made to inpatient psychiatric facilities (IPF) to determine whether appropriate adjustments were made for facilities that operate emergency departments. Pursuant to Federal regulations at 42 CFR § 412.424, some of these facilities receive adjusted rates if they maintain qualifying emergency departments.

*(OAS; W-00-09-35403; various reviews; expected issue date: FY 2009; new start)*

### **Interrupted Stays at Inpatient Psychiatric Facilities Payments**

We will review IPFs' claims for Medicare reimbursement in cases of transfers from IPFs to the same or other IPFs. Federal regulations at 42 CFR pt. 412, subpart N, implemented a PPS for IPFs. Pursuant to 42 CFR § 412.424(d)(2)(v), CMS adjusts the PPS per diem payment based on the number of days that have lapsed since the IPF admitted a patient, the earlier days of a stay receiving larger adjustments than the later days. To ensure that IPFs do not discharge and then readmit patients to obtain per diem payments with higher adjustments, section 412.424(d)(3)(iii) states that interrupted stays in which a patient is discharged and then readmitted to the same or another IPF within 3 days following the discharge will be treated as one continuous stay.

Specifically, we will determine the extent to which coding errors for claims that should have been paid as transfers have resulted in IPFs submitting improper claims under the IPF PPS.

*(OAS; W-00-08-35192; various reviews; expected issue date: FY 2009; work in progress)*

### **Provider Bad Debts**

We will review Medicare bad debts claimed by acute care inpatient hospitals, LTCHs, inpatient rehabilitation facilities, inpatient psychiatric facilities, and SNFs to determine whether they were reimbursable. Pursuant to Federal regulations at 42 CFR § 413.89, uncollectible debts related to unpaid deductible and coinsurance amounts may be claimed as Medicare bad debt if specific criteria are met. We will determine whether the bad debt payments were appropriate under Medicare regulations and whether recoveries of prior year writeoffs were properly used to reduce the cost of beneficiary services for the period in which the recoveries were made.

*(OAS; W-00-08-35404; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare Secondary Payer**

We will review Medicare payments for beneficiaries who have other insurance. Pursuant to the Social Security Act, § 1862(b), Medicare payments for such beneficiaries are required to be secondary to certain types of insurance coverage. We will assess the effectiveness of current procedures in preventing inappropriate Medicare payments for beneficiaries with other insurance coverage. For example, we will evaluate procedures for identifying and resolving credit balance

situations, which occur when payments from Medicare and other insurers exceed the providers' charges or the allowed amount.

*(OAS; W-00-08-35317; various reviews; expected issue date: FY 2010; work in progress)*

### **Reliability of Hospital-Reported Quality Measure Data**

We will review hospitals' controls for ensuring the accuracy of data related to quality of care that they submit to CMS for Medicare reimbursement. The Social Security Act, § 1886(b)(3)(B)(vii), requires that hospitals report quality measures for a set of 10 indicators established by the Secretary as of November 1, 2003. Section 501(b) of the MMA established a reduction in payments of 0.4 percent to hospitals that did not report quality measures to CMS. The Social Security Act, § 1886(b)(3)(viii), as added by section 5001(a) of the DRA, expanded this payment reduction to 2 percent effective at the beginning of FY 2007. We will determine whether hospitals have implemented sufficient controls to ensure that their quality measurement data are valid.

*(OAS; W-00-09-35218; various reviews; expected issue date: FY 2010; new start)*

### **Payments for Diagnostic X Rays in Hospital Emergency Departments**

We will review a sample of Medicare Part B paid claims and medical records for diagnostic x-rays performed in hospital emergency departments to determine the appropriateness of payments. Radiology services furnished by a physician are reimbursed by the MPFS provided that the conditions for payment for radiology services at 42 CFR §§ 415.102 (a) and 415.120 are met. The Medicare Payment Advisory Commission (MedPAC), in its March 2005 testimony before Congress, reported concerns regarding the increasing cost of imaging services for Medicare beneficiaries and potential overuse of diagnostic imaging services. In 2004, about 4.7 million diagnostic x rays were performed in Medicare-certified hospitals with emergency departments, a 9.6-percent increase since 2001. Medicare spent approximately \$48.3 million for these services in 2004. We will determine the appropriateness of payments for diagnostic x rays and interpretations.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Oversight of Hospitals' Compliance With the Emergency Medical Treatment and Labor Act**

We will review CMS's oversight of hospitals' compliance with the Emergency Medical Treatment and Labor Act of 1986 (EMTALA). Pursuant to the Social Security Act, §§ 1866 and 1867, and regulations at 42 CFR § 489.24, hospitals must agree to comply with EMTALA requirements. Hospitals with emergency departments are required to provide medical screening examinations to individuals who come to their emergency departments requesting such examinations, regardless of whether the individuals have insurance. CMS is responsible for evaluating EMTALA complaints and referring to State licensing agencies cases that warrant investigation. CMS may terminate facilities' participation in Medicare if investigations, which must include peer review if a medical opinion is required, identify EMTALA violations. A previous OIG review raised concerns about CMS's EMTALA oversight, specifically regarding long delays to investigate complaints and inadequate feedback provided to hospitals on alleged violations. We will identify any variation among regions in the number of EMTALA complaints and cases referred to States, examine CMS's methods for tracking complaints and cases, and

determine whether required peer reviews have been conducted prior to CMS's making a determination about whether to terminate noncompliant providers from the Medicare program. (OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **Coding and Documentation Changes Under the Medicare Severity Diagnosis Related Group System**

We will review the impact of the October 1, 2007, implementation of the Medicare Severity Diagnosis Related Group (MS-DRG) system. CMS revised its hospital inpatient reimbursement system to improve recognition of severity of illness and resource consumption, as recommended in a March 2005 MedPAC report. As a result, the number of DRGs has increased from 538 to 745. We will examine coding trends and patterns under the new system and determine whether specific MS-DRGs are vulnerable to potential upcoding. (OEI; 00-00-00000; expected issue date: FY 2010; new start)

### **Serious Medical Errors (“Never Events”)**

We will review the incidences of and payments for serious medical errors, known as “never events,” in the Medicare population. Section 203 of Division B of the Tax Relief and Health Care Act of 2006 (TRHCA) requires OIG to conduct a study of never events, examining types of events and payments by any party; the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events; and the extent to which beneficiaries paid for such services. OIG is also required to review CMS's administrative processes regarding detecting and paying for never events. We will conduct a series of reviews to address the requirements of this mandate. More specifically, we will review key issues, policies, and practices regarding never events in hospitals. We will also conduct a review of hospitals' compliance with CMS requirements by identifying several hospital-acquired conditions using the Present on Admission coding system implemented on October 1, 2007. (OAS; W-00-08-35422; various reviews; expected issue date: FY 2009; work in progress; OEI; 06-07-00470; 06-07-00471; 06-08-00220; various reviews; expected issue dates: FY 2009 and 2010; work in progress and new start)

### **Financial Status of Hospitals in the New Orleans Area**

We will review the financial status of hospitals in the New Orleans area in the aftermath of Hurricane Katrina to assess the needs of hospitals and options for policymakers as the area rebuilds its health care infrastructure. The Department has played a central role in Katrina recovery efforts, including the funding of provider stabilization grants under the authority of section 6201(a)(4) of the DRA; 72 Fed. Reg. 9538 (Mar. 2, 2007). Among other things, these grants were intended to compensate health care providers for wage rates that had not yet been reflected in the Medicare reimbursement system methodologies and to help retain and recruit the licensed health care professionals needed to restore access to health care. We will determine if the grantees were effective in meeting the objectives. (OAS; W-00-07-35203; various reviews; expected issue date: FY 2009; work in progress)

## Home Health Agencies

### **Part B Therapy Payments for Home Health Beneficiaries**

We will review Part B payments for therapy services provided to beneficiaries in home health episodes. Therapy services furnished to Medicare beneficiaries during home health episodes are included in HHA prospective payments. The Social Security Act, §§ 1832(a)(1) and 1842(b)(6)(F), require that, in the case of home health services furnished under a plan of care of an HHA, payment for those services be made to the HHA, including payment for therapy services provided under arrangements by outside suppliers. We will determine whether payments made to HHAs are correct and supported for the service level claimed. We will identify Part B payments made to outside suppliers for therapy services that are included in the HHA prospective payment and examine the adequacy of controls established to prevent inappropriate Part B payments for therapy services.

*(OAS; W-00-09-35418; various reviews; expected issue date: FY 2009; new start)*

### **Accuracy of Coding and Claims for Medicare Home Health Resource Groups**

We will review Medicare claims submitted by HHAs to determine the extent to which the home health resource group (HHRG) billing codes that are used in determining payments to HHAs are accurate and supported by documentation in the medical record. The Social Security Act, § 1895, governs the payment basis and reimbursement for claims submitted by HHAs including a case-mix adjustment using HHRGs. Medicare pays for home health episodes based on a PPS that categorizes beneficiaries into groups, referred to as HHRGs. Each HHRG has an assigned weight that affects the payment rate. We will assess the accuracy of HHRG assignment and identify patterns of coding by HHAs.

*(OEI; 01-08-00390; expected issue date: FY 2009; new start)*

### **Physician Referrals for Home Health Agency Services**

We will review Medicare payments for home health claims to identify potential aberrant billing by referring physicians. Medicare home health expenditures were approximately \$14.2 billion in 2007. The regulation at 42 CFR § 484.18 includes as a condition of participation for HHAs that a physician establish a plan of care. The instruction in CMS's "Home Health Agency Manual," Pub. No. 11, Ch. II, § 204.5, requires that a physician certification be included in the plan of care. CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 10, § 40.2, requires home health claims to include an attending/referring physician identifier to receive Medicare reimbursement. We will examine trends in utilization patterns and Medicare reimbursement for services ordered by referring physicians.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Medicare Home Health Payments for Insulin Injections**

We will review the incidence of Medicare home health services outlier payments for insulin injections. Insulin is customarily self-injected by a patient or is injected by a family member. However, CMS's "Medicare Benefit Policy Manual," Pub. No. 100-02, ch. 7, § 40.1.2.4.A.2, states that when a patient is either physically or mentally unable to self-inject insulin and no other person is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service under the Medicare home health benefit. The unit of payment under the home health PPS is a national 60-day episode rate with applicable adjustments. The law requires the 60-day episode to include all covered home health services,

including medical supplies, paid on a reasonable cost basis. When cases experience an unusually high level of services in a 60-day period, Medicare systems will provide additional “outlier” payments to the episode payment. Outlier payments can result from medically necessary high utilization of home health services. CMS makes outlier payments when the cost of care exceeds a threshold dollar amount. We will examine billing patterns in geographic areas with high rates of home health visits for insulin injections to determine the appropriateness of services billed. *(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Comprehensive Error Rate Testing Program: Fiscal Year 2008 Home Health Agency Claims Error Rate**

We will review certain aspects of CMS’s Comprehensive Error Rate Testing (CERT) methodology for determining the 2008 HHA error rate. The Improper Payments Information Act of 2002 (IPIA) and the Office of Management and Budget’s (OMB) implementation of that act in memorandum M-06-23 require Federal agencies to annually develop a statistically valid estimate of improper payments made under programs with a significant risk of erroneous payments. To accomplish our objective, we will review HHA claims that were selected for review by the FY 2008 CERT program. Our review will consist of a statistical subsample of claims from the CERT’s sample of HHA claims. For the sampled claims, we will obtain medical records and other supporting documentation used to determine whether payments for services and items such as skilled nursing, therapy, home health aides, and medical supplies were adequately documented, medically necessary, and coded correctly. We will obtain additional information for the sampled claims by conducting site visits to the HHAs that submitted the claims, the referring physicians, and the beneficiaries. We will also determine whether the beneficiaries met the requirements for “homebound.” We will engage independent medical reviewers to determine the medical necessity and sufficiency of documentation for these claims. *(OAS; W-00-09-40034; expected issue date: FY 2009; new start)*

## **Nursing Homes**

### **Skilled Nursing Facility Consolidated Billing**

We will review Medicare Part B claims submitted by suppliers for items, supplies, or services provided to beneficiaries during Part A Medicare-covered SNF stays. Pursuant to the Social Security Act, §§ 1842(b)(6)(E) and 1862(a)(18), the supplier must bill and receive payment from SNF, rather than from Medicare, for these items or services. Prior work has identified significant improper claims submission and reimbursement in this area, and we are continuing our work to identify additional overpayments. We will also determine whether edits in CMS’s main claims-processing system, the Common Working File (CWF), are effective in detecting and preventing improper payments. *(OAS; W-00-08-35185; various reviews; expected issue date: FY 2009; work in progress)*

### **Accuracy of Coding for Medicare Skilled Nursing Facility Resource Utilization Groups’ Claims**

We will review a national sample of Medicare claims submitted by SNFs to determine the extent to which Resource Utilization Groups (RUG) included on SNF claims for Medicare reimbursement are accurate and supported by the residents’ medical records. The Social Security Act, § 1888(e), provides the basis for the establishment of the per diem Federal payment

rates applied under a PPS to SNFs effective July 1, 1998. Medicare pays for Part A-covered SNF stays based upon a PPS that includes a case-mix adjustment based upon RUGs. A 2006 OIG report found that 22 percent of claims were upcoded, representing \$542 million in potential overpayments for FY 2002. As part of our follow-up work, we will also identify methods to improve the accuracy of payments to SNFs.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Part B Services in Nursing Homes: Mental Health Needs and Psychotherapy Services**

We will review Medicare Part B payments for psychotherapy services provided to nursing home residents during noncovered Medicare Part A SNF stays. Pursuant to 42 CFR § 483.25, certified nursing homes are required to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. A previous OIG review found that approximately 31 percent of outpatient claims for Part B mental health services allowed by Medicare did not meet coverage guidelines, resulting in \$185 million in inappropriate payments. We will determine the medical necessity of services, appropriateness of coding, and adequacy of nursing home documentation.

*(OEI; 06-06-00580; expected issue date: FY 2009; work in progress)*

### **Calculation of Medicare Benefit Days**

We will review whether SNFs submit no-pay bills as required. No-pay bills are submitted to Medicare without a request for reimbursement to track beneficiaries' benefit periods. Under the Social Security Act, § 1812 (a)(2)(A), Medicare allows up to 100 days of SNF services per spell of illness. As described in the Social Security Act, § 1861(a), a spell of illness begins on the first day on which SNF services are provided and ends after those services have not been utilized for 60 days. The "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 6, § 40.8, requires that a SNF submit a bill for a beneficiary that has started a spell of illness under the SNF Part A benefit for every month of the related stay even though no benefits may be payable. A SNF provider must also submit no-pay bills for a beneficiary who has previously received Medicare-covered skilled care and subsequently dropped to a noncovered level of service but continues to reside in a Medicare-certified area of a facility. We will review whether failure to submit no-pay bills contributes to inappropriate calculations of SNF eligibility periods. We will also examine CMS's oversight mechanisms in place to ensure that no-pay bills are submitted by SNFs.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Oversight of Nursing Home Minimum Data Set Data**

We will review CMS's oversight of Minimum Data Set (MDS) data submitted by nursing homes certified to participate in Medicare or Medicaid. The Social Security Act, §§ 1819(b)(3)(A)(iii) and 1819(e)(5), and corresponding sections of Title XIX of the Social Security Act require nursing homes to conduct accurate comprehensive assessments for residents using a resident assessment instrument that includes the MDS. Regulations at 42 CFR § 483.20 specify the requirements of the assessment instrument. MDS data include the residents' physical and cognitive functioning, health status and diagnoses, preferences, and life care wishes. CMS implemented a SNF PPS based on MDS data in July 1998 and began posting MDS-based quality performance information on its Nursing Home Compare Web site in 2002. Approximately half

of the States also use MDS data as the basis of their Medicaid payment systems. We will review CMS's processes for ensuring that nursing homes submit accurate and complete MDS data. (OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **Nursing Home Residents Aged 65 or Older Who Received Antipsychotic Drugs**

We will review the extent to which nursing home residents aged 65 or older received selected antipsychotic drugs in the absence of conditions approved by the Food and Drug Administration (FDA). The Social Security Act, §§ 1819 and 1919, requires SNFs to respect certain rights of patients, including the right to be free from chemical restraints administered for discipline or convenience. The regulation at 42 CFR § 483.25(l) defines safeguards to protect nursing home residents from being prescribed unnecessary drugs. We will examine Medicare Part D and Part B program reimbursements for selected antipsychotic drugs received by elderly nursing home residents and the extent to which these drugs were prescribed and paid for in accordance with Federal regulations.

(OEI; 07-08-00150; expected issue date: FY 2009; work in progress)

## **Hospice Care**

### **Medicare Hospice Care for Nursing Home Residents: Services and Appropriate Payments**

We will review the nature and extent of hospice services that are provided to Medicare beneficiaries who reside in nursing facilities and assess the appropriateness of payments for these services. The Social Security Act, § 1861(dd), governs hospice care in the Medicare program. Medicare hospice spending doubled from \$3.5 billion to \$7 billion from 2001 to 2004, with the growth associated mostly with nursing home residents. A previous OIG review found that hospice beneficiaries in nursing facilities received nearly 46 percent fewer nursing and aid services than hospice beneficiaries residing at home. By conducting a medical record review of hospice services provided to selected beneficiaries, we will assess beneficiaries' plans of care and determine whether the services that they receive are consistent with their plans of care and whether payments are appropriate.

(OEI; 02-06-00221; expected issue date: FY 2009; work in progress)

### **Physician Billing for Medicare Hospice Beneficiaries**

We will review the extent of Part B billing for physician services provided to Medicare hospice beneficiaries. The regulations at 42 CFR § 418.304 list the physician services that are already covered by Medicare under the hospice benefit. The regulation provides that, for physicians employed by or in an arrangement with the hospice, payments for certain services are reimbursed to the hospice as part of the hospice payment, while other services are paid to the hospice under the Part B MPFS. Physicians may receive reimbursement for hospice services under Medicare Part A or Part B. This study is a followup to recent OIG studies on hospice care. We will determine the frequency of and total expenditures for physician services under Part A and Part B for hospice beneficiaries. We will identify whether physicians double-billed hospice services to Part A and Part B.

(OEI; 00-00-00000; expected issue date: FY 2009; new start)

## **Trends in Medicare Hospice Utilization**

We will review Medicare Part A hospice claims to identify trends in hospice utilization. When the hospice benefit was created in section 122 of the Tax Equity and Fiscal Responsibility Act of 1982, Medicare did not cover more than 210 days of hospice care per beneficiary. Congress changed the benefit in section 4443 of the Balanced Budget Act of 1997 implemented by CMS at 42 CFR § 418.21, to eliminate the limit on the number of days covered by Medicare. Since then, the number and types of diagnoses associated with hospice utilization have increased, and longer stays have become more common. We will examine the characteristics of hospice beneficiaries, geographical variations in utilization, and differences between for-profit and not-for-profit providers.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Physicians and Other Health Professionals**

### **Place of Service Errors**

We will review physician coding of place of service on Medicare Part B claims for services performed in ambulatory surgical centers (ASC) and hospital outpatient departments. Federal regulations at 42 CFR § 414.22(b)(5)(i)(B) provide for different levels of payments to physicians depending on where the services are performed. Medicare pays a physician a higher amount when a service is performed in a nonfacility setting, such as a physician's office, than it does when the service is performed in a hospital outpatient department or, with certain exceptions, in an ASC. We will determine whether physicians properly coded the places of service on claims for services provided in ASCs and hospital outpatient departments.

*(OAS; W-00-08-35113; various reviews; expected issue date: FY 2009; work in progress)*

### **Evaluation and Management Services During Global Surgery Periods**

We will review industry practices related to the number of evaluation and management (E&M) services provided by physicians and reimbursed as part of the global surgery fee. CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 12, § 40, contains the criteria for the global surgery policy. Under the global surgery fee concept, physicians bill a single fee for all of their services usually associated with a surgical procedure and related E&M services provided during the global surgery period. We will determine whether industry practices related to the number of E&M services provided during the global surgery period have changed since the global surgery fee concept was developed in 1992.

*(OAS; W-00-07-35207; various reviews; expected issue date: FY 2009 and FY 2010; work in progress)*

### **Medicare Practice Expenses Incurred by Selected Physician Specialties**

We will review the actual expenses of selected physician specialties. Physician services include medical and surgical procedures, office visits, and medical consultations. Physicians are paid for services pursuant to the MPFS, which covers the major categories of costs including the physician professional cost component, malpractice costs, and practice expense. The Social Security Act, § 1848(c)(1)(B), defines "practice expense" as the portion of the resources used in furnishing the service that reflects the general categories of expenses, such as office rent, wages of personnel, and equipment. We will determine whether Medicare payments for physician

services performed by selected specialties are comparable to the actual expenses incurred by the physicians in providing services and operating their practices.

*(OAS; W-00-09-35219; various reviews; expected issue date: FY 2009; new start)*

### **Services Performed by Clinical Social Workers**

We will review services furnished by clinical social workers (CSW) to inpatients of Medicare participating hospitals or SNFs to determine whether the services were separately billed to Medicare Part B. Federal regulations at 42 CFR § 410.73(b)(2) describe services performed by a CSW that cannot be billed as CSW services under Medicare Part B when provided to inpatients of certain facilities. We will examine Medicare Part A and Part B claims with overlapping dates of service to determine whether services performed by CSWs in inpatient facilities were separately billed to Medicare Part B.

*(OAS; W-00-09-35405; various reviews; expected issue date: FY 2009; new start)*

### **Outpatient Physical Therapy Services Provided by Independent Therapists**

We will review outpatient physical therapy services provided by independent therapists to determine if they are in compliance with Medicare reimbursement regulations. The Social Security Act, § 1862(a)(1)(A), provides that Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” CMS’s “Medicare Benefit Policy Manual,” Pub. No. 100-02, ch. 15, § 220.3, contains documentation requirements for therapy services. Previous OIG work has identified claims for therapy services provided by independent physical therapists that were not reasonable, medically necessary, or properly documented. Focusing on independent therapists who have a high utilization rate for outpatient physical therapy services, we will determine whether the services that they billed to Medicare were in accordance with Federal requirements.

*(OAS; W-00-09-35220; various reviews; expected issue date: FY 2009; new start)*

### **Medicare Payments for Colonoscopy Services**

We will review the appropriateness of Medicare payments to physicians for colonoscopy services. A colonoscopy is a complex procedure for examining the entire colon and may include, for example, biopsy to remove polyps, tumors, or other lesions or related services that the physician may deem necessary, such as medical consultations and office visits. A colonoscopy generally requires that the patient be placed under sedation in an outpatient hospital setting. The Social Security Act, § 1833(e), precludes payment to any service provider unless the provider has furnished the information necessary to determine the amounts due such provider. We will determine whether Medicare payments for colonoscopy services were properly supported, billed, and paid in accordance with Medicare requirements.

*(OAS; W-00-09-35221; various reviews; expected issue date: FY 2009; new start)*

### **Physicians’ Medicare Services Performed by Nonphysicians**

We will review services physicians bill to Medicare but do not perform personally. Such services, called “incident to,” are typically performed by nonphysician staff members in physicians’ offices. The Social Security Act, § 18610(s)(2)(A), provides for Medicare coverage of services and supplies performed “incident to” the professional services of a physician. However, these services may be vulnerable to overutilization or put beneficiaries at risk of receiving services that do not meet professionally recognized standards of care. We will

examine the qualifications of nonphysician staff that perform “incident to” services and assess whether these qualifications are consistent with professionally recognized standards of care. (OEI; 09-06-00430; expected issue date: FY 2009; work in progress)

### **Appropriateness of Medicare Payments for Polysomnography**

We will examine the appropriateness of Medicare payments for sleep studies. Sleep studies are reimbursable for patients with symptoms consistent with sleep apnea, narcolepsy, impotence, or parasomnia in accordance with the CMS “Medicare Benefit Policy Manual,” Pub. No. 100-02, ch. 15, § 70. Medicare payments for polysomnography increased from \$62 million in 2001 to \$215 million in 2005. We will also examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements. (OEI; 00-00-00000; expected issue date: FY 2010; new start)

### **Long-Distance Physician Claims Requiring a Face-to-Face Visit**

We will review the appropriateness of Medicare claims for long-distance evaluation and management services. Pursuant to the CMS “Medicare Benefits Policy Manual,” Pub. No. 100-02, ch. 15, § 30, a service may be considered a physician’s service if the physician either examines the patient in person or is able to visualize some aspect of the patient’s condition without a third person’s judgment. Although services provided by means of a telephone call between the physician and the beneficiary may be covered under Medicare, there are certain services that require a face-to-face visit. Previous OIG work indentified instances of physicians billing for services that would normally require a face-to-face examination for beneficiaries who lived a significant distance from the physician. We will also examine factors that contribute to the submission of long-distance physician claims. (OEI; 07-08-00350; expected issue date: FY 2009; work in progress)

### **Geographic Areas With a High Density of Independent Diagnostic Testing Facilities**

We will review services and billing patterns in geographic areas with high concentrations of independent diagnostic testing facilities (IDTF). An IDTF is a facility that performs diagnostic procedures and is independent of a physician’s office or hospital. It may have a fixed location or be a mobile entity, and the practitioner performing the procedures may be a nonphysician. IDTFs must meet performance requirements at 42 CFR § 410.33 to obtain and maintain Medicare billing privileges. A 2006 OIG review found numerous problems with IDTFs, including noncompliance with Medicare standards and potential improper payments of \$71.5 million. In areas with a high density of IDTFs, we will examine service profiles, provider profiles, beneficiary profiles, and billing patterns. (OEI; 00-00-00000; expected issue date: FY 2010; new start)

### **Patterns Related to High Utilization of Ultrasound Services**

We will review services and billing patterns in geographic areas with high utilization of ultrasound services paid under the MPFS. The Social Security Act, § 1848(a)(1), establishes the MPFS as the basis for Medicare reimbursement for all physician services, including ultrasound services, and section 1862(a)(1)(A) provides that Medicare will pay for services only if they are medically necessary. In areas of high utilization of ultrasound services, we will examine service profiles, provider profiles, and beneficiary profiles. (OEI; 01-08-00100; expected issue date: FY 2009; work in progress)

## **Medicare Payments for Chiropractic Services Billed With the Acute Treatment Modifier**

We will review chiropractor billings with acute treatment (AT) modifiers to determine whether they comply with Medicare coverage criteria and documentation requirements. The Social Security Act, § 1861(r)(5), defines physicians as including chiropractors, but only for treatment by manual manipulation of the spine to correct subluxations of the spine. Chiropractors must use an AT modifier to identify services that are active or corrective treatment of an acute or chronic subluxation. Federal regulations at 42 CFR § 410.21(b) further limit Medicare payment to treatment of subluxations that result in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. The Social Security Act, §§ 1862(a)(1)(A) and 1833(e), provides that Medicare pay for services only if they are medically necessary and supported by documentation. A prior OIG review of services allowed in 2001 found that 40 percent of chiropractic services were for maintenance therapy and thus did not meet Medicare coverage criteria, potentially costing the program and its beneficiaries approximately \$186 million in improper payments. We will determine the appropriateness of Medicare payments for chiropractic claims identified as maintenance therapy.

*(OEI; 07-07-00390; expected issue date: FY 2009; work in progress)*

## **Physician Reassignment of Benefits**

We will review the extent to which Medicare physicians reassign their benefits to other entities. The Social Security Act, § 1842(b)(6), prohibits physicians who provide services to Medicare beneficiaries from reassigning their right to Medicare payments to other entities, unless a specific exception applies. For example, physicians are permitted to reassign benefits to other entities enrolled in Medicare when contractual arrangements that meet certain program integrity safeguards exist between the physicians and the entities or when payments are being made to the physicians' employers. Investigations in South Florida have revealed schemes in which fraudulent providers obtain identifying information about legitimate physicians and request reassignments on their behalf. We will examine a national sample of Medicare physicians to determine the extent to which they reassign their benefits to other entities and the extent to which the physicians are aware of their reassignments.

*(OEI; 07-08-00180; expected issue date: FY 2009; work in progress)*

## **Medicare Payments for Unlisted Procedure Codes**

We will review the accuracy of Medicare payments for services billed using unlisted procedure codes. Unlisted procedure medical codes are miscellaneous codes used by service providers only when there are no specific Healthcare Common Procedure Coding System (HCPCS) codes that accurately identify the medical service furnished. The Social Security Act, § 1848(a)(1), establishes the MPFS, which provides a payment amount for almost all HCPCS codes, as the basis for Medicare reimbursement for physician services. However, unlisted procedure codes are not paid under the fee schedule. The Medicare contractors that process such claims suspend them for individual review and manual pricing. We will examine provider usage of procedure codes for services not listed in the HCPCS.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **Laboratory Test Unbundling by Clinical Laboratories**

We will review the extent to which clinical laboratories have inappropriately unbundled laboratory profile or panel tests to maximize Medicare payments. Pursuant to the "Medicare

Claims Processing Manual,” Pub. No. 100-04, ch. 16, § 90, to ensure the accuracy of payments, Medicare contractors must group together individual laboratory tests that clinical laboratories can perform at the same time on the same equipment and then consider the price of related profile tests. Payment for individual tests must not exceed the lower of the profile price or the total price of all the individual tests. We will determine whether clinical laboratories have unbundled profile or panel tests by submitting claims for multiple dates of service or by drawing specimens on sequential days. We will also determine the extent to which the Medicare carriers have controls in place to detect and prevent inappropriate payments for laboratory tests. *(OAS; W-00-09-35222; various reviews; expected issue date: FY 2010; new start)*

### **Variation of Laboratory Pricing**

We will review the extent of variation in laboratory test payment rates among Medicare contractors. The Social Security Act, § 1833(h), requires the Secretary to establish a payment fee schedule for clinical diagnostic laboratory tests. In 2007, Medicare payments for laboratory services exceeded \$6 billion. Prior OIG work found that Medicare had paid significantly higher prices than other payers for certain laboratory tests. We will analyze claims data to determine pricing variances among Medicare contractors for the most commonly performed tests. *(OEI; 05-08-00400; expected issue date: FY 2009; work in progress)*

### **Clotting Factor Furnishing Fee**

We will review the appropriateness of the furnishing fee that Medicare pays to providers of blood clotting factor. Hemophilia is a deficiency in one of the proteins that causes blood to clot. The term “blood clotting factor” generally refers to both the protein that is deficient in hemophiliacs and the biological substance infused for hemophilia treatment. A 2003 Government Accountability Office (GAO) report recommended that CMS establish separate Medicare payments for services related to blood clotting factor, specifically to establish a payment related to providers’ acquisition costs and a separate payment for the cost of delivering blood clotting factor to Medicare beneficiaries. Effective January 1, 2005, section 303 of the MMA implemented a new formula for Medicare’s payment for blood clotting factor based on the ASP. The new formula pays providers of blood clotting factor a furnishing fee to cover the costs of providing the product to Medicare beneficiaries. We will determine whether providers performed all of the services covered by the furnishing fee. *(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Medicare Billings With Modifier GY**

We will review the appropriateness of providers’ use of modifier GY on claims for services that are not covered by Medicare. CMS’s “Medicare Carriers Manual,” Pub. No. 14-3, pt. 3, § 4508.1, states that modifier GY is to be used for coding services that are statutorily excluded or do not meet the definition of a covered service. Beneficiaries are liable, either personally or through other insurance, for all charges associated with the provision of these services. Pursuant to CMS’s “Medicare Claims Processing Manual,” Pub. No. 100-04, ch. 1, § 60.1.1, providers are not required to provide beneficiaries with advance notice of charges for services that are excluded from Medicare by statute. As a result, beneficiaries may unknowingly acquire large medical bills that they are responsible for paying. In FY 2006, Medicare received over 53 million claims with a modifier GY and denied claims totaling over \$400 million. We will examine patterns and trends for physicians’ and suppliers’ use of modifier GY. *(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Durable Medical Equipment and Supplies**

### **Durable Medical Equipment Payments for Beneficiaries Receiving Home Health Services**

We will review Medicare Part B claims for DME, prosthetics, orthotics, and supplies that are furnished to beneficiaries receiving HHA services. The Social Security Act, § 1862(a)(1)(A), provides that Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” CMS’s “Medicare Benefit Policy Manual,” Pub. No. 100-02, ch. 15, § 110.1.C, provides additional guidance on the application of the medical necessity requirement for DME. Based on OIG interviews with home health patients, there were indications of unnecessary DME being ordered for beneficiaries receiving home health services. We will determine whether DME claims paid by Medicare on behalf of beneficiaries receiving home health services were allowable.

*(OAS; W-00-07-35196; various reviews; expected issue date: FY 2010; work in progress)*

### **Medicare Payments for Various Categories of Durable Medical Equipment**

We will review the appropriateness of Medicare Part B payments to DME suppliers of power mobility devices (e.g., scooters), hospital beds and accessories, oxygen concentrators, and enteral/parenteral nutrition. The Social Security Act, §§ 1862(a)(1)(A) and 1833(e), provides that Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” Prior OIG reviews have identified issues such as Medicare paying for DME that was not ordered by physicians, not delivered to the beneficiaries, or not needed by beneficiaries. We will identify DME suppliers in selected geographic areas with high-volume claims and reimbursement to determine whether payments were made in accordance with Medicare requirements.

*(OAS; W-00-09-35223; various reviews; expected issue date: FY 2009; new start)*

### **Medicare Payments for Durable Medical Equipment Claims With Modifiers**

We will review the appropriateness of Medicare Part B payments to DME suppliers that submitted claims with modifiers. The Social Security Act, § 1833(e), precludes payments to any service provider unless the provider has furnished the information necessary to determine the amounts due such provider. For certain items to be covered under the Medicare program, DME suppliers must use modifiers to indicate that they have the appropriate documentation on file; upon request, the suppliers are required to provide the documentation to support their claims for payment. Reviews of suppliers conducted by several of CMS’s DME regional carriers found that suppliers had little or no documentation to support their claims. This suggests that many of the claims submitted may have been invalid and should not have been paid by Medicare. We will determine whether payments to DME suppliers were made in accordance with Medicare requirements.

*(OAS; W-00-08-35305; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare Payments for Continuous Positive Airway Pressure Devices**

We will review the appropriateness of Medicare Part B payments for continuous positive airway pressure (CPAP) devices. Pursuant to the Social Security Act, § 1862(a)(1)(A), Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and

treatment of illness or injury or to improve the functioning of a malformed body member.” CMS’s “Medicare National Coverage Determinations Manual,” Pub. No. 100-03, ch. 1, pt. 4, § 240.4, states that Medicare covers CPAP devices and therapy only if beneficiaries have obstructive sleep apnea and the results of the polysomnography performed in facility-based sleep study laboratories meet certain benchmarks. Previous OIG work revealed cases in which Medicare paid for CPAP devices that were not used by or delivered to beneficiaries. We will determine whether Medicare payments for CPAP devices were supported, billed, and paid in accordance with Medicare requirements.

*(OAS; W-00-09-35224; various reviews; expected issue date: FY 2009; new start)*

### **Comprehensive Error Rate Testing Program: Fiscal Year 2009 Durable Medical Equipment Error Rate**

We will review certain aspects of CMS’s CERT methodology for determining the 2008 DME error rate. The IPJA and OMB’s implementation of that Act in memorandum M-06-23 require Federal agencies to annually develop statistically valid estimates of improper payments made under programs with significant risks of erroneous payments. CMS and one of its contractors plan to review a subsample of claims from the 2008 CERT program to determine the reasonableness of the error rate and confirm that the CERT contractor followed CMS’s requirements in establishing the error rate. OIG will review the same subsample of DME claims to evaluate the adequacy and reasonableness of CMS’s DME subsample review and verify corrective actions that CMS has taken to improve the accuracy of the CERT DME error rate process.

*(OAS; W-00-09-40043; expected issue date: FY 2010; new start)*

### **Comprehensive Error Rate Testing Program: Durable Medical Equipment Corrective Actions**

We will review CMS’s corrective actions in response to recommendations in OIG’s final report dated August 22, 2008 regarding the medical review of claims for the FY 2006 CERT DME review. In the report we recommended that CMS require the CERT contractor to review all available supplier documentation, review all medical records necessary to determine medical necessity, and contact beneficiaries named on high-risk claims. In response to the recommendations, CMS stated that beginning with the 2009 measurement cycle, it would implement the recommendation for reviews of claims for diabetic test strips, oxygen, and powered mobility devices. CMS also indicated that it had issued directions on the appropriate use of clinical inference; would ensure that oral guidances, policy clarifications, and technical directions are followed up with written directions to medical reviewers; and would provide Medicare providers the information they need to understand the program, be informed timely about changes, and bill correctly. We will verify actions taken by CMS to implement our recommendations.

*(OAS; W-00-09-40044; expected issue date: FY 2009; new start)*

### **Part B Services in Nursing Homes: Overview**

We will review the extent of Part B services provided to nursing home residents whose stays are not paid for under Medicare’s Part A SNF benefit. Unlike services provided during a Part A SNF stay, which are billed to Medicare directly by the SNF in accordance with consolidated billing requirements, Part B services are provided and billed directly by suppliers and other providers. In repealing consolidated billing provisions that would have applied to non-Part A

SNF stays, Congress directed OIG in section 313 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to monitor these services for abuse. This review will determine the extent of Part B services provided to nursing home residents during 2006 and assess patterns of billing among nursing homes and providers. As a followup to this study, we also plan a number of in-depth reviews on specific Part B services, such as those associated with DME and enteral nutrition therapy (ENT). These reviews will identify inappropriate payments and aberrant billing patterns by providers and suppliers.  
*(OEI; 06-07-00580; expected issue date: FY 2009; work in progress)*

### **Part B Services in Nursing Homes: Enteral Nutrition Therapy**

We will review Part B ENT, commonly called tube feeding, to determine the appropriateness of payments for associated services. This review will specifically assess the medical necessity, adequacy of documentation, and coding accuracy of claims submitted for Medicare beneficiaries during a nursing home stay that is not covered under the Part A SNF benefit. (ENT provided during a Part A SNF stay is the subject of another OIG review that will focus on consolidated billing for SNFs and will address ENT provided during a Part A SNF stay.) The Social Security Act, § 1861(s)(8), authorizes Medicare Part B coverage of ENT under a prosthetic device benefit provision for beneficiaries residing at home or in nursing facilities when the stays are not covered by Medicare Part A. We will assess the appropriateness of payments for claims for ENT.

*(OEI; 06-07-00090; expected issue date: FY 2009; work in progress)*

### **Part B Pricing of Enteral Nutrients for Nursing Homes**

We will review Part B pricing of enteral nutrients used in ENT. Medicare covers enteral nutrients for beneficiaries who cannot swallow because of permanent or severe medical problems. The Social Security Act, § 1861(s)(8), authorizes Medicare Part B coverage of enteral nutrients under the prosthetic device benefit provision for beneficiaries residing at home or in nursing facilities when the stays are not covered by Medicare Part A. Past OIG work found that Medicare reimbursement for enteral nutrients substantially exceeded prices commonly available to purchasers, such as nursing homes. We will compare Medicare's fee schedule for enteral nutrients to prices available to nursing homes.

*(OEI; 06-07-00590; expected issue date: FY 2009; work in progress)*

### **Medicare Pricing for Parenteral Nutrition**

We will review Medicare's fee schedule for parenteral nutrition in comparison with fees paid by other sources of reimbursement. Parenteral nutrition, which is covered under the prosthetic device benefit of the Social Security Act, § 1861(s)(8), is the practice of feeding a person intravenously to replace the function of a permanently inoperative or malfunctioning internal body organ. In 2007, Medicare spent more than \$100 million for parenteral nutrition related services. Previous OIG work found that Medicare allowances for major parenteral nutrition codes averaged 45 percent higher than Medicaid prices, 78 percent higher than prices available to Medicare risk contract health maintenance organizations, and 11 times higher than some manufacturers' contract prices. We will identify reimbursement amounts paid by public and private payers for parenteral nutrition services.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Part B Services in Nursing Homes: Durable Medical Equipment**

We will review Medicare Part B DME payments allowed for items or supplies provided to beneficiaries in nursing homes. The Social Security Act, § 1834(a), authorizes Medicare payments for DME claims. Pursuant to the Social Security Act, § 1861(n), a nursing home is specifically excluded from qualifying as a beneficiary's home for DME payment purposes when the nursing home is engaged primarily in providing skilled nursing care or rehabilitation services. A previous OIG report found that \$210 million was potentially inappropriately paid for DME for beneficiaries residing in nursing homes. We will review Medicare claims data to determine the extent of inappropriate Medicare Part B DME payments made on behalf of Medicare beneficiaries during nursing home stays not covered by Medicare Part A.

*(OEI; 06-07-00100; expected issue date: FY 2009; work in progress)*

## **Medicare Part B Payments for Home Blood-Glucose-Testing Supplies**

We will review Medicare Part B payments made for home blood glucose test strips and lancet supplies. The Social Security Act, § 1862(a)(1)(A), provides that Medicare will not pay for items or services that are "not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." The Local Medical Review Policies (LMRP) or local coverage determinations, whichever are applicable, issued by the four DME MACs require that the physician's order for each item billed to Medicare include certain elements and be retained by the supplier to support billing for those services. Further, the LMRP require that suppliers add a modifier to identify when the patient is insulin-treated or noninsulin-treated. The amount of supplies allowable for Medicare reimbursement differs depending on the applicable modifier. We will determine the appropriateness of Medicare Part B payments to DME suppliers for home blood glucose test strips and lancet supplies.

*(OAS; W-00-08-35407; various reviews; expected issue date: FY 2009; work in progress)*

## **Duplicate Payments to Durable Medical Equipment Suppliers With Multiple National Provider Identifiers**

We will review Medicare Part B payments to DME suppliers having multiple national provider identifiers (NPI). Federal regulations at 45 CFR § 162.406 describe the NPI as the standard health identifier for health care providers. Regulations at 45 CFR § 162.408 state that the National Provider System (NPS) assigns the NPI to health care providers. Medicare allows health care providers to obtain, by application, NPIs from the NPS for themselves or for any subparts of covered entities if qualifying conditions are met. We will determine whether and the extent to which DME suppliers may have submitted duplicate Medicare claims using multiple NPIs.

*(OAS; W-00-09-35225; various reviews; expected issue date: FY 2009; new start)*

## **Payments to Medical Suppliers and Home Health Agencies Associated With "Currently Not Collectible" Overpayments**

We will review Medicare-related business activities of selected suppliers of DME, prosthetics, orthotics and supplies (DMEPOS) and HHAs that have "currently not collectible" (CNC) overpayments. CMS estimated that Medicare expenditures for DMEPOS were \$9.2 billion in FY 2006. CMS also determined that an estimated 10 percent of these expenditures were inappropriate overpayments. CMS's "Medicare Financial Management Manual,"

Pub. No. 100-06, ch. 4, § 80.2 and ch. 5, § 400.20, deems a Medicare overpayment to be CNC if an overpayment remains uncollected after 180 days despite recovery attempts by CMS

contractors and the Department of the Treasury (Treasury). DMEPOS and HHAs that have overpayments currently considered CNC may also be receiving Medicare payments through their connections with other businesses. We will examine associations between selected suppliers with CNC debt and other businesses that also received Medicare payments.

*(OEI; 06-07-00080; expected issue date: FY 2009; work in progress)*

### **Appropriateness of Medicare Reimbursement for Pressure-Reducing Support Surfaces**

We will review the appropriateness of payments for pressure-reducing support surfaces. Pressure-reducing support surfaces are a kind of DME used for the care of pressure sores. The Social Security Act, § 1861(s)(6), specifies that medical and other health services include DME. However, section 1862(a)(1)(A), provides that Medicare will not pay for items or services that are “not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.” In 2006, Medicare-allowed charges for support surfaces reached \$164 million. We will conduct a medical review of claims to determine the appropriateness of payments for support surfaces.

*(OEI; 02-07-00420; expected issue date: FY 2009; work in progress)*

### **Comparison of Prices for the Negative Pressure Wound Therapy Pump**

We will review Medicare reimbursement for certain negative pressure wound therapy pumps (pump). The Social Security Act, § 1861(s)(4), provides Medicare Part B coverage of medically necessary DME, including this type of pump when appropriate. A previous OIG review found that 24 percent of pump claims did not meet Medicare coverage criteria. Between 2001 and 2006, Medicare payment for the pump rose 692 percent. We will assess the range of supplier purchase prices for the pump to determine how Medicare reimbursement compares to the median supplier purchase price.

*(OEI; 02-08-00140; expected issue date: FY 2009; work in progress)*

### **Medicare Payments for Power Wheelchairs**

We will review documentation supporting claims for power wheelchairs paid for by Medicare and determine whether Medicare beneficiaries received the required face-to-face examinations from the referring practitioners prior to receipt of power wheelchairs, in accordance with the Social Security Act, §§ 1862(a)(1)(A), and 1834(a). The Social Security Act, § 1861(n), defines DME as including power-operated wheelchairs. In 2003, Medicare payments for power wheelchairs peaked at \$1.2 billion. In 2004, as a result of expanded CMS program integrity initiatives, power wheelchair spending decreased to \$850 million. However, Medicare payments for power wheelchairs increased again in 2005 to approximately \$920 million. We will determine the appropriateness of Medicare payments for power wheelchairs.

*(OEI; 04-07-00401; expected issue date: FY 2009; work in progress)*

### **Supplier Purchase Prices for Power Wheelchairs in the Medicare Program**

We will review invoice prices for power wheelchairs and compare those prices to the Medicare fee schedule to assess pricing. In 2004, we found that the reimbursement rate paid by Medicare for power wheelchairs exceeded the prices suppliers paid by 242 percent. The Social Security Act, § 1861(n), defines DME as including power-operated wheelchairs. On November 15, 2006, CMS implemented a revised Medicare fee schedule for power wheelchairs as part of a strategy to curb fraud and abuse and address the significant growth in expenditures for power wheelchairs

and similar items under the Medicare program. We will determine the difference between the Medicare fee schedule for power wheelchairs and suppliers' invoice prices.  
(*OEI; 04-07-00400; expected issue date: FY 2009; work in progress*)

### **Repair and Servicing of Capped Rental Durable Medical Equipment**

We will review the extent and appropriateness of payments for repair and servicing of capped rental DME. Capped rental DME items include wheelchairs and hospital beds. Section 5101(a) of the DRA mandated changes in the way Medicare pays for capped rental DME items. For capped rental DME furnished on or after January 1, 2006, Medicare requires suppliers to transfer the title of DME to the beneficiary after Medicare pays 13 months' rent under a capped rental arrangement. After that time, Medicare continues to pay for reasonable and necessary repairs to the equipment. Previous OIG work found that Medicare paid substantially more for maintenance on rented equipment than repairs on purchased equipment. We will examine servicing records from suppliers and interview beneficiaries regarding their experiences with capped rental DME to determine if Medicare made proper payments for maintenance and repair services.

(*OEI; 07-08-00550; expected issue date: FY 2009; new start*)

### **Appropriateness of Durable Medical Equipment Categorization**

We will review the appropriateness of DME categorization in the Medicare fee schedule for selected DME items. The Social Security Act, § 1833, provides for the payment of benefits for DME items. However, DME products have evolved since the DME fee schedule was created more than 20 years ago. As a result of these changes, some DME items may be in categories that no longer reflect the current costs of the equipment, expected time of beneficiary use, or extent of servicing involved to maintain the equipment. The DME categories defined in the Social Security Act, § 1834, are: inexpensive or other routinely purchased DME; items requiring frequent and substantial servicing; customized items; oxygen and oxygen equipment; other covered items (other than DME); and capped rental items. Using the DME suppliers' records and information from beneficiaries, we will determine whether DME items are properly classified in association with current payment methodologies.

(*OEI; 00-00-00000; expected issue date: FY 2009; new start*)

## **Part B Payments for Prescription Drugs**

### **Payments to Dialysis Facilities for Epogen**

We will review the appropriateness of Medicare Part B claims submitted by dialysis facilities for Epogen administration. Epogen is a biologically engineered protein that is used to treat anemia associated with chronic renal failure. Federal regulations at 42 CFR § 405.2139 require that ESRD facilities maintain complete medical records on all patients in accordance with accepted professional standards and practices. The records must be completely and accurately documented and contain sufficient information to identify the patient, justify the diagnosis and treatment, and document the treatment results accurately. We will determine whether claims submitted for Epogen administered at dialysis facilities were supported and billed in accordance with Medicare requirements. We will also assess CMS's and the Medicare contractors' oversight of claims for Epogen administration.

(*OAS; W-00-07-35306; various reviews; expected issue date: FY 2009; work in progress*)

### **Medicare Payment for Chemotherapy Drug Administration Services**

We will review Medicare payments for chemotherapy drug administration services pursuant to the Social Security Act, § 1832, that occur without corresponding chemotherapy administration drug claims. MedPAC found that Medicare payments for chemotherapy drug administration services increased 217 percent between 2003 and 2004, while payments for chemotherapy drugs increased only 4 percent. We will examine whether billing for chemotherapy administration codes are proper, based on documentation associated with the claims data.

*(OEI; 09-08-00190; expected issue date: FY 2009; work in progress)*

### **Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Widely Available Market Prices**

We will periodically review WAMPs for selected prescription drugs covered by Part B and compare them to ASPs for those drugs. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The Social Security Act, § 1847A(d), enacted by section 303(c)(1) of the MMA, mandates that OIG compare ASPs to WAMPs (if any) for Part B drugs and notify the Secretary, at such times as the Secretary may specify, if the ASP for a selected drug exceeds the WAMP by a threshold of 5 percent. We will compare ASPs to WAMPs and identify drug prices that exceed the threshold.

*(OEI; 00-00-00000; various studies; expected issue date: FY 2009; new start)*

### **Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Average Manufacturer Prices**

We will periodically review Medicare Part B drug prices by comparing ASPs to AMPs. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The Social Security Act, § 1847A(d), enacted by section 303(c)(1) of the MMA, mandates that OIG compare ASPs to AMPs for Part B drugs and notify the Secretary, at such times as the Secretary may specify, if the ASP for a selected drug exceeds the AMP by a threshold of 5 percent. We will compare ASPs to AMPs for Part B drugs and identify drug prices that exceed the threshold.

*(OEI; 03-08-00530; 03-08-00450; various studies; expected issue date: FY 2009; work in progress)*

### **Aberrant Claim Patterns for Inhalation Drugs in South Florida**

We will review aberrant claim patterns for inhalation drugs in South Florida. Inhalation drugs are used to treat lung diseases. Medicare Part B covers inhalation drugs used in conjunction with DME if they are medically necessary. Previous OIG work identified fraud, waste, and abuse in Medicare billings for DME in South Florida. Moreover, in 2006, payments in South Florida made up 19 percent of the \$900 million Medicare spent on inhalation drugs. We will compare inhalation drug claims in South Florida to claims from other areas of the country to assess reimbursement differences and identify potentially fraudulent billing practices.

*(OEI; 03-08-00290; expected issue date: FY 2009; work in progress)*

### **Oversight of Manufacturers' Average Sales Price Data Submissions**

We will review the impact on Medicare Part B payments when drug manufacturers do not submit their ASP data to CMS timely. Manufacturers are required to submit ASP data to CMS 30 days after the close of each quarter. The Social Security Act, § 1847A(b), enacted by section 303 of the MMA, established the ASP as the basis of payment for Part B drugs, effective January 1, 2005. The accuracy of payment for Part B drugs—which cost Medicare and its beneficiaries

over \$11 billion in 2006—depends on drug manufacturers providing CMS with timely and accurate ASP data. We will assess the impact of late ASP submissions and the adequacy of CMS’s oversight of manufacturers’ submissions of ASP data.

*(OEI; 03-08-00480; expected issue date: FY 2009; work in progress)*

### **Utilization of Albuterol and Levalbuterol Among Medicare Beneficiaries**

We will review Medicare Part B claims for albuterol and levalbuterol from 2003 through 2007 to consider the impacts of reimbursement, payment, and coding changes that may have created financial incentives for prescribing one drug over another. In the MMA, Congress mandated an ASP-based Part B payment methodology that better reflects actual drug prices. The change was intended to lower Medicare payments for most inhalation drugs. However, based on data from the Medicare Part B Extract Summary System, cost savings were less than expected because beneficiary utilization shifted from multiple-source generic drugs to single-source brand name drugs. We will determine the number of beneficiaries associated with claims for albuterol and levalbuterol who switched from multiple-source to single-source drugs and also survey a sample of physicians treating those beneficiaries to determine the reasons for the shift in utilization.

*(OEI; 03-07-00440; expected issue date: FY 2009; work in progress)*

## **Other Reviews Related to Part A and Part B**

### **Separately Billable Laboratory Services Under the End Stage Renal Disease Program**

We will review providers’ compliance with the current payment policies for automated multichannel chemistry (AMCC) tests furnished to ESRD beneficiaries. Section 623(f) of the MMA requires the Secretary to develop a report on a bundled PPS for ESRD services. A bundled PPS could include certain clinical laboratory tests that are currently separately billable to Medicare. The current facility payment, the composite rate, includes payments for certain AMCC tests provided routinely at specified frequencies. CMS’s “Medicare Benefit Policy Manual,” Pub. No. 100-02, ch. 11, § 30.2, contains the conditions for coverage and laboratory tests that are included in the composite rate. Any AMCC tests performed in excess of specified frequencies or not included in the composite rate payment are to be billed separately, provided that medical necessity is documented. CMS’s “Medicare Claims Processing Manual,” Pub. No. 100-04, ch. 16, § 40.6, outlines the billing requirements for ESRD-related laboratory tests. Prior OIG reviews found that providers were paid separately for AMCC tests included in the composite rate. To ensure that the bundled PPS rate is based on valid data, we will review providers’ compliance with the current payment policies for AMCC tests furnished to ESRD beneficiaries. We will also identify separately billed clinical laboratory tests that are regularly provided to ESRD beneficiaries in addition to the clinical laboratory tests included in the composite rate.

*(OAS; W-00-07-35202; W-00-08-35202; various reviews; expected issue date: FY 2009; work in progress)*

### **Ambulance Services Used To Transport End Stage Renal Disease Beneficiaries**

We will review the extent to which ambulance services are used to transport ESRD beneficiaries to and from dialysis facilities. CMS’s “Medicare Benefit Policy Manual,” Pub. No. 100-02,

ch. 10, § 10.3, describes coverage of ambulance services to and from renal dialysis facilities for ESRD patients who require dialysis. Furthermore, section 623(f) of the MMA requires the Secretary to develop a report on a bundled PPS for ESRD services. The bundled PPS for ESRD services generally does not provide for ambulance services. In calendar year (CY) 2005, payments for ambulance services between beneficiaries' residences and hospital-based or freestanding ESRD facilities were approximately \$262 million. We will examine factors such as the percentage of the population using ambulance services, the feasibility of freestanding facilities to contract with ambulance suppliers, and the coverage policies of other health insurance programs.

*(OAS; W-00-09-35417; various reviews; expected issue date: FY 2010; new start)*

### **Ambulatory Surgical Center Payment System**

We will review the appropriateness of the methodology for setting ASC payment rates under the revised ASC payment system. Section 626(b) of the MMA requires the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs. We will examine changes to the revised ASC payment system and the rate-setting methodology used to calculate ASC payment rates.

*(OAS; W-00-09-35423; various reviews; expected issue date: FY 2010; new start)*

### **Medical Identity Theft in Medicare**

We will review CMS's activities designed to deter medical identity theft in Medicare. The Social Security Act, § 1893(a), established the Medicare Integrity Program in an effort to combat fraud, waste, and abuse in the Medicare program. In 2007, the Department of Justice (DOJ) and the Federal Trade Commission reported identity theft as one of the fastest growing crimes, with data showing annual monetary losses in the billions of dollars. Early detection and notification of medical identity theft could deter or limit the impact of Medicare fraud. We will review CMS's medical identity theft deterrence measures, including its outreach to beneficiaries.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Comprehensive Error Rate Testing Program: FY 2008 Transportation Claims Error Rate**

We will review certain aspects of CMS's CERT methodology for determining the FY 2008 transportation/ambulance claims error rate. The IPFA requires Federal agencies to annually develop a statistically valid estimate of improper payments made under programs with a significant risk of erroneous payments. To accomplish our objective, we will review transportation claims that were selected for review by the FY 2008 CERT program. Our review will consist of a statistical subsample of claims from the CERT sample of transportation claims. For the sampled claims, we will review the beneficiaries' medical records, including pertinent records from physicians, to support claims from transportation providers. We will determine whether payments for services such as transporting the patient one way, mileage while the patient is on board, and all supplies and services are included in the charge and were appropriate. We will also determine whether the documentation supports the claims, whether the services were medically necessary, and whether the beneficiaries actually received the services. We will engage independent medical reviewers to determine the medical necessity and sufficiency of documentation for these claims.

*(OAS; 00-09-40035; expected issue date: FY 2010; new start)*

## Medicare Part A and Part B Contractor Operations

### Preaward Reviews of Contract Proposals

We will review the cost proposals of various bidders for Medicare contracts based on criteria in OMB Circular A-122, Cost Principles for Non-Profit Organizations. The reports produced by these reviews assist CMS in negotiating favorable and cost-beneficial contract awards.

*(OAS; W-00-08-35002; various reviews; expected issue date: FY 2009; work in progress)*

### Contractors' Administrative Costs

We will review administrative costs claimed by various contractors for their Medicare activities, focusing on costs claimed by terminated contractors. We will determine whether the costs claimed were reasonable, allocable, and allowable under Appendix B of the Medicare contract with CMS, as well as the Federal Acquisition Regulation (FAR) at 48 CFR pt. 31. We will coordinate the selection of contractors with CMS.

*(OAS; W-00-08-35005; various reviews; expected issue date: FY 2009; work in progress)*

### Contracting Operations

We will review CMS's Office of Acquisition and Grants Management (OAGM) contracting operations to understand the procedures that CMS uses to solicit and manage its contracts and determine compliance with various provisions of the FAR. In FY 2005, OAGM initiated an estimated \$1.6 billion in contracts. We will initially document OAGM's operations by addressing activities for presolicitation, solicitation, evaluation, award, and postaward activities.

*(OAS; W-00-08-30003; various reviews; expected issue date: FY 2009; work in progress)*

### Pension Segmentation

We will review whether Medicare contractors have fully implemented contract clauses requiring them to determine and separately account for the assets and liabilities of the Medicare segments of their pension plans. We will also assess Medicare's share of future pension costs on a segmented basis. Applicable requirements are found in the FAR at 48 CFR § 31.205; Cost Accounting Standards (CAS) 412 and 413; and the Medicare contract, Appendix B, section XVI.

*(OAS; W-00-08-35094; various reviews; expected issue date: FY 2009; work in progress)*

### Pension Costs Claimed

We will review whether Medicare contractors have calculated pension costs claimed for reimbursement in accordance with their Medicare contracts and the CAS. We will also determine whether the costs claimed were allocable and allowable under the Medicare contracts pursuant to the FAR at 48 CFR § 31.205; the CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.

*(OAS; W-00-08-35067; various reviews; expected issue date: FY 2009; work in progress)*

### Unfunded Pension Costs

We will review whether Medicare contractors identified and eliminated unallowable costs when computing pension costs charged to the Medicare program. We will also determine whether pension costs that would have been tax deductible had they been funded were properly reassigned to future periods to ensure that only allowable pension costs were claimed for

reimbursement. Applicable requirements are found in the FAR at 48 CFR § 31.205; the CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.  
(OAS; W-00-08-35148; various reviews; expected issue date: FY 2009; work in progress)

### **Pension Segment Closing**

We will review Medicare carriers and FIs whose Medicare contracts have been terminated, resulting in the closing of their Medicare segments. We will determine the amount of any excess pension assets related to each Medicare segment as of the segment closing date. Requirements of the FAR at 48 CFR § 31.205; the CAS 412 and 413; and the Medicare contract, Appendix B, section XVI, of the Medicare contract provide that pension gains that occur when a Medicare segment closes should be credited to the Medicare program.

(OAS; W-00-08-35067; various reviews; expected issue date: FY 2009; work in progress)

### **Postretirement Benefits and Supplemental Employee Retirement Plan Costs**

We will review the postretirement health benefit costs and the supplemental employee retirement plans of FIs and carriers. Our reviews will determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts in accordance with the FAR at 48 CFR §§ 31.201 through 31.205.

(OAS; W-00-08-35095; various reviews; expected issue date: FY 2009; work in progress)

### **Medicare Summary Notice**

We will review beneficiaries' use and understanding of Medicare Summary Notices (MSN). MSNs advise beneficiaries of claims paid for health care services and supplies. CMS's "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 21, § 10, contains contractor requirements for issuing MSNs. On its Web site and in the "Medicare & You" publication, CMS emphasizes the importance of beneficiaries checking their MSNs for any services or supplies that they do not recognize. We will review beneficiaries' experiences with MSNs and the results of their inquiries about unrecognized services.

(OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **Medicare and Medicaid Data Match Project**

We will review CMS's oversight and monitoring of the Medicare and Medicaid Data Match Project (Medi-Medi) contractors to determine whether they are meeting contractual requirements outlined in the Medi-Medi task orders. The Medi-Medi Project was initiated in 2001 by CMS in partnership with the State of California and continues, pursuant to the Social Security Act, § 1893, to improve coordination of Medicare and Medicaid program integrity efforts. The objective of the project is to match Medicare and Medicaid data to proactively identify program vulnerabilities and potential fraud and abuse that may have gone undetected by reviewing Medicare and Medicaid program data individually. As of 2007, there were 10 active Medi-Medi Task Orders in the States of California, Texas, Washington, Pennsylvania, North Carolina, New Jersey, New York, Florida, Ohio, and Illinois. Federal regulations at 48 CFR § 42.1500 provide policies and establish responsibilities for agencies recording and maintaining contractor performance information.

(OEI; 09-08-00370; expected issue date: FY 2009; work in progress)

### **Accuracy and Completeness of the National Provider Identifier**

We will review the accuracy and completeness of NPIs, which are unique identification numbers for health care providers. CMS regulations at 45 CFR § 162.404 require that, beginning May 23, 2007 (May 23, 2008, for small health plans), NPIs be used in lieu of legacy provider identifiers when submitting claims. Providers failing to obtain their NPIs risk losing their ability to receive payment for services provided to Medicare and Medicaid beneficiaries. By May 23, 2008, all Medicare providers had to include their NPIs when submitting claims. We will determine whether CMS has met program goals for implementation of NPIs.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Recovery Audit Contractors: Reducing Medicare Improper Payments**

We will review CMS's oversight and monitoring of recovery audit contractors (RAC) to determine whether they meet contractual requirements outlined in the RAC Task Orders. The RAC program, authorized in section 306 of the MMA, is designed to reduce Medicare improper payments through the detection and collection of overpayments, the identification of underpayments, and the implementation of actions that will prevent future improper payments. Section 302 in Division B of the TRHCA requires the Secretary to utilize RACs in the Medicare Integrity Program to identify underpayments and overpayments and recoup overpayments associated with services for which payments are made under Medicare Part A or Part B.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Medicare Contractors' Use of Payment Suspensions and Other Administrative Sanctions**

We will review MACs' and Program Safeguard Contractors' use of payment suspensions and other administrative sanctions intended to prevent payments to providers and suppliers suspected of fraud. Pursuant to 42 CFR § 405.371, CMS or its contractors can suspend payments to providers or suppliers based upon the existence of reliable information of an overpayment or fraud. Payment suspensions temporarily stop payment until contractors identify and determine overpayments. We will examine CMS's oversight and contractors' implementation of payment suspensions and other administrative sanctions.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Collection of Medicare Overpayments Referred by Program Safeguard Contractors**

We will review overpayments that program safeguard contractors referred to claims processors for collection in 2007. Section 202(a) of the HIPAA established the Medicare Integrity Program, which requires CMS to engage contractors to review Medicare claims, among other things, for possible overpayments. Pursuant to this provision, program safeguard contractors perform investigative work on Medicare payments to detect and deter fraud and abuse. When they identify overpayments that have been made to Medicare providers and beneficiaries, they refer them to Medicare claims processors for collection. We will examine the amount of overpayments that Medicare claims processors have collected as a result of overpayment referrals and identify the procedures the program safeguard contractors and claims processors use to identify and track possible fraud and abuse related to the overpayments.

*(OEI; 03-08-00030; expected issue date: FY 2009; work in progress)*

### **Handling of Complaints Referred by the 1-800-HHS-TIPS Hotline**

We will review CMS's handling of complaints referred by OIG from callers to 1-800-HHS-TIPS, which is a hotline OIG operates to receive calls alleging fraud, waste, or mismanagement of HHS programs, such as Medicare. The availability of the hotline is widely publicized on the Internet and in various publications, including CMS's "Medicare & You" booklet that is distributed annually to Medicare beneficiaries. In 2007, the hotline referred approximately 4,000 complaints to CMS for assessment and appropriate action. We will review CMS's handling of these referrals, including its research related to the issues of the complaints, corrective actions taken, and communications with the complainants.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Validation of National Claims History File**

We will review CMS's National Claims History (NCH) file to determine the accuracy and completeness of paid claims and utilization data on Medicare beneficiaries enrolled in Part A or Part B. The data are used by CMS and other outside healthcare organizations for statistical and research purposes related to evaluating and studying the operation and effectiveness of the Medicare program. The information contained in the NCH is also used to support regulatory, reimbursement, and policy functions performed by CMS or by a contractor, consultant, or grantee. The NCH is populated on a daily basis with claims fully adjudicated by the CWF. Prior OIG work determined that contractors do not correctly process canceled claims when a provider remits a check to the Medicare program representing multiple claims. We will assess Medicare contractors' policies and procedures for processing returned funds, canceled claims, and other adjustments that affect the original Medicare claim and which are not always processed through the CWF.

*(OAS; W-09-00-41043; expected issue date: FY 2009; new start)*

### **Medicare Payments for Medical Equipment and Supply Claims With Invalid or Inactive Physician Identifiers**

We will review Medicare claims for medical equipment and supplies submitted with invalid or inactive unique physician identification numbers (UPIN) or invalid NPIs. The Consolidated Omnibus Budget Reconciliation Act of 1985 required CMS to establish UPINs for all physicians who provide services to Medicare beneficiaries, and the Administrative Simplification provisions of HIPAA included the requirement for CMS to create NPIs to replace UPINs. Suppliers of medical equipment and supplies must include the provider identifier of the prescribing physician on claims to receive Medicare reimbursement. Prior to May 2008, Medicare accepted medical equipment and supply claims that included UPINs, NPIs, or a combination of both. As of May 23, 2008, suppliers were required to use the NPI. We will examine the extent to which Medicare paid medical equipment and supply claims submitted with invalid or inactive UPINs or invalid NPIs.

*(OEI; 04-07-00470; expected issue date: FY 2009; work in progress)*

## **Medicare Part C (Medicare Advantage)**

Beneficiaries must be enrolled in both Part A and Part B to join one of the Part C MA plans, which are administered by MA organizations (MAO). MAOs are public or private organizations

licensed by States as risk-bearing entities that are under contract with CMS to provide covered services. MAOs can offer one or more MA plans. The plans provide all Part A and Part B services and generally provide additional services. Beneficiaries usually pay monthly premiums and copayments that will likely be less than the coinsurance and deductibles under the original Medicare Parts A and B. In most cases, these plans also offer Part D prescription drug coverage. Costs and benefits vary by plan.

Descriptions of our ongoing and planned reviews of Medicare Part C follow.

### **Stabilization Fund**

We will review compliance with CMS's former guidance in the "Medicare Managed Care Manual," Pub. No. 100-16, ch. 8, § 80, pertaining to the establishment and management of the Plan Stabilization Fund for CYs 2004 and 2005. The stabilization fund was a payment reserve to be used in future contract periods to stabilize and prevent undue fluctuations in additional benefits. We will also examine the adequacy, propriety, and timeliness of CMS's review processes for evaluating MA plan proposals and the awarding of stabilization funds in accordance with Federal requirements found at 42 CFR pt. 422 and in CMS's "Medicare Managed Care Manual," Pub. No. 100-16, ch. 8, § 80.

*(OAS; W-00-07-35171; A-05-07-00020; expected issue date: FY 2009; work in progress)*

### **Managed Care Encounter Data**

We will review the accuracy of Part A encounter data on Medicare beneficiaries. All MA plans are required to submit these data for CMS's use in developing a portion of each organization's monthly capitation rate. CMS's "Medicare Managed Care Manual," Pub. No. 100-16, ch. 7, §§ 110 and 111, requires that medical records substantiate all diagnostic information provided in the encounter data to CMS. The portion of the monthly rate that relates to the encounter data is the risk-adjusted portion, which made up 10 percent of the rate in 2003. The risk-adjusted portion increased to 50 percent in 2005 and 75 percent in 2006; it will eventually be 100 percent of the monthly rate. Thus, incorrect or incomplete encounter data could have a significant impact on future Medicare reimbursement.

*(OAS; W-00-08-35078; various reviews; expected issue date: FY 2009; work in progress)*

### **Payments to Medicare Advantage Plans for Deceased Enrollees**

We will review payments to MAOs for enrollees who have died. Each month, MAOs receive capitation payments from CMS to provide medically necessary services for each of their Medicare enrollees. Pursuant to Federal regulations at 42 CFR § 422.74(d)(6), disenrollment from the organization is effective in the month following an enrollee's death. Therefore, except for rare exceptions, such as for adjustments to payments made before the enrollee's death, CMS should not make subsequent payments to these organizations for deceased enrollees. We will review CMS's data systems to determine the accuracy of payments made subsequent to enrollees' deaths.

*(OAS; W-00-07-35421; A-07-07-01046; expected issue date: FY 2009; work in progress)*

### **Enhanced Payments for Certain Beneficiary Types**

We will review the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, ESRD, or Medicaid eligible. Pursuant to the Social Security Act, § 1853(a)(1)(c), CMS adjusts the payment to MAOs for risk factors including disability

status, institutional status, and such other factors deemed appropriate. We will determine the impact of inaccurate or invalid classification of beneficiaries on Medicare payments to MA plans.

*(OAS; W-00-09-35227; various reviews; expected issue date: FY 2010; new start)*

### **Medicare Advantage Payments to Critical Access Hospitals**

We will review the appropriateness of Medicare reimbursements paid to CAHs for services provided to MA beneficiaries. Under the Social Security Act, §§ 1814(1) and 1834(g), CAHs are generally to be paid 101 percent of the reasonable costs of providing covered inpatient and outpatient services. Our review will involve examining the financial arrangements between MAOs and CAHs for services furnished to MA beneficiaries, including the application of the 101-percent provision.

*(OAS; W-00-09-35228; various reviews; expected issue date: FY 2010; new start)*

### **Administrative Costs Included in Medicare Advantage Bid Submissions**

We will review administrative costs supporting the amounts submitted by MA plans in their annual bid proposals to CMS. Under the Social Security Act, § 1854(a) and 42 CFR § 422.254, MA plans are required to submit bid amounts for all services covered under their planned MA plans, including administrative costs. Congress has expressed interest in how MA plans determine funding amounts to meet administrative costs. In previous OIG reviews, we found insufficient documentation of administrative costs and improper allocation of administrative costs to Medicare contracts. We will determine whether MA plans have improved their reporting of administrative costs and the impact of inappropriate cost submissions on the MA program.

*(OAS; W-00-09-35229; various reviews; expected issue date: FY 2010; new start)*

### **Graduate Medical Education Payments Included in Payments to Medicare Advantage Plans**

We will review direct graduate medical education (GME) payments made to MA plans. Pursuant to Federal regulations at 42 CFR § 422.324, MAOs may receive GME payments for the time that residents spend in connection with approved programs in nonhospital provider settings, such as freestanding clinics, nursing homes, and physicians' offices. Through visits to MAOs and nonhospital providers, we will determine whether payments made by Medicare for such claims were appropriate.

*(OAS; W-00-09-35230; various reviews; expected issue date: FY 2010; new start)*

### **Investment Income Earned by Medicare Advantage Plans**

We will review the effect of using computations that include income earned by MAOs from their investments of current Medicare funds. Pursuant to the Social Security Act, § 1854, MAOs are required to provide additional services in an amount equal to any excess amount remaining in their plans for the contract year and to return any remaining funds to the Medicare trust fund. However, neither the Social Security Act nor the Federal regulations require MAOs to include investment income earned on monthly capitation payments prior to their expenditure in developing the benefit packages or calculating the excess for the purposes of section 1854. In responding to prior OIG audits, CMS has agreed that policies and procedures are needed to ensure that investment income funds are used to benefit Medicare enrollees, but no such requirement has been implemented. We will determine the financial impact of requiring MAOs

to factor investment income earned on current Medicare funds in computing the annual bid proposal for estimated revenues needed to provide the Medicare benefit package and the impact of investment income in computing additional benefits and Medicare payments.

*(OAS; W-00-08-35426; various reviews; expected issue date: FY 2009; work in progress)*

### **Disenrollments From Medicare Advantage Plans**

We will review the financial impact on the Medicare program when beneficiaries disenroll from MA plans. A previous OIG review showed that under Medicare fee-for-service, the costs of providing medical services to disenrollees increased by approximately 800 percent in the first 6 months after disenrollment. Following our work, CMS initiated various election periods that limit the window of opportunity for enrollees to disenroll from the MA plan. We will examine the cost of providing health services in both the fee-for-service and managed care arenas for Medicare beneficiaries who were enrolled in an MA plan and subsequently disenrolled during 2004–2007. We will also review MA plans' compliance with the election of coverage period.

*(OAS; W-00-08-35427; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare Advantage Rebate Benefits**

We will review MA plans' use of rebates to provide additional services to MA enrollees. Pursuant to the Social Security Act, § 1854(b)(1)(C), and the regulation at 42 CFR § 422.266(a), MAOs offering a coordinated care plan or private fee-for-service plan are required to provide enrollees with rebates equal to 75 percent of the difference between the organization's bid amount for the plan and the statutory benchmark amount that applies to that plan. The rebate may come in any of the three forms listed in the regulation, including providing additional benefits at no additional cost to the beneficiary. The Social Security Act, § 1853(a)(1)(B), and the regulations at 42 CFR § 422.304(a)(1) state that CMS will include in its payment to MA plans an additional amount equal to the rebate. In 2006, 95 percent of MA plans were subject to these rebate requirements. We will assess MA plans' utilization of rebates and the benefits offered to MA enrollees.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Medicare Advantage Risk Adjustment Validation**

We will review CMS's process for validating MA risk adjustment scores that are used to calculate the MA plans' capitated payment rates. Pursuant to the regulation at 42 CFR § 422.310(b), MAOs must report risk adjustment data to CMS. Risk adjustment scores are also used to align Medicare payment rates with beneficiaries' predicted costs. To ensure the integrity and accuracy of risk adjustment data and risk adjustment scores, CMS conducts risk score validations of plan submissions for each contract year. We will determine the extent to which CMS validates MA plans' submissions and uses findings of data discrepancies to change payments.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Beneficiary Appeals in the Medicare Advantage Program**

We will review the response of MA plans and CMS's independent contractor to beneficiaries' appeals of denials, reductions, or terminations of services. The first level of appeal is called a "request for reconsideration." Under 42 CFR § 422.578, beneficiaries may request that the MA plan reconsider an adverse determination. If the plan's reconsideration is unfavorable to the beneficiary, 42 CFR § 422.592 requires that the determination be reviewed by an independent

contractor. Federal regulations require CMS to monitor and assess MA plans' operations and independent contractors' performances. We will determine whether MA plans and the independent contractors have fulfilled their appeal review requirements and assess CMS's oversight of the appeals system for MA plans.

*(OEI; 01-08-00280; expected issue date: FY 2009; work in progress)*

### **Comparing Special Needs Plan Beneficiaries to Other Medicare Advantage Prescription Drug Plan Beneficiaries**

We will review drug utilization and costs of special needs plan (SNP) beneficiaries compared with other MA PDP beneficiaries. Section 231 of the MMA established SNPs, which are intended to provide care for vulnerable populations, such as institutionalized Medicare beneficiaries, dual-eligible Medicare beneficiaries, and those beneficiaries with severe or disabling chronic conditions. We will also compare potential medication errors associated with SNP beneficiaries with those of other MA PDP beneficiaries.

*(OEI; 05-07-00490; expected issue date: FY 2009; work in progress)*

## **Medicare Part D Prescription Drug Program**

The MMA established a Medicare outpatient prescription drug benefit, known as Medicare Part D, which took effect on January 1, 2006. This voluntary benefit is available to all Medicare beneficiaries. In 2007, we included oversight of Medicare Part D in our list of HHS's Top Management Challenges. The 2008 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds stated that, during CY 2007, Part D expenditures totaled \$49.5 billion and are expected to grow at an average annual rate of 11.1 percent over a 10-year period, reaching \$142.1 billion in 2017. CMS has estimated that, as of January 2008, 25 million beneficiaries were enrolled in Part D, and an additional 7 million beneficiaries were enrolled in employer- or union-sponsored retiree drug coverage plans that receive retiree drug subsidies from Part D.

The administration of Part D is dependent upon extensive coordination and information sharing among Federal and State government agencies, drug plan sponsors, contractors, health care providers, and third-party payers. CMS and drug plan sponsors share responsibility for protecting the Part D program from fraud, waste, and abuse. Payments to drug plan sponsors based on bids, risk adjustments, and reconciliations add to the complexities and challenges of the benefit.

Descriptions of our ongoing and planned reviews of Medicare Part D program administration follow.

### **Part D Dual-Eligible Demonstration Project**

We will review CMS's system to reimburse States participating in the Part D Dual-Eligible Demonstration Project. As part of the transition of beneficiaries into the Part D program, CMS has initiated a demonstration project pursuant to the Social Security Act, § 402(a)(1)(A), to reimburse States for their efforts in assisting their dual-eligible and low income subsidy-entitled populations in obtaining Medicare Part D coverage and paying for prescriptions for beneficiaries

lacking coverage. Medicare reimbursed States for beneficiaries' Part D drugs to the extent that those costs were not recoverable from Part D Plans, as well as for certain State administrative costs. We will review States' submissions of data under the Part D Dual-Eligible Demonstration Project to determine whether the payments were accurate and properly supported. We will also determine whether payments were duplicated within Part D and/or duplicated in both Part D and the Medicaid programs.

*(OAS; W-00-07-35214; W-00-08-35214; various reviews; expected issue date: FY 2009; work in progress)*

### **Duplicate Drug Claims for Hospice Beneficiaries**

We will review the appropriateness of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D. Per the "Medicare Claims Processing Manual," Pub. No. 100-04, ch. 11, § 30.2, CMS publishes the hospice payment rates, which include prescription drugs (used for pain relief and symptom control) related to the beneficiary's terminal illness. Hospice providers are paid per diem amounts, which include drugs related to a hospice beneficiary's terminal illness. Medicare Part D, which was implemented in January 2006, covers prescription drugs for Medicare beneficiaries enrolled in this voluntary benefit. Because the hospice program continues to cover prescription drugs related to a hospice beneficiary's terminal illness, Medicare Part D drug plans may unknowingly duplicate payments for such drugs. We will determine whether payments made under Part D are correct, supported, and not duplicated in hospice per diem amounts. We will identify the extent of duplication and the controls to prevent duplicate drug payments.

*(OAS; W-00-09-35307; various reviews; expected issue date: FY 2010; new start)*

### **Medicare Part D Duplicate Payments**

We will review the effectiveness of CMS's controls to prevent duplicate Part D monthly capitated payments to Part D sponsors for the same beneficiaries, particularly when beneficiaries change plans or try to enroll in more than one plan. When CMS has made duplicate payments, it may recoup such payments in accordance with 42 CFR §§ 423.343 and 422.308(f), which permit CMS to adjust payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment. As of January 2008, there were more than 25 million beneficiaries enrolled in Part D plans. We will determine the extent to which CMS has made duplicate monthly capitated payments for individual beneficiaries to multiple plans.

*(OAS; W-00-09-35408; various reviews; expected issue date: FY 2009; new start)*

### **Duplicate Medicare Part A and Part B Claims Included With Part D Claims**

We will review claims submitted for payment under Medicare Part D to determine whether they were duplicated in Medicare Part A or Part B. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), a drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. Medicare Part A covers drugs for people with Medicare who are receiving treatments as inpatients of hospitals. Drugs covered under Medicare Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with DME, and some vaccines. Medicare Part A and Part B do not cover most outpatient prescription

drugs that may be covered under Part D. We will also determine the extent to which payments for the sampled Part D claims were correct and supported.

*(OAS; W-00-09-35409; various reviews; expected issue date: FY 2009; new start)*

### **Coordination and Oversight of Medicare Parts B and D To Avoid Duplicate Payments**

We will review CMS's oversight of Medicare Parts B and D to determine whether there is sufficient coordination to prevent duplicate payments for prescription drugs. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), drugs for which payment is available under Medicare Part B should not be covered under Medicare Part D. We will review CMS's oversight of the coordination processes and determine whether the processes are effective in preventing duplicate payments for the same prescription.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Payments for Drugs Under Medicare Part D During Part A Skilled Nursing Stays**

We will review the extent to which Medicare Part D has paid for drugs that were already paid for by Medicare Part A for beneficiaries in SNF stays. The Social Security Act, § 1860D-2(e)(2)(B), provides that all drugs that are prescribed, dispensed, or administered to individuals receiving coverage for those drugs under Medicare Part A should be excluded from coverage under Medicare Part D. We will also identify any patterns associated with this type of payment error.

*(OEI; 02-07-00230; expected issue date: FY 2009; work in progress)*

### **Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse**

We will review the extent to which PDP sponsors identify potential Medicare Part D fraud and abuse. Pursuant to 42 CFR § 423.504(b)(4)(vi), PDP sponsors are required to institute comprehensive compliance plans to detect, correct, and prevent Part D fraud and abuse.

A previous OIG report found that some PDP sponsors' compliance plans did not address all required elements regarding fraud. We will determine the extent to which plan sponsors conduct inquiries, initiate corrective actions and make referrals regarding potential fraud and abuse.

*(OEI; 03-07-00380; expected issue date: FY 2009; work in progress)*

### **Medicare Drug Integrity Contractors' Adherence to Contractual Arrangements**

We will review whether the Medicare Drug Integrity Contractors (MEDIC) have adhered to their contractual arrangements with CMS. CMS contracts with private organizations, known as MEDICs, to assist in conducting program integrity activities relating to the Part D benefit.

Pursuant to Federal regulations at 42 CFR § 421.304, the contracts between MEDICs and CMS may include conducting medical reviews, utilization reviews, and reviews of potential fraud; auditing cost report payments; and educating providers, suppliers, and beneficiaries. We will also review CMS's handling of issues discovered by MEDICs.

*(OAS; W-00-09-35231; various reviews; expected issue date: FY 2010; new start)*

### **Medicare Prescription Drug Integrity Contractors' Detection of Fraud and Abuse**

We will review the extent to which MEDICs have conducted investigations, made referrals to law enforcement, and conducted data analysis. CMS awarded contracts to three regional MEDICs to perform antifraud and antiabuse functions for the Part D program. We will assess

the volume of MEDICs reporting of fraud and abuse investigations and their referrals to law enforcement.

*(OEI; 03-08-00420; expected issue date: FY 2009; work in progress)*

### **Accuracy of Drug Prices on the Medicare Prescription Drug Plan Finder**

We will review the accuracy of prices listed on the Medicare Prescription Drug Plan Finder (Plan Finder). The Plan Finder is a CMS-initiated interactive Web-based tool that enables beneficiaries to search for a Medicare PDP. We will determine whether prices listed on the Plan Finder are current and accurately reflect pharmacy prices.

*(OEI; 03-07-00600; expected issue date: FY 2009; work in progress)*

### **Medicare Part D Reconciliation Calculations**

We will review whether CMS's reconciliation calculations of Part D sponsors were performed in accordance with applicable regulations. Pursuant to the Social Security Act, § 1860D-15(e), Medicare shares a portion of sponsors' losses or profits from the Part D program. Regulations at 42 CFR § 423.343 provide for retroactive adjustments and reconciliations to account for changes in health status risk or a difference in the amount payable to a sponsor for eligible individuals and the amount actually paid. These adjustments are calculated based on information provided by the sponsors. We will determine whether payments made to sponsors or recoveries made by CMS are correct and properly paid or received for the end-of-year reconciliations.

*(OAS; W-00-09-35232; various reviews; expected issue date: FY 2009; new start)*

### **Medicare Part D Data Submitted by Sponsors for Reconciliations**

We will review the accuracy of Part D sponsors' data submissions for reconciliation purposes to CMS, pursuant to Federal regulations at 42 CFR §§ 423.343(c)(1) and (d)(1). Specifically, we will determine the accuracy of Prescription Drug Event (PDE) data and Direct and Indirect Remunerations (DIR) data (which are required information for reconciliation purposes) reported in accordance with these provisions. The PDE summary is a record that documents the final adjudication of a dispensing event. Regulations at 42 CFR § 423.308 state that DIR data include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions. Medicare shares a portion of sponsors' losses or profits from the Part D program, and the reconciliation identifies the amount of any such losses or profits.

*(OAS; W-00-08-35200; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2007**

We will review the reconciliation amounts that Part D sponsors owed or received from Medicare in 2007. Pursuant to 42 CFR § 423.343, after the close of the plan year, CMS reconciles its payments to Medicare Part D plan sponsors with actual costs. In addition, Medicare shares a portion of sponsors' profits and losses from the Part D program. A recent OIG report estimated that Part D sponsors owed Medicare a net total of \$4.4 billion for 2006, generally because sponsors overestimated the cost of providing the Part D benefit in their bids. The report further found that sponsors might also owe significant amounts to CMS for the 2007 plan year. We will compare 2007 Medicare Part D reconciliation amounts with 2006 totals to determine the extent to which amounts changed.

*(OEI; 02-08-00460; expected issue date: FY 2009; work in progress)*

### **Retiree Drug Subsidy Program: Eligibility of Plans and Individuals**

We will review eligibility issues related to a sample of payments made to plan sponsors under the Retiree Drug Subsidy program. Pursuant to the Social Security Act, § 1860D-22, subsidy payments are made to sponsors (employers and unions) of qualified retiree PDPs for each qualifying retiree covered under the plan. The subsidy payment for each qualifying retiree generally equals 28 percent of allowable retiree drug costs. We will determine whether each sponsor's employment-based retiree health coverage met requirements in section 1860D-22(a)(2) to be considered a qualified PDP and whether the drug costs reported were incurred on behalf of individuals who were qualifying covered retirees as defined in section 1860D-22(a)(4).

*(OAS; W-00-08-35309; various reviews; expected issue date: FY 2009; work in progress)*

### **Allowable Costs Under the Retiree Drug Subsidy Program**

We will review costs submitted by employers to CMS under the Retiree Drug Subsidy program. Pursuant to the Social Security Act, § 1860D-22(a)(3)(C), plan-related prescription drug costs are defined as nonadministrative costs, which include those costs directly related to the dispensing of the covered Part D drugs. Section 1860D-22(a)(3)(C) also specifies that allowable retiree drug costs include only costs actually paid, net of any discounts, rebates, or other price concessions. Under the Social Security Act, § 1860D-2(e), Part D coverage excludes certain drugs (i.e., weight-loss drugs, cosmetic drugs, nonprescription drugs, and drugs covered under Medicare Part A and Part B). We will determine whether employers reported gross plan-related costs and allowable retiree costs in a manner consistent with these provisions.

*(OAS; W-00-08-35310; various reviews; expected issue date: FY 2009; work in progress)*

### **Medication Therapy Management Program**

We will review whether Part D sponsors have enrolled qualified beneficiaries into a medication therapy management program (MTMP) and submitted administrative costs that were supportable, reasonable, and allowable. An MTMP is designed to ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use and to help reduce the risk of adverse events. Pursuant to Federal regulations at 42 CFR § 423.153(d)(2), sponsors must establish an MTMP targeted at Part D beneficiaries who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs of at least \$4,000 for all covered Part D drugs. We will determine whether MTMPs have operated in accordance with Federal regulations.

*(OAS; W-00-08-35410; various reviews; expected issue date: FY 2009; work in progress)*

### **Less-Than-Effective and Terminated Drugs in Part D**

We will review PDE data to determine whether less-than-effective or terminated drugs were included in the Part D drug claims. The Social Security Act, § 1860D-2(e)(1), defines a Part D drug to include those drugs that may be dispensed only by prescription and that meet the requirements of the Social Security Act, § 1927(k)(2), which requires drug approval by FDA. FDA may disapprove an application for approval of a new drug as being less than effective if, pursuant to 21 CFR § 314.125(b), the application lacks substantial evidence of effectiveness of the drug for all conditions of use prescribed, recommended, or suggested in its labeling. Terminated drugs are drugs that have been pulled from the market or whose expiration dates on the last batches sold have passed; manufacturers identify a drug's termination date based upon the shelf-life expiration date of the last batch sold for a drug. We will determine whether PDEs

for less-than-effective or terminated drugs are included as part of the Part D sponsors' reconciliations.

*(OAS; W-00-08-35233; various reviews; expected issue date: FY 2009; work in progress)*

### **Aberrant Part D Claims**

We will review Medicare Part D claims to identify aberrant claims, which are those that deviate from the usual patterns of claims, and determine how these claims relate to pharmacies, physicians, and/or beneficiaries. For example, we will determine whether Part D sponsors are appropriately processing Medicare Part D claims for Schedule II (street value) drugs. Pursuant to the Social Security Act, § 1860(D)-15(f)(1), sponsors must submit the information necessary for the Secretary to determine payments to the plan and HHS has the right to inspect and audit the sponsors' records pertaining to this information.

*(OAS; W-00-08-35411; various reviews; expected issue date: FY 2009; work in progress)*

### **Part D Catastrophic Coverage**

We will review whether the drugs charged to Medicare enrollees' accounts were appropriate for those enrollees who reached the Part D catastrophic coverage limit. The Social Security Act, § 1860D, established the Medicare Prescription Drug Benefit, known as Medicare Part D. The Social Security Act, § 1860D-2 (b)(4)(B), "Annual Out-of-Pocket Threshold," provides that, for 2006, once an enrollee has reached \$3,600 in annual true out-of-pocket (TrOOP) costs (or \$5,100 in total drug spending), the enrollee has met the annual out-of-pocket threshold and enters the catastrophic coverage phase. The Social Security Act, § 1860D-2 (b)(4)(A)(i), provides that, under catastrophic coverage, the enrollee pays the greater of \$2 (for generic or preferred multisource drugs) and \$5 (for other drugs) in copayments or 5-percent coinsurance. Pursuant to the Social Security Act, § 1860D-15(b)(1), Medicare pays 80 percent of the drug costs. The PDP pays the remaining 15 percent. We will determine whether payments made by enrollees during the catastrophic coverage phase are correct and supported.

*(OAS; W-00-09-35412; various reviews; expected issue date: FY 2010; new start)*

### **True Out-of-Pocket Costs for Part D**

We will review the accuracy of Part D sponsors' tracking of beneficiaries' TrOOP costs. The Social Security Act, § 1860D-2 (b)(4), "Annual Out-of-Pocket Threshold," states that, for 2007, once an enrollee has reached \$3,850 in annual TrOOP costs (or \$5,451 in total drug spending), the enrollee has met the annual out-of-pocket threshold and the enrollee's cost sharing is capped (referred to as the catastrophic coverage phase). We will determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify toward such catastrophic coverage.

*(OAS; W-00-09-35234; various reviews; expected issue date: FY 2010; new start)*

### **Bid Submission by Part D Sponsors**

We will review the approved bids submitted to CMS by Part D sponsors to determine whether negotiated price estimates were properly supported. As provided in the Social Security Act, § 1860D-11(b), to become a Part D sponsor, each applicant is required to submit a bid for prescription drug coverage for each plan it intends to offer. The bid represents the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage. The Secretary determines the monthly payment amounts based on these approved bids as described in the Social Security Act,

§ 1860D-15(a)(1)(A) and 42 CFR § 423.329. CMS's Bid Instructions require sponsors to report all rebates as part of bid proposals. Specifically, all rebates and price concessions not used to directly reduce the cost at the point of sale must be included in a bid. Further, rebates and price concessions must be reported in full. This review will determine whether sponsors followed CMS's instructions for reporting price concession estimates in their bids.  
(OAS; W-00-08-35413; various reviews; expected issue date: FY 2009; work in progress)

### **Part D Sponsors' Audits of Pharmacies**

We will review the process that Part D sponsors and their pharmacy benefit managers (PBM) use in auditing pharmacies. These audits are needed to validate payments by the sponsors to pharmacies and the contracts between pharmacies and sponsors generally allow for these audits. We will identify amounts recouped from the pharmacies and ensure that the amounts have been properly reported as overpayments to CMS. The Medicare Part D Reporting Requirements for Contract Year 2007, section X, "Overpayments," states: "Part D Contracts will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Contract erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit." We will determine whether recoveries made by Part D sponsors or their PBMs are properly accounted for.  
(OAS; W-00-09-35235; various reviews; expected issue date: FY 2009; new start)

### **Disenrollment of Deceased Beneficiaries**

We will review whether Part D sponsors carry deceased beneficiaries as current enrollees. Pursuant to Federal regulations at 42 CFR § 423.44(b)(2)(iii), "Required Involuntary Disenrollment," Part D sponsors must disenroll individuals upon their deaths. We will determine whether CMS made payments to Part D sponsors for deceased beneficiaries. We performed similar reviews in Medicaid and found several instances in which States reimbursed claims for deceased beneficiaries.  
(OAS; W-00-08-35415; A-05-08-00047; expected issue date: FY 2009; work in progress)

### **Part D Negotiated Drug Prices and Price Concessions**

We will review Part D sponsors' implementation of and compliance with provisions associated with passing on negotiated drug prices to the Medicare program and/or its beneficiaries. We will also review CMS's oversight of sponsors' disclosure and pass-through of negotiated price concessions. The Social Security Act, § 1860D-2(d)(1)(A), requires a Part D sponsor to provide its enrollees with access to negotiated prices for covered Part D drugs included in its formulary. Regulations at 42 CFR § 423.100 define negotiated prices as prices for covered Part D drugs that are available to beneficiaries at the point of sale at network pharmacies; are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and include pharmacy dispensing fees. Pursuant to 42 CFR § 423.104(g)(3), Part D sponsors are also required to disclose to CMS data on aggregate negotiated price concessions. This OIG initiative will incorporate multiple specific reviews related to Part D negotiated prices and price concessions.  
(OAS; W-00-08-35414; OEI-05-07-00560; OEI-02-08-00050; various reviews; expected issue date: FY 2009; work in progress)

## **Comparing Pharmacy Reimbursement Amounts: Medicare Part D to Medicaid**

We will review Medicare Part D drug reimbursement amounts in comparison with amounts reimbursed by Medicaid for the same drugs. The Social Security Act, § 1860D, governs coverage and payments of prescription drugs under Medicare Part D while the Social Security Act, § 1927, and 42 CFR §§ 447.331 to 447.334 govern payments for prescription drugs under Medicaid. Many beneficiaries covered under the Part D program previously received drug coverage under Medicaid. We will compare the reimbursement amounts for a sample of drugs to determine the extent of any variations.

*(OEI; 03-07-00350; expected issue date: FY 2009; work in progress)*

## **Medicare Part D Coverage Gap**

We will review prescription drug purchases and payments for beneficiaries who entered the Medicare Part D coverage gap in 2006. Under standard Part D prescription drug coverage, while in the coverage gap, beneficiaries pay a 100-percent coinsurance rate for their prescription drug benefits until they reach the out-of-pocket threshold, as set forth at 42 CFR § 423.104(d). As a result, beneficiaries may alter their drug utilization because of the increased financial burden. We will determine the number of Part D beneficiaries who entered the coverage gap in 2006. We will also examine changes in these beneficiaries' drug use and costs.

*(OEI; 05-07-00610; expected issue date: FY 2009; work in progress)*

## **E-Prescribing in Part D**

We will review the extent to which Medicare Part D sponsors have adopted the standards established by CMS for e-prescribing. E-prescribing allows providers and pharmacists to electronically transmit prescriptions and other prescription related information for Part D eligible individuals. The Social Security Act, § 1860D-(4)(e), as amended by the MMA, requires Part D plans to support an electronic prescription program for any providers and pharmacies that voluntarily choose to use e-prescribing. CMS promulgated technical standards for e-prescribing at 42 CFR § 423.160. The Secretary identified e-prescribing as a priority health information technology initiative for HHS. We will examine experiences Part D sponsors have had establishing e-prescribing programs and implementing standards for e-prescribing.

*(OEI; 05-08-00320; expected issue date: FY 2009; work in progress)*

## **Oversight of Pharmacy Benefit Managers**

We will review the effectiveness of CMS's and Medicare Part D plan sponsors' oversight of PBMs. PBMs are subcontractors that administer important Part D functions on behalf of the Part D plan sponsors. Part D sponsors' contracts with PBMs are required by 42 CFR § 423.505(i) to contain certain administrative and legal provisions that include reporting responsibilities, performance monitoring, and compliance. As part of our review of the effectiveness of CMS's and sponsors' oversight of PBMs, we will specifically determine whether Part D plan sponsors' contracts with PBMs include provisions required by Federal regulations.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Impact of Rebates on Long Term Care Pharmacies**

We will review the impact of drug manufacturer rebates on the dispensing patterns of long-term care pharmacies, which are pharmacies that dispense drugs to residents in nursing homes. Pursuant to the Social Security Act, § 1860D-2(d)(1)(B), rebates and discounts are permitted

under Medicare Part D. CMS raised concerns that rebates may create incentives for pharmacists to recommend certain drugs based on financial considerations rather than clinical considerations. CMS expressed concerns that rebates may have an impact on drug utilization as well. For selected drugs, we will determine the extent to which rebates were associated with long-term care pharmacists dispensing of those drugs.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Medicare Prescription Drug Plans Formulary Changes**

We will review whether Medicare Part D sponsors reporting of midyear formulary changes to CMS complies with applicable requirements. Pursuant to 42 CFR § 423.120(b)(5), Part D sponsors must notify CMS and receive approval prior to removing covered Part D drugs from their plans' formularies or changing the preferred or tiered cost-sharing status of covered Part D drugs during a contract year. Changes in formularies during the contract year can adversely affect beneficiaries. Beneficiaries may lose coverage of a needed drug or may pay larger copayments if a Part D sponsor moves a drug to a higher tier. We will determine the extent to which Part D sponsors met the 60-day requirement to submit proposed midyear formulary changes to CMS.

*(OEI; 01-08-00540; expected issue date: FY 2009; work in progress)*

## **Medicaid Program**

The Federal and State governments jointly fund Medicaid, a program that provides medical assistance to certain low-income individuals. Overall, HHS estimated that the Federal Government will pay for approximately 57 percent of medical assistance payments in FY 2009. The Federal share of a State's expenditures is called the Federal medical assistance percentage (FMAP). The FMAP has a floor rate of 50 percent, and, for FY 2009, the highest FMAP is 75.84 percent. States have considerable flexibility in structuring their Medicaid programs within broad Federal guidelines governing eligibility, provider payment levels, and benefits. As a result, Medicaid programs vary widely from State to State.

Our ongoing and new reviews of Medicaid in FY 2009 address payments related to hospitals, long-term and community care, prescription drugs, other services, Medicaid administration, and information systems controls. We are also continuing to review issues related to Medicaid payments and costs related to the Gulf Coast hurricanes.

## **Medicaid Hospitals**

### **Hospital Outlier Payments**

We will review State Medicaid payments for hospital outliers, which are cases that incur extraordinarily high costs. Some States make supplemental Medicaid payments for hospital outliers based on methodologies similar to Medicare methodologies. Prior OIG work involving Medicare claims for hospital outliers identified vulnerabilities in the Medicare payment methodology. The Social Security Act, § 1886(d)(5)(A), provides for supplemental Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for

outlier cases. We will determine whether similar vulnerabilities exist in Medicaid State agencies' methods of computing inpatient hospital cost outlier payments. This is a followup to work previously performed involving Medicaid outlier payments.

*(OAS; W-00-08-31069; various reviews; expected issue date: FY 2009; work in progress)*

### **States' Disproportionate Share Hospital Payments for Care for Individuals in Institutions for Mental Diseases**

We will review several State Medicaid programs to determine the magnitude of the Federal DSH funding being used to pay for the cost of uncompensated care provided to individuals aged 21 to 64 residing in institutions for mental diseases (IMD). Pursuant to the Social Security Act, § 1923(g), DSH payments to an individual hospital may not exceed that hospital's uncompensated care costs. Some States have provisions in their State Medicaid plans that allow DSH payments to hospitals for the cost of uncompensated care provided to persons not covered by the Medicaid program, including individuals between the ages of 21 and 64 residing in IMDs.

*(OAS; W-00-08-31300; various reviews; expected issue date: FY 2009; work in progress)*

### **Provider Eligibility for Medicaid Reimbursement**

We will review whether States appropriately determined provider eligibility for Medicaid reimbursement. Federal regulations at 42 CFR § 440.10 require hospital providers to meet Medicare program participation requirements to receive Medicaid funding. In addition, various State regulations may extend this Federal requirement to cover other provider types, such as DME or home health. We have previously identified significant unallowable Medicaid payments made to hospitals that did not meet Medicare program eligibility requirements as part of the DSH program.

*(OAS; W-00-07-31301; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Disproportionate Share Hospital Payment Distribution**

We will review the Medicaid inpatient utilization rate used to determine eligibility for Medicaid DSH payments. The Social Security Act, § 1923(d)(3), requires hospitals to have a Medicaid inpatient utilization rate of not less than 1 percent before being deemed eligible to receive Medicaid DSH payments. We will examine the appropriateness of this threshold and, if appropriate, recommend changes to the program.

*(OAS; W-00-08-31302; various reviews; expected issue date: FY 2009; work in progress)*

### **Supplemental Payments to Private Hospitals**

We will review Medicaid supplemental payments made by States to private hospitals. States are permitted to make payments under their approved plans to hospitals up to the applicable aggregate UPL, and many States use this flexibility to make lump-sum supplemental payments based on the difference between the ordinary rate and the UPL. Federal Regulations at 42 CFR § 447.272 define the UPL for inpatient hospital services as a reasonable estimate of the maximum amount that would be paid for Medicaid services under Medicare payment principles. Federal funds are not available for Medicaid payments that exceed these limits. In addition, 42 CFR § 447.253(i) requires the Medicaid agency to pay "for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan." Prior OIG work involving supplemental payments to public facilities

identified errors. We will determine if errors exist involving supplemental payments to private facilities.

*(OAS; W-00-09-31126; various reviews; expected issue date: FY 2010; new start)*

### **Potentially Excessive Medicaid Payments for Inpatient and Outpatient Services**

We will review State controls to detect potentially excessive Medicaid payments to institutional providers for inpatient and outpatient services. OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Att. A, § C.1.a, states that to be allowable, costs must be necessary and reasonable for the proper and efficient performance and administration of Federal awards. Further, section C.1.c of the circular states that costs must be authorized, or not prohibited, under State or local laws or regulations. The Social Security Act, § 1903(d)(2)(A), and the regulations at 42 CFR pt. 433, subpart E, provide for the adjustment of quarterly payments to States by CMS to account for overpayments and underpayments made by States to providers. Prior OIG work involving Medicare inpatient and outpatient claims found that many claims resulting in excessive payments to the hospitals were attributable to billing errors on the submitted claims, such as inaccuracies in the diagnosis codes, admission codes, discharge codes, procedure codes, charges, HCPCS codes, and number of units billed. We will determine whether similar vulnerabilities exist in State agencies' controls for detecting potentially excessive Medicaid payments.

*(OAS; W-00-09-31127; various reviews; expected issue date: FY 2009; new start)*

## **Medicaid Home, Community, and Nursing Home Care**

### **Community Residence Rehabilitation Services**

We will review Medicaid payments made for beneficiaries who reside in community residences for persons with mental illness to determine whether States improperly claimed Federal financial participation (FFP). OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, establishes cost principles for State and local governments. Attachment A, § C.1.c. of the circular states that, to be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. Previous OIG work in one State found improperly claimed Medicaid reimbursement for individuals who were no longer residing in a community residence.

*(OAS; W-00-08-31087; various reviews; expected issue date: FY 2009; work in progress)*

### **Targeted Case Management**

We will review Medicaid payments made for targeted case management services. The Social Security Act, § 1915(g)(2), defines case management as services that assist individuals eligible under the State plan in gaining access to needed medical, social, educational, and other services. Case management does not include the direct delivery of an underlying medical, educational, social, or other service for which an eligible individual has been referred. Payments for case management services may not duplicate payments made to public agencies under other program authorities for the same service. Prior OIG work in one State identified unallowable claims. We will determine whether Medicaid payments claimed by States for targeted case management services were made in accordance with Federal requirements.

*(OAS; W-00-05-31082; W-00-06-31082; W-00-08-31082; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Payments to Continuing Day Treatment Providers**

We will review Medicaid payments made to continuing day treatment (CDT) providers in one State. CDT providers render an array of services to persons with mental illness on a relatively long-term basis. A CDT provider bills Medicaid based on the number of service hours rendered to a beneficiary. OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Att. A, § C.1.c., states that, to be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. One State's regulations require that a billing for a visit/service hour be supported by documentation indicating the nature and extent of services provided. A State commission found that more than 50 percent of the service hours billed by CDT providers could not be substantiated. We will follow up on the commission's findings and determine whether Medicaid payments made to CDT providers in that State are adequately supported.

*(OAS; W-00-09-31128; various reviews; expected issue date: FY 2010; new start)*

### **Medicaid Payments to Nursing Homes While Dual-Eligible Beneficiaries Received Covered Medicare Part A Services**

We will review Medicaid payments made to nursing homes for dual-eligible beneficiaries while the beneficiaries were receiving Medicare Part A services (e.g., hospital or SNF stays). The Social Security Act, § 1905(a)(4)(A), authorizes States to make payments for nursing facility services for individuals 21 years of age or older. If a State Medicaid program makes full per diem payments to a nursing home for days a beneficiary is not in the nursing home, but in an inpatient hospital, it is paying for services not rendered. A previous OIG review found that some States made full per diem payments for dates that overlapped hospital stays. For selected States, we will examine nursing home per diem payments with dates of service that overlap a covered Medicare Part A service.

*(OAS; W-00-09-31129; various reviews; expected issue date: FY 2009; new start)*

### **Transparency Within Nursing Facility Ownership**

We will review ownership structures at investor-owned nursing homes. Nursing facilities are increasingly being purchased by private equity or other for-profit investor firms. Prior OIG work showed that, after the facility purchase, in some cases, new owners created a complex web of ownership that essentially left the operators of the nursing facility with no assets. Determination of which entity is legally liable for patient care can be made difficult because of the ownership structure. In addition, after the facility purchase, in some cases new owners have reduced staffing levels and taken other cost-cutting measures that increase profit at the expense of quality of care. We will determine which entities are benefiting from the Medicaid reimbursement and study the effects of these types of ownership changes on the care received by beneficiaries in nursing homes.

*(OAS; W-00-09-31130; various reviews; expected issue date: FY 2010; new start)*

### **Medicaid Home Health Agency Claims**

We will review HHA claims to determine whether providers have met applicable criteria to provide services and whether beneficiaries have met eligibility criteria. Federal regulations at 42 CFR § 440.70 and 42 CFR pt. 484 set forth standards and conditions for HHAs' participation. Providers must meet criteria such as minimum number of professional staff, proper licensing and certification, review of service plans of care, and proper authorization and documentation of provided services. A doctor must determine that the beneficiary needs medical care at home and

prepare a plan for that care. The care must include intermittent (not full-time) skilled nursing care and may include physical therapy or speech language pathology services.  
(OAS; W-00-08-31304; various reviews; expected issue date: FY 2009; work in progress)

### **Medicaid Payments for Personal Care Services**

We will review Medicaid payments for personal care services to determine whether States have appropriately claimed FFP. Pursuant to the Social Security Act, § 1905(a)(24), Medicaid covers personal care services only for individuals who are not inpatients or residents of hospitals, nursing facilities, IMDs, or intermediate care facilities for persons with mental retardation. Personal care services must be authorized for the individual by a physician in accordance with a plan of treatment, provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and furnished in a home or other location. Section 6087 of the DRA further allowed States, beginning January 1, 2007, to provide payments to individuals for self-directed personal assistance services for the elderly and disabled. These include personal care services that could be provided by a member of a person's family.  
(OAS; W-00-07-31035; W-00-08-31035; various reviews; expected issue date: FY 2009; work in progress)

### **Medicaid Payments for Medicare-Covered Home Health Services**

We will review the appropriateness of Medicaid payments for Medicare-paid home health services. Pursuant to the Social Security Act, § 1902(a)(10)(D), States are required to offer home health services to Medicaid beneficiaries who meet the States' criteria for nursing home coverage. Under § 1902(a)(25), Medicaid is the payer of last resort, paying only after Medicare has met its legal obligation to pay. We will determine in selected States the extent to which both Medicare and Medicaid have paid for the same home health services. We will also identify the controls that selected States have established to prevent duplicative payments.  
(OAS; W-00-08-31305; various reviews; expected issue date: FY 2009; work in progress)

### **Compliance With States' Requirements for Medicaid-Funded Personal Care Service Attendants**

We will review the extent to which personal care service attendants' qualifications meet the requirements established by their respective States. CMS's "State Medicaid Manual," Pub. No. 45, pt. 4, §§ 4442.4 and 4480, requires States to develop qualifications for providers of personal care services and establish mechanisms for monitoring the quality of the services. Pursuant to the Social Security Act, §§ 1902 and 1915, States can receive FFP for personal care services only if the providers have met State-established qualifications. A 2005 OIG review found that requirements for attendants often differed among and between various State plan and waiver programs. Based on a sample of personal care claims in selected States, we will determine whether attendants' qualifications have met their States' requirements.  
(OEI-07-08-00430; expected issue date: FY 2009; work in progress)

### **State and Federal Oversight of Home- and Community-Based Services Provided in Assisted Living Facilities**

We will review State and Federal oversight of Medicaid Home- and Community-Based Services (HCBS) provided in assisted living facilities (ALF). These facilities may receive Medicaid funding through the HCBS waiver program under the Social Security Act, § 1915(c). Under 42 CFR § 441.302, States are required to set their own assurances that necessary safeguards have

been taken to protect the health and welfare of HCBS beneficiaries. We will determine the extent to which States are complying with Federal requirements for HCBS services provided in ALFs.

*(OEI; 09-08-00360; expected issue date: FY 2009; work in progress)*

### **State and Federal Oversight of Home- and Community-Based Services**

We will review States' and CMS's oversight of HCBS waiver programs. Medicaid HCBS waiver programs allow States to provide alternative services for individuals who would otherwise require care in nursing homes. Pursuant to 42 CFR § 441.302, States must provide assurances that necessary safeguards have been taken to protect the health and welfare of the recipients. However, a 2003 GAO review found that CMS and the States did not provide adequate oversight of HCBS waivers. We will determine the extent to which States are complying with Federal regulations for HCBS waiver programs. We will also review CMS's processes for monitoring States' compliance with these requirements.

*(OEI; 02-08-00170; expected issue date: FY 2009; work in progress)*

### **Medicaid Adult Day Health Service Payments for Ineligible and Absent Beneficiaries**

We will review the appropriateness of Medicaid payments for adult day health services. The Social Security Act, § 1915(c)(4)(B), allows Medicaid payments for adult health services through home- and community-based waiver programs. Previous reviews of Medicaid adult day health services have identified inappropriate payments for these services. Facilities were found to have billed Medicaid for deceased patients, patients who did not require center services, and patients who attended facilities for only a fraction of the time authorized by the State. We will identify whether payments were improperly made on behalf of individuals who were not eligible for adult day health services or who were not in attendance at the adult daycare facilities.

*(OEI; 09-07-00500; expected issue date: FY 2009; work in progress)*

### **Community Transition Services Provided to Medicaid Home- and Community-Based Services Waiver Beneficiaries**

We will analyze information about the types and costs of community transition services provided by States to Medicaid HCBS beneficiaries. This information will help to ensure that Medicaid is paying appropriately for these services. The Social Security Act, § 1915(c), expanded the availability of HCBS through the authorization of the Medicaid HCBS waiver program. To help move Medicaid beneficiaries from institutions to HCBS, many States have chosen to provide transitional services to help eliminate barriers to living at home or in the community. In May 2002, through State Medicaid Directors Letter No. 02-008 clarifying allowable services, CMS began allowing States to amend their Medicaid HCBS waivers to offer community transition services. Although data are limited regarding States' community transition programs, there appears to be significant variation in the types and costs of transition services provided. This review will also examine case management processes used by States to facilitate transition to the community and identify potentially inappropriate payments.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **Plans of Care: Addressing Minimum Data Set and Resident Assessment Protocols Through Provided Services**

We will review nursing homes' use of the federally required Minimum Data Set and Resident Assessment Protocols to develop nursing home residents' plans of care and guide the provision of appropriate and necessary care. The Social Security Act, §§ 1819(b)(3) and 1919(b)(3), requires nursing homes participating in the Medicare or Medicaid program to use a standardized Resident Assessment Instrument (RAI) to assess each nursing home resident's strengths and needs. Prior OIG reports revealed that approximately one-quarter of residents' needs for care, as identified through the RAI, were not reflected in their care plans and that nursing home residents did not receive all psychosocial services identified on care plans.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **States' Use of Civil Monetary Penalty Funds**

We will review whether States are correctly applying civil monetary penalty (CMP) funds to programs that protect the health or property of nursing facility residents pursuant to the Social Security Act, § 1919(h)(2)(A)(ii). CMPs are remedies that CMS and States may use to address a nursing facility's failure to meet Medicare and Medicaid health and safety requirements. We will examine the amounts that States have received from CMPs, States' use of CMP funds, and States' and CMS's oversight of the use of CMP funds.

*(OAS; W-00-08-31303; various reviews; expected issue date: FY 2010; work in progress; OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **Payments for "Bed Holds"**

We will review the appropriateness of Medicaid payments for "bed holds." States have implemented bed hold policies to encourage nursing homes to provide continuity of residence and care for Medicaid beneficiaries. Under 42 CFR § 447.40, State Medicaid agencies are authorized to make payments to nursing homes for reserving beds while residents are on temporary leaves of absence. Failure of nursing homes to report bed hold days accurately could result in increased cost to State Medicaid programs and the Federal Government. We will determine whether CMS has effectively provided oversight of States' compliance with their bed hold policies and assess the adequacy of States' oversight of facilities' compliance with temporary-absence-reporting requirements.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

# **Medicaid Prescription Drugs**

## **Timely Submission of Average Manufacturer Price Data**

We will review whether drug manufacturers have reported AMPs to CMS in a timely manner. The Social Security Act, § 1927(b)(3), requires manufacturers to report AMP data quarterly to CMS within 30 days of the close of each quarter. Section 6001(b) of the DRA expands the reporting obligations by requiring manufacturers to report AMP data on a monthly basis. AMPs are necessary to calculate the ceiling price under section 340B of the Public Health Service Act, and, in the future, may be used to establish Medicaid Federal upper limits (FUL) pursuant to section 6001 of the DRA. If AMPs are not reported within the required timelines, the 340B program and CMS will not have complete data on which to base 340B prices and FUL amounts, thereby causing both programs potentially to overpay for prescription drugs. In a

previous OIG report, we found that for almost 14 percent of drugs AMP data were missing, thus preventing the calculation of the 340B ceiling price. We will assess the timeliness of drug manufacturers reporting of AMPs to CMS during CY 2008.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Manufacturer Submissions of Outlier Average Manufacturer Prices**

We will review manufacturers' submissions to CMS of AMPs for FUL multiple-source drugs to identify the number of AMPs that meet the regulatory definition of "outliers." Section 6001(a) of the DRA requires CMS to calculate FULs based on 250 percent of the lowest AMP for a drug. The final rule at 42 CFR § 447.514 excludes AMPs that are outliers when establishing FULs for drugs and defines an outlier as the lowest AMP for a multiple-source drug if it is less than 40 percent of the second-lowest AMP for that drug. Previous OIG work found that 14 percent of the lowest AMPs met the criteria for outliers in the second quarter of 2006. If these outliers had been used in FUL calculations, they could have reduced the FULs to amounts below pharmacy acquisition costs, thus potentially limiting beneficiaries' access to certain drugs. We will determine whether AMPs that are potentially excludable as outliers for purposes of establishing FULs have been reported correctly by manufacturers and the extent to which they may reflect prices readily available in the marketplace for these drugs.

*(OEI; 03-07-00740; expected issue date: FY 2009; work in progress)*

### **Calculation of Average Manufacturer Prices**

We will review selected drug manufacturers to evaluate the methodologies that they use to calculate their AMPs and the best price for the Medicaid drug rebate program and for Medicaid drug reimbursement purposes. We will determine whether the methodologies are consistent with applicable statutes, regulations, their rebate agreements, and CMS's Drug Manufacturer Releases. Section 6001 of the DRA makes several changes to the Medicaid drug rebate statute and to Medicaid drug reimbursement for multiple-source drugs. These changes involve revisions to the calculation of the AMP and the best price that will affect the amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program and affect the FUL for drug reimbursement. CMS uses the AMP and the best price to determine a unit rebate amount (URA). Manufacturers must pay rebates to States based on the URAs.

*(OAS; W-00-09-31202; various reviews; expected issue date: FY 2010; new start)*

### **States' Medicaid Drug Claims**

We will review the accuracy of States' submission of Medicaid drug claims to CMS for reimbursement. Pursuant to the Social Security Act, § 1927(a)(1), a drug manufacturer must have a rebate agreement with CMS to have its outpatient drugs covered under Medicaid. Under the drug rebate program, CMS provides States with a quarterly Medicaid drug tape that should list all covered outpatient drugs and indicate a drug's termination date, if applicable. CMS guidance instructs States to use the tape to verify coverage of the drugs for which they claim reimbursement. We will determine whether the tape CMS provides to States includes all covered drugs and indicates drugs' termination dates, if applicable. We will also determine whether reimbursements made to States are correct and supported for the drugs claimed.

*(OAS; W-00-07-31203, W-00-08-31203; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Payments for Drugs Not Approved for Use by Children**

We will review Medicaid paid claims to determine whether payments were made for drugs that are not approved for children by FDA. The Social Security Act, §1905(a), provides that State Medicaid plans may cover prescription drugs. Pursuant to the Social Security Act, §§ 1927(k)(3) and 1927(k)(6), Medicaid will pay for an outpatient drug if it is prescribed for indications approved by FDA or supported by the drug compendia listed in 1927(g)(1). We will examine drug services paid for children under the age of 18 in 2007 by reviewing States' Medicaid and SCHIP paid claims files.

*(OAS; W-00-09-31131; various reviews; expected issue date: FY 2009; new start)*

### **Family Planning Access and Care and Treatment Adjustments**

We will review a State agency's claims for Family Planning Access and Care and Treatment (PACT) section 1115 waiver reimbursement for Medicaid outpatient drug expenditures. Pursuant to 42 CFR § 430.30(c)(2), the expenditures are required to be based on the State's accounting of actual recorded expenditures. One State reported increased expenditures of \$34 million in FFP in FY 2005 relating to PACT. We will review supporting documentation to determine whether the State's claims for reimbursement complied with Federal requirements.

*(OAS; W-00-09-31132; various reviews; expected issue date: FY 2010; new start)*

### **Alien Emergency Drug Claims**

We will review a State's drug claims for alien emergency services to determine whether they met Federal requirements for reimbursement. The Social Security Act, § 1903(v), prohibits payment to States for services provided to an alien not lawfully admitted, except for emergency medical treatment to such an alien who otherwise meets the Medicaid eligibility requirements. OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, Att. A, § C.1.c., requires that costs be authorized or not prohibited under State laws or regulations. Regulations for the State whose claims we will review require a pharmacist's statement describing the nature of the emergency and indicating why the service was considered to be immediately necessary. Emergency services are defined as those services required for alleviation of severe pain, or immediate diagnosis and treatment of unforeseen medical conditions which, if not immediately diagnosed and treated, would lead to disability or death. For FYs 2004 and 2005, the State estimated alien emergency service claims of at least \$83 million (\$42 million in FFP) for drugs distributed by pharmacies.

*(OAS; W-00-09-31133; various reviews; expected issue date: FY 2010; new start)*

### **Medicaid Third-Party Liability for Prescription Drug Payments**

We will review a State's controls to determine whether third-party providers are billed for Medicaid fee-for-service prescription drug claims prior to Medicaid paying. Pursuant to the Social Security Act, § 1902(a)(25), participating States must "take reasonable measures to ascertain the legal liability of third parties to pay for care and services available under the [Medicaid] plan." In this regard, the Office of the Auditor General for one State identified almost \$30 million in drug claims during a 2-year period that may have been the responsibility of a third-party insurance payer. We will review the State's process for identifying and billing third-party payers.

*(OAS; W-00-09-31134; various reviews; expected issue date: FY 2009; new start)*

## **Compound Drugs**

We will review whether a State agency's Medicaid claims for compound drugs and drug components complied with Federal requirements for reimbursement and collection of rebates. The Social Security Act, § 1927, generally requires manufacturers to have a rebate agreement with CMS for States to claim FFP and report drug utilization to the manufacturers for rebates. The CMS Medicaid Drug Rebate Program State Release No. 130 requires States to use the CMS drug tape, which lists all drugs covered by rebate agreements pursuant to the Social Security Act, § 1927(a)(1), to determine whether drugs they purchase are eligible for Medicaid coverage. CMS Medicaid Drug Rebate Program State Release No. 19 outlines States' responsibility for preventing claims for terminated drugs. We will identify claimed drug components that are not eligible for Medicaid coverage and determine whether accountability and controls were established for collecting eligible drug component rebates.  
*(OAS; W-00-08-31317; A-09-08-00034; expected issue date: FY 2009; work in progress)*

## **Medicaid Reimbursement for Unapproved Drugs**

We will review whether Medicaid pays for drugs that have not been approved by the FDA. The Social Security Act, § 1905(a), provides that State Medicaid plans may cover prescription drugs. Specifically, pursuant to Social Security Act, § 1927(k)(2), apart from a few specified exceptions, Medicaid will pay for an outpatient drug, for the purposes of section 1905(a), only if it has been approved by FDA. Preliminary analysis of Medicaid payment data indicates that the program may be paying for drugs that have not received FDA approval. We will review reimbursement data to determine whether Medicaid has paid for drugs that were not approved by FDA.  
*(OEI; 03-08-00500; expected issue date: FY 2009; work in progress)*

## **Zero Dollar Unit Rebate Amounts**

We will review whether States are properly collecting drug rebates for drugs with \$0 URA. CMS provides the URA information quarterly to States; however, this information may contain a \$0 URA if a drug labeler (e.g., a manufacturer) did not provide timely information or if the pricing information significantly varies from the previous quarter. In the Medicaid Drug Rebate Program Release No. 38, CMS instructs the State agency to invoice the units at \$0, and the manufacturer is required to calculate the URA and remit the proper amount with its quarterly payment. We will determine whether the rebates for these drugs were properly billed and collected.  
*(OAS; W-00-08-31106; various reviews; expected issue date: FY 2009; work in progress)*

## **States' Accountability Over Medicaid Drug Rebate Programs**

We will conduct follow-up reviews to determine whether States have established adequate accountability and internal controls over their Medicaid drug rebate programs. Federal regulations at 45 CFR § 433.32 require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. During our follow-up reviews, we will review State Medicaid agencies' collection of brand-name drug manufacturer rebates for physician-administered drugs since the passage of the DRA. Pursuant to section 6002 of the DRA, States are required to collect data necessary to enable them to collect rebates on physician-administered drugs. Previous OIG work found that the majority of States were not collecting Medicaid rebates for physician-administered drugs and that most States had weaknesses in accountability and internal controls over their drug rebate programs. We will

determine whether States have established adequate internal controls over their Medicaid drug rebate programs. We will also determine whether State Medicaid agencies followed Federal regulations when collecting brand-name drug manufacturer rebates for physician-administered drugs.

*(OAS; W-00-07-31205; W-00-08-31205; various reviews; expected issue date: FY 2009; work in progress)*

### **Additional Rebates of Brand-Name Drugs**

We will review the additional rebate component of the Medicaid drug rebate law to determine whether it was properly calculated. Section 4401 of the Omnibus Budget Reconciliation Act of 1990, enacted in November 1990 and effective January 1991, requires drug manufacturers to pay rebates to States for covered outpatient prescription drugs reimbursed under States' Medicaid drug programs. The manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period, as well as each subsequent quarter that the drug is on the market. For brand-name drugs, manufacturers must pay an additional rebate when the AMP increases above the base period (baseline) AMP at a rate greater than the increases in the Consumer Price Index-Urban. CMS calculates the URA for each drug based on the AMP and best price data provided by drug manufacturers.

*(OAS; W-00-09-31306; various reviews; expected issue date: FY 2009; new start)*

### **Assessing the Accuracy of Drug Type Classification in the Medicaid Drug Rebate Initiative File**

We will review the accuracy of drug type classification within the Medicaid Drug Rebate Program. The Social Security Act, § 1927(a)(1), requires drug manufacturers to enter into a national rebate agreement with the Secretary for States to receive Federal funding for outpatient drugs dispensed to Medicaid patients. The formula to calculate rebates owed to States varies by drug type classification. Previous OIG work revealed that some manufacturers do not classify their drugs in accordance with Medicaid rebate laws and may not be paying appropriate rebate amounts to State Medicaid agencies. We will determine the extent to which drugs are incorrectly classified and the potential financial impact to States.

*(OEI; 03-08-00300; expected issue date: FY 2009; work in progress)*

### **Comparison of Medicaid Federal Upper Limit Amounts to Wholesale, Retail, and Medicare Pricing**

We will review how FULs calculated using the pre-DRA methodology compare to other pricing points. Federal reimbursement to States for certain outpatient prescription drugs are subject to ceilings called FULs. FULs cap Federal matching payments to States for generic drugs. Previous OIG reviews found that pre-DRA FULs resulted in Medicaid payments to pharmacies for generic drugs that were higher than estimates of pharmacy acquisition costs. Prompted in part by OIG's results, section 6001(a) of the DRA sought to make FULs more closely align with prices available in the marketplace by basing them on AMPs, a change estimated by the Congressional Budget Office to reduce Medicaid expenditures by \$3.6 billion over 5 years. However, a court injunction imposed in December 2007, has prevented CMS from implementing new FULs. Additionally, section 203 of the Medicare Improvements for Patients and Providers Act of 2008 delayed the adoption of AMP-based FULs for multiple-source drugs until October 1, 2009. We will compare current FULs to the following pricing points: estimated pharmacy acquisition costs of drugs available through wholesale distributors; retail prices available through

discount programs at large chain pharmacies; and the average Part D pharmacy reimbursement amounts for all FUL drugs in the fourth quarter of 2007.

*(OEI; 03-08-00490; expected issue date: FY 2009; work in progress)*

## **Other Medicaid Services**

### **Medicaid Dental Services**

We will review Medicaid payments for dental services to determine whether States have properly claimed FFP. Pursuant to the Social Security Act, §§ 1905(a)(4)(B) and 1905(r), dental services are required for most Medicaid-eligible individuals under the age of 21 as a component of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services benefit. Federal regulations at 42 CFR § 440.100 define dental services as diagnostic, preventative, or corrective procedures provided by or under the supervision of a dentist. Services include the treatment of the teeth and associated structure of the oral cavity and disease, injury, or impairment that may affect the oral cavity or general health of the recipient. In 2007, Medicaid costs for dental services totaled more than \$3 billion.

*(OAS; W-00-09-31135; various reviews; expected issue date: FY 2009; new start)*

### **Family Planning Services**

We will review family planning services in several States to determine whether enhanced Federal funding was improperly claimed for such services and the resulting financial impact on the Medicaid program. Pursuant to the Social Security Act, § 1903(a)(5), States may claim Medicaid reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. Prior OIG work identified improper claims for enhanced funds for family planning services.

*(OAS; W-00-06-31078; W-00-07-31078; W-00-08-31078; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Payments for Transportation Services**

We will review payments made to providers for transportation services. Federal regulations at 42 CFR § 431.53 require States to ensure necessary transportation for Medicaid beneficiaries to and from providers. 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 State Medicaid agencies' payments for transportation services.

*(OAS; W-00-07-31121; W-00-08-31121; various reviews; expected issue date: FY 2009; work in progress)*

### **State Policies To Safeguard Medicaid Nonemergency Transportation Services**

We will review current State policies, procedures, and oversight activities to safeguard Medicaid nonemergency transportation services against fraud and abuse. Pursuant to 42 CFR § 431.53, Medicaid must ensure necessary transportation for recipients to and from providers. Prior OIG reviews found that State Medicaid program internal controls were lacking or not fully enforced and that Medicaid nonemergency transportation services were at high risk for fraud. We will determine the extent of safeguards used by States to prevent and detect fraud and abuse of Medicaid nonemergency transportation services.

*(OEI; 06-07-00320; expected issue date: FY 2009; work in progress)*

## **Medical Equipment**

We will review Medicaid payments for medical supplies and equipment and identify providers for detailed review. Prior OIG reviews have found various problems with medical equipment claims, including Medicaid allowable reimbursement rates for equipment that are much higher than the actual costs to the provider. We have also identified concerns regarding the allowability of Medicare claims for medical supplies and equipment. We will determine whether Medicaid beneficiaries received the items billed on their behalf and whether the supplies and equipment were actually used and were necessary for the beneficiaries' conditions

*(OAS; W-00-08-31307; various reviews; expected issue date: FY 2009; work in progress)*

## **Early and Periodic Screening, Diagnostic, and Treatment Services**

We will review the extent to which Medicaid-eligible children receive appropriate EPSDT services. The Social Security Act, §§ 1905(a)(4) and 1905(r), provides for periodic screening, vision, dental, hearing, and other necessary health services to Medicaid-eligible individuals under the age of 21. The EPSDT program is designed to screen at periodic intervals and diagnose and treat medical conditions that might otherwise go undetected or untreated. This study will also examine CMS's oversight of State reporting of EPSDT services in accordance with Federal requirements.

*(OEI; 05-08-00520; expected issue date: FY 2009; work in progress)*

## **Providers Billing More Time Than Is Feasible in a Day**

We will review services provided by physicians to determine whether claims are submitted for more time than is feasible in a day. Prior partnership audits in one State identified significant improper claims submission and service upcoding by physicians. We will analyze provider claims to identify providers with potential billing problems.

*(OAS; W-00-09-31137; various reviews; expected issue date: FY 2009; new start)*

## **Rehabilitative Services**

We will review claims for rehabilitative services to determine whether the services met Federal reimbursement requirements. The Social Security Act, § 1905(a)(13), defines rehabilitative services as any medical or remedial services provided in a facility, a home, or other setting. The services must be recommended by a physician or other licensed practitioner of the healing arts for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level. Previous OIG reviews found a significant number of services claimed that were not eligible for reimbursement.

*(OAS; W-00-08-31028; various reviews; expected issue date: FY 2009; work in progress)*

## **Enhanced Reimbursement to States for Indian Health Service Claims**

We will review the appropriateness of States' claims at an FFP rate of 100 percent for services provided by facilities of the Indian Health Service (IHS) to Indians who are Medicaid beneficiaries. Section 402 of the Indian Health Care Improvement Act of 1976 (IHCA) authorizes IHS facilities to be reimbursed for services that are provided to Indians eligible for Medicaid. Under the Social Security Act, § 1905(b), the FFP share of State Medicaid expenditures for services provided through IHS facilities is 100 percent. We will determine whether States are properly claiming FFP at 100 percent for services provided by IHS facilities to Indians who are Medicaid beneficiaries.

*(OAS; W-00-09-31138; various reviews; expected issue date: FY 2009; new start)*

### **Reimbursement Rates for Services Provided by Indian Health Service Facilities**

We will review IHS hospital cost reports to determine the allowability of costs for Medicare and Medicaid reimbursement. Section 402 of the IHCA authorizes IHS facilities to be reimbursed for services that are provided to individuals eligible for Medicare and Medicaid. The services are reimbursed using rates that are developed from data contained in the cost reports of 46 IHS hospitals. The rates are used as the basis for payment for services provided for all inpatient and outpatient IHS facilities. For Medicaid services, there is no State share; the Federal Government reimburses 100 percent of the costs. In 2005, Medicare and Medicaid reimbursement for services provided by IHS facilities totaled nearly \$140 million and \$800 million, respectively. *(OAS; W-00-07-31221; various reviews; expected issue date: FY 2009; work in progress)*

### **Medical Services for Undocumented Aliens**

We will review Medicaid payments for medical services rendered to undocumented aliens to determine whether States appropriately claimed Federal funds for allowable medical services. Pursuant to the Social Security Act, § 1903(v), States may claim Federal funds for medical services provided to undocumented aliens only when those services are necessary to treat emergency conditions. Our work in one State and discussions with CMS officials indicated the possibility of improper claims in this area. *(OAS; W-00-07-31108; W-00-08-31108; various reviews, expected issued date: FY 2009; work in progress)*

### **Medicaid Payments for Laboratory Services for Dual-Eligible Beneficiaries**

We will review Medicaid payments for outpatient laboratory services provided to dual-eligible beneficiaries. Under the Social Security Act, § 1902(a)(25), Medicare will reimburse 100 percent of allowable laboratory-service charges for beneficiaries who are enrolled in both Medicare and Medicaid pursuant to the Social Security Act, §§ 1833(a)(1)(D) and 1822(h)(5)(C). Because Medicaid is the payer of last resort, Medicaid should not pay any portion of charges for laboratory services provided to dual-eligible beneficiaries unless the services are provided in a hospital or rural health clinic. We will determine whether selected State Medicaid programs made improper payments for outpatient laboratory services provided to dual eligibles in FY 2005. *(OEI; 04-07-00340; expected issue date: FY 2009; work in progress)*

## **Medicaid Administration**

### **Contingency Fee Payment Arrangements**

We will review the extent to which State Medicaid agencies have contracted with consultants through contingency fee payment arrangements and the impact these arrangements have had on the submission of questionable or improper claims to the Federal Government. Some State Medicaid agencies use consulting firms to help identify ways to maximize Federal Medicaid reimbursement. In some cases, States pay the consulting firms a percentage of the increase in Federal Medicaid funding. Under OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, the cost of such contingency fee arrangements may not be claimed

from the Federal Government. Prior OIG work in one State found that improper claims had been submitted by the State as a result of a contingency fee payment arrangement.

*(OAS; W-00-06-31045; W-00-07-31045; W-00-08-31045; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Payments for Services Provided Under Section 1115 Demonstration Projects**

We will review selected States' demonstration projects pursuant to the Social Security Act, § 1115 to determine whether services are being provided in accordance with the conditions of the projects' approval. The Social Security Act, § 1115, authorizes the Secretary to approve demonstration projects that are likely to assist in promoting the objectives of the Medicaid program. Under this authority, some States have expanded Medicaid eligibility to individuals not otherwise eligible for Medicaid, provided services not typically covered by Medicaid, or used innovative systems to deliver services.

*(OAS; W-00-08-31208; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Waiver Safety Net Care Pools**

We will review section 1115 demonstration projects that contain safety net care pools (SNCP) to determine whether States are abiding by the Medicaid demonstration terms and conditions as they relate to the SNCP. The Social Security Act, § 1115, provides broad authority to authorize experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid statute. SNCPs permit the reimbursement of a broad array of uncompensated costs. For example, the pools may be used to reimburse the cost of providing to the uninsured physician services, clinic services, and any other services that CMS does not consider to be inpatient or outpatient hospital services.

*(OAS; W-00-09-31308; various reviews; expected issue date: FY 2009; new start)*

### **Medicaid Payments for Services Provided Under Section 1915(b) Managed Care/Freedom of Choice Waivers**

We will review the cost effectiveness of selected States' section 1915(b) waivers. Under the waiver authority in the Social Security Act, § 1915(b), CMS may authorize States to provide medical assistance through managed care organizations. These waivers affect service delivery to some or all of the individuals eligible for Medicaid in the State. States may elect to enroll on a mandatory basis beneficiaries in managed care programs or may carve out specialty care. Section 1915(b) and regulations at 42 CFR § 431.55 provide that these waivers are not to negatively affect beneficiary access or quality of care or service and must be cost effective. We will also review the effectiveness of CMS's national review protocol for the oversight process.

*(OAS; W-00-08-31125; W-00-08-31316; various reviews; expected issue date: FY 2009; work in progress)*

### **Sections 1915(b) and (c) Concurrent Waivers**

We will review each portion of sections 1915(b) and (c) concurrent waivers to determine whether the waivers are cost effective and whether the services provided through the waivers were provided in accordance with the approved waiver terms and conditions. The section 1915(b) waivers are also known as managed care/freedom of choice waivers, and section 1915(c) waivers are also known as home- and community-based waivers. Concurrent

waivers allow States to simultaneously utilize sections 1915(b) and (c) program authorities to provide services to a specific group with specific providers. States must meet the Federal requirements for each of the waivers and comply with the separate reporting requirements for each waiver.

*(OAS; W-00-08-31309; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Payments for Services Provided Under Section 1915(c) Home- and Community-Based Service Waivers**

We will review Medicaid payments to providers and selected States to determine whether services provided under section 1915(c) waivers are rendered in accordance with approved waiver agreements. Under the Social Security Act, § 1915(c) waiver authority, CMS may authorize States to expand the term medical assistance to include HCBS pursuant to written plans of care. Such services can include both traditional medical services and support services, e.g., respite care and case management. In addition, the waivers allow family members to provide services if they meet certain requirements.

*(OAS; W-00-07-39045; W-00-07-31124; W-00-08-31124; various reviews; expected issue date: FY 2009; work in progress)*

### **Enrollment of Excluded Medicaid Providers**

We will review States' processes for enrolling Medicaid providers. Specifically, we will focus on a subset of Medicaid providers who were subsequently excluded from participating in federally funded health care programs. Pursuant to 42 CFR pt. 455, subpart B, States are required to collect information from providers regarding the ownership of health care entities and criminal convictions as part of the enrollment process for participating in Federal health care programs. However, there is no corresponding requirement that States verify the information. Previous GAO and OIG reviews found that most States had not verified information that providers submitted in their applications nor required periodic reenrollment. We will assess the prevalence of judgments, tax liens, and criminal convictions among a population of excluded Medicaid providers and the extent to which States had checked providers' backgrounds both before and after enrollment. We will also determine how much States reimbursed these providers when they were active.

*(OEI; 09-08-00330; expected issue date: FY 2009; work in progress)*

### **Medicaid Transformation Grants**

We will review Medicaid Transformation Grants (MTG) to determine whether costs claimed by State agencies were adequately supported and allowable. MTGs, which were established by section 6081 of the DRA, were permitted to be used for health information technology (HIT) and health information exchange (HIE) initiatives in FY 2007 and FY 2008. Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs were cited as permissible use of funds. In January 2007, CMS awarded 33 grants, totaling \$103 million. Eighteen of these grants were for HIT and HIE initiatives, totaling \$64 million.

*(OAS; W-00-09-31139; various reviews; expected issue date: FY 2010; new start)*

### **Medicaid Provider Tax Issues**

We will review State and health-care-related taxes imposed on various Medicaid providers to determine whether such taxes comply with applicable Federal laws and regulations and

are being used for the stated purposes. The Social Security Act, § 1903(w)(1)(A), requires a reduction in a State's medical assistance expenditures equal to the amount of any impermissible health-care-related taxes. Federal regulations at 42 CFR § 433.68 set forth the standard for permissible health-care-related taxes. Prior OIG work has raised concerns regarding States' use of health-care-related taxes, including whether taxes received by States adversely affect the providers required to pay the taxes.

*(OAS; W-00-08-31094; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Eligibility in Multiple States**

We will review the appropriateness of Medicaid payments for beneficiaries with Medicaid eligibility in multiple States. Federal regulations at 42 CFR § 435.403 require States to provide Medicaid to eligible residents, including residents who are absent from the State. We have determined that individual beneficiaries have been eligible in more than one State during a specific period. Initial survey work has confirmed that, contrary to the requirements of 42 CFR § 431.52, duplicate payments are made to providers in different States, for a specific beneficiary, for identical or overlapping dates of service.

*(OAS; W-00-08-31114; various reviews; expected issue date: FY 2009; work in progress)*

### **Duplicate Medicaid Payments to Providers on Behalf of Hurricane Evacuees**

We will review Medicaid payments to determine whether two providers were paid for the same service. As a result of the 2005 hurricanes, thousands of beneficiaries were evacuated from their home States and relocated to other (host) States. Beneficiaries were eligible for Medicaid in their new host States and may have received services from providers in their host States. We will determine whether providers in the host States billed and received payment from both the beneficiaries' home States and host States.

*(OAS; W-00-08-31117; various reviews; expected issue date: FY 2009; work in progress)*

### **State Agencies' Redeterminations of Medicaid Eligibility**

We will review the State agencies' procedures for redetermining the eligibility status of Medicaid beneficiaries. During recent audits of Medicaid payments for services provided to beneficiaries with concurrent eligibility in two States, we found that eligibility status reviews were not always performed in a timely manner. Federal regulations at 42 CFR § 435.916 provide that State agencies must redetermine the eligibility of Medicaid beneficiaries, with respect to circumstances that may change, at least every 12 months. We will determine the amount of unallowable payments associated with beneficiaries who did not receive the required Medicaid eligibility redeterminations.

*(OAS; W-00-09-31140; various reviews; expected issue date: FY 2010; new start)*

### **Use of Public Assistance Reporting To Reduce Improper Medicaid Payments by Multiple States**

We will review States' use of the Public Assistance Reporting Information System (PARIS) to identify ineligible Medicaid recipients. PARIS is a voluntary computer matching and information exchange system operated by the Administration for Children and Families. Using States' eligibility data, PARIS detects individuals who are receiving Medicaid benefits in more than one State simultaneously. Pursuant to the Social Security Act, § 1902(a)(16), and 42 CFR § 435.403, States must provide Medicaid benefits to eligible residents of the State even if they are absent at the time of the medical need. Additionally, regulations at 42 CFR § 431.52 require

States to establish procedures to facilitate the furnishing of medical services to individuals who are present in their State but are eligible under another State's plan. Previous OIG work has found recipients receiving Medicaid services in more than one State simultaneously. This study will examine the extent to which States have used PARIS to identify potentially improper payments when the point of service to the individual and the individual's Medicaid eligibility are in different States.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Medicaid Administrative Costs**

We will review administrative costs claimed by several States. The Social Security Act, § 1903(a)(7), provides Federal cost sharing for the proper and efficient administration of Medicaid State plans. The Federal share of Medicaid administrative costs is typically 50 percent, with enhanced rates for specific types of costs. Prior reviews in one State noted problems in this area. We will determine whether administrative costs were properly allocated or directly charged to the Medicaid program and claimed in accordance with OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, and State requirements.

*(OAS; W-00-07-39044; W-00-06-31123; W-00-08-31123; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicare/Medicaid Credit Balances**

We will review providers, including independent laboratories and hospitals, to determine whether there are Medicare/Medicaid overpayments in patient accounts with credit balances. For Medicare, the Social Security Act, § 1862(b), and 42 CFR pt. 411 require participating providers to furnish information about payments made to them and to refund any monies incorrectly paid. For Medicaid, the Social Security Act, § 1902(a)(25), regulations at 42 CFR pt. 433, subpart D, and various State laws require that Medicaid be the payer of last resort and that providers identify and refund overpayments received. Prior OIG work has identified Medicare/Medicaid overpayments in patients' accounts with credit balances.

*(OAS; W-00-08-31311; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Management Information System Costs**

We will review MMIS costs in selected States to determine whether costs allocated to Medicaid are allowable. The Social Security Act, § 1903(a)(3), as implemented by 42 CFR pt. 433, subpart C, provides FFP in State expenditures for the design, development, or installation of mechanized claims-processing and information retrieval systems and for the operation of certain systems. Reviews of Medicaid management information system (MMIS) costs have not been performed by OIG in recent years.

*(OAS; W-00-08-31312; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Statistical Information System Data Reporting**

We will review Medicaid Statistical Information System (MSIS) data to determine whether the data are current, accurate, and sufficiently comprehensive for use in detecting Medicaid fraud, waste, and abuse. The Social Security Act, section 1903(r), requires States to submit MSIS claims and eligibility information electronically to CMS. The MSIS is the only comprehensive national database of Medicaid beneficiary-level claims and eligibility information and is the

source for a wide range of analysis. We will review data accuracy, identify State barriers to submitting accurate MSIS data, and evaluate CMS's oversight of MSIS data quality.  
*(OEI; 04-07-00240; expected issue date: FY 2009; work in progress)*

### **Medicaid Managed Care Encounter Data: Reporting and Utilization**

We will review the reporting and utilization of Medicaid managed care encounter data. The Social Security Act, § 1903(r), requires that, for claims processed after January 1, 1999, each State have in operation an electronic claims-processing system deemed by the Secretary to be consistent with the MSIS format. We will determine the extent to which State Medicaid agencies are reporting encounter data to CMS in MSIS and how Medicaid managed care encounter data are being used.

*(OEI; 07-06-00540; expected issue date: FY 2009; work in progress)*

### **State Buy-In of Medicare Coverage**

We will review States' Medicaid buy-in programs of Medicare Part B. States may enroll dual-eligible beneficiaries in the Medicare Part B program. If States operate a Medicaid buy-in program, the Social Security Act, § 1843, and 42 CFR §§ 407.40 through 407.42 require States to pay the Medicare Part B premium for each dual-eligible individual that they enroll in the Medicare Part B program. We will determine whether States have adequate controls to ensure that Medicare premiums are paid only for individuals eligible for State buy-in coverage of Medicare services.

*(OAS; W-00-08-31220; various reviews; expected issue date: FY 2009; work in progress)*

### **Medicaid Services to Incarcerated Juveniles**

We will review States' compliance with Federal rules that exclude Federal funding for medical services to incarcerated juveniles. The Social Security Act, § 1905(a)(28)(A), specifically excludes Federal funding for services provided to inmates of a public institution (except patients in medical institutions). Further, 42 CFR § 435.1010 defines an inmate of a public institution as "a person who is living in a public institution." It defines "public institution" as "an institution that is the responsibility of a governmental unit over which a governmental unit exercises administrative control." Previous work had identified unallowable claims in this area. We will determine whether States have improperly claimed Federal funding for medical services provided to incarcerated juveniles.

*(OAS; W-00-07-31222; various reviews; expected issue date: FY 2009; work in progress)*

### **Early Implementation of the Medicaid Transfer of Asset Rules**

We will review the extent to which States have implemented the Medicaid transfer of asset rules required by the DRA. To be eligible for Medicaid, applicants must meet specific income and asset standards. Those with assets must spend down many of these assets before they become eligible. Section 6011 of the DRA changed the transfer of asset rules related to Medicaid eligibility for long-term care by extending the look-back period for asset transfers from 3 years to 5 years. We will also review the extent to which States' Medicaid enrollment processes address these asset transfer requirements.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Medicaid's All-Inclusive Rate for Reimbursement to the Indian Health Service**

We will review IHS's calculation of the all-inclusive rate (AIR). Pursuant to section 402 of the IHCIA, Medicaid programs reimburse IHS and tribal facilities for outpatient services provided to Medicaid beneficiaries. Medicaid programs reimburse the facilities using the AIR, which is derived from hospital cost reports and is published in the Federal Register on an annual basis. However, the types of outpatient services billed to Medicaid at the AIR vary by State. We will also examine CMS's oversight of AIR.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **States' Subsidies of Employer-Sponsored Insurance Premium Assistance Programs**

We will review various aspects of employer-sponsored insurance (ESI) provided through SCHIP and State Medicaid programs. The Social Security Act, § 1906(a)(3), requires that the State Medicaid program pay the premiums of Medicaid-eligible individuals who are enrolled in a group health plan, such as an ESI. Federal regulations at 42 CFR § 457.810(c) authorize the use of SCHIP funds for the same purpose. States may choose to assist SCHIP and Medicaid beneficiaries with access to ESIs by subsidizing the cost of that insurance rather than providing direct coverage through SCHIP or Medicaid. We will determine the extent to which States utilize ESI programs, the characteristics of those programs, and any associated cost savings.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **Medicare and Medicaid Information Systems and Data Security**

OIG reviews the design, development, and maintenance of HHS computer-based systems by performing comprehensive audits of general and applications controls in accordance with applicable requirements. Our work in progress and planned reviews deal with standards, security, controls, and oversight of the information systems that support Medicare and Medicaid payments and operations. This section describes reviews involving the controls, security, and oversight aspects of Medicare and Medicaid systems and data.

### **Medicare: Annual Reports to Congress on Contractor Information Systems Security Programs**

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and MACs. Section 912 of the MMA requires annual independent evaluations of FIs, carriers, and MACs' security programs and subsequent OIG assessment of these evaluations. OIG is required to annually report the results of its assessments to Congress. Our report to Congress will include our assessment of the scope and sufficiency of the evaluations performed and summarize the results of independent evaluations.

*(OAS; W-00-09-41042; expected issue date: FY 2009; new start)*

### **Medicare: Assessment of Claims Bypassing the Common Working File and the Impact on the National Claims History File**

We will review Medicare claims to determine the extent to which claims are processed and paid without the CWF's editing and the impact on the completeness of the NCH. The CWF is a

system that uses localized databases, which are maintained by host contractors, to validate and approve prepayment of Medicare claims and to coordinate Medicare Part A and B benefits. The system also provides contractors with beneficiary entitlement and utilization information. In addition, the CWF is used by CMS to populate its NCH File, which is used to support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, consultant, or grantee. The independent auditors of HHS's financial statements disclosed that some Medicare fee-for-service claims are processed and paid without being adjudicated through the CWF.

*(OAS; W-00-08-40002; W-00-08-40024; A-01-08-00523; A-17-08-00523; expected issue date: FY 2009; work in progress)*

### **Medicare Contractor Information Technology Closeout Audits**

We will review CMS's policies, instructions, and procedures designed to ensure adherence to Federal data privacy, information security, and contractual requirements and conduct information technology closeout audits at Medicare contractors that left the program during FYs 2007 and 2008 to assess compliance with applicable Federal requirements. Section 911 of the MMA requires the Secretary to submit to Congress a plan outlining a strategy for accomplishing the replacement of current FIs and carriers with MACs no later than 2011. The plan that the Secretary submitted to Congress calls for the establishment of 23 new administrative contracts by 2009. It also includes steps to consolidate the number of contracted data centers from 16 to no more than 4. Consequently, over the next several years, a number of contractors will leave the program. Our experience with previous workload transitions suggests that problems could arise with the disposition of Government systems and data when contractors leave Medicare. For example, these contractors' access rights to Medicare shared systems, the CWF system, and Medicare banking records need to be terminated as soon as the contractors' performance periods end.

*(OAS; W-00-09-41044; various reviews; expected issue date: FY 2009; new start)*

### **Medicare Part D Selected General and Application Controls for Systems That Track True Out-of-Pocket Costs**

We will review selected Medicare Part D general and application controls at the CMS contractor, known as the TrOOP facilitator, responsible for collecting information on TrOOP from payers secondary to Medicare Part D. TrOOP calculations are critical to the Medicare Part D payment process because they affect the proportions of the drug cost for which the beneficiary, the Part D plan, and Medicare are each responsible. With respect to general controls, we will focus on continuity of service planning and software development change controls. We will also review the application controls, including the accuracy and completeness of standard transactions generated at the TrOOP facilitator for covered prescriptions and documenting payers secondary to Medicare. The transactions are transmitted by the TrOOP facilitator to the plans, which use them to compute beneficiary TrOOP for covered prescription drugs. We will follow up on issues identified in a prior audit of a TrOOP facilitator.

*(OAS; W-00-09-41048; expected issue date: FY 2009; new start)*

### **Medicare Part D: Implementation of Supporting Systems at Small- and Medium-Size Plans and Plans New to Medicare**

We will review implementation of systems to support the Part D prescription drug benefit plan and expansion of beneficiary choices at MA plans and small- to medium-size Part D sponsors

and other Part D sponsors with little or no previous involvement in the Medicare program. We will evaluate systems that support designated Part D functions and the general and application controls that are critical to support these functions. We will also assess the plans' compliance with Medicare Part D contractual requirements; CMS regulations; and CMS instructions for systems supporting key Part D components, such as beneficiary enrollment, coordination of benefits TrOOP costs, and PDE operations. We will follow up on issues identified in prior reviews of larger plans.

*(OAS; W-00-09-41049; various reviews; expected issue date: FY 2009; new start)*

### **Medicare and Medicaid: Security of Portable Devices Containing Personal Health Information at Contractors and Hospitals**

We will review security controls implemented by Medicare and Medicaid contractors as well as hospitals to prevent the loss of protected health information stored on portable devices and media, such as laptops, jump drives, backup tapes, and equipment considered for disposal. Recent breaches related to Federal computers, including one involving a CMS contractor, have heightened concerns about protecting sensitive information. OMB Memorandum M-06-16, issued June 23, 2006, recommended that all Federal Departments and agencies take action to protect sensitive information by following the National Institute of Standards and Technology's Special Publications 800-53 and 800-53A. We will assess and test contractors' and hospitals' policies and procedures pertaining to electronic health information protections, access, storage, and transport.

*(OAS; W-00-09-41047; various reviews; expected issue date: FY 2009; new start)*

### **Medicare and Medicaid Health Information Data Security and Privacy**

We will review CMS's oversight, implementation, and enforcement of the HIPAA Security Rule. The data security standards required under sections 261 and 262 of the HIPAA are known as the HIPAA Security Rule. The HIPAA Security Rule applies to HIPAA-covered entities, including Medicare and Medicaid providers. CMS is responsible for overseeing compliance with this regulation. We will also review various HIPAA-covered Medicare program providers' compliance with the HIPAA Privacy Rule requirements defined in 45 CFR § 160.103 and will determine the adequacy of oversight provided by the Office for Civil Rights for the HIPAA Privacy Rule.

*(OAS; W-00-08-41021; W-09-00-41050; various reviews; expected issue date: FY 2009; work in progress and new start; OEI; 00-00-00000; various reviews; expected issue date: FY 2009; new start)*

### **Medicaid Management Information Systems—Business Associate Agreements**

We will review CMS's oversight activities related to data security requirements of States' MMISs, which process and pay claims for Medicaid health benefits. Business associates of States' MMISs typically include support organizations, such as data processing services and medical review services. State Medicaid agencies are among the covered entities that must comply with HIPAA Security Final Rules, which stipulate minimum requirements that contracts with business associates must include to protect the privacy and security of certain electronic personally identifiable health information. We will determine whether business associate agreements have been properly executed to protect beneficiary information, including safeguards implemented pursuant to the HIPAA standards.

*(OAS; W-00-09-41045; various reviews; expected issue date: FY 2009; new start)*

### **Medicaid: Security Controls Over State Web-Based Applications**

We will review States' security controls over Web-based applications that allow Medicaid providers to electronically submit claims. The electronic transactions may contain protected health information as defined under the HIPAA. The regulation at 45 CFR § 160.103 includes Medicaid programs within the meaning of "health plans" that must comply with the security standards set forth in 45 CFR § 164.306, pt. 164, subpart C of the HIPAA Security Rule. Using an application security assessment tool, we will determine whether States' Web-based applications contain any vulnerabilities that would potentially affect the confidentiality, integrity, and availability of the Medicaid claims' protected health information.

*(OAS; W-00-09-41046; various reviews; expected issue date: FY 2009; new start)*

### **Medicaid: Security Controls at the Mainframe Data Center That Processes States' Claims Data**

We will review security controls at CMS's mainframe data center that processes Medicaid claims data received from States. OMB Circular A-130, Management of Federal Information Resources, Appendix III, paragraph A.3, states that agencies shall implement and maintain programs to ensure that adequate security is provided for all agency information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. The Appendix also establishes a minimum set of controls to be included in Federal automated information security programs. We will focus on security controls over CMS's mainframe computer, such as access controls over the mainframe operating system and security software. In addition, we will review some limited general controls, such as disaster recovery plans and physical security.

*(OAS; W-00-07-40019; expected issue date: FY 2009; work in progress)*

## **State Children's Health Insurance Program**

SCHIP is a partnership between Federal and State governments that helps provide low-income children with the health insurance coverage that they need. The program improves access to health care and quality of life for millions of vulnerable children under 19 years of age. SCHIP reaches children whose families have incomes too high to qualify for Medicaid, but too low to afford private health insurance. States with approved SCHIP plans are eligible for Federal matching payments. Our reviews focus on eligibility and payment issues, administrative costs, and error rate measurement.

### **Medicaid and State Children's Health Insurance Program Citizenship Requirements**

We will review the eligibility status of Medicaid beneficiaries to ensure that States are meeting the new citizenship requirements. As of July 1, 2006, all individuals who apply for Medicaid or renew their Medicaid eligibility must prove their citizenship by presenting, among other possible documents, a U.S. passport or the combination of a U.S. birth certificate and an identification document. States that provide Medicaid eligibility to individuals who have not proven their citizenship may not claim Federal matching funds for Medicaid-covered services to those individuals. The new requirement was mandated by section 6036 of the DRA. We will

determine whether States implemented the citizenship requirement and document the amount of payments made on behalf of individuals not meeting the new citizenship requirements. (OAS; W-00-09-31224; various reviews; expected issue date: FY 2010; new start)

### **State Children's Health Insurance Program Payments for Residents in Institutions for Mental Diseases**

We will review SCHIP payments to determine whether such payments were made during the time that children were in IMDs. Federal regulations at 42 CFR § 457.310(c)(2)(ii) provide that a child is not eligible for SCHIP funding if the child is a patient in an IMD. An IMD is defined as a hospital, nursing facility, or other institution of more than 16 beds that is engaged primarily in providing diagnosis, treatment, or care of persons with mental diseases. We will determine whether States have improperly claimed SCHIP reimbursement during periods that children were in IMDs.

(OAS; W-00-09-31225; various reviews; expected issue date: FY 2009; new start)

### **State Children's Health Insurance Program Administrative Costs**

We will review States' SCHIP compliance with the 10-percent cap on administrative costs. The Social Security Act, § 2105(c)(2)(A), establishes a limit on administrative funds that are eligible for Federal matching equal to 10 percent of the amounts expended to provide child health assistance. Administrative expenditures include expenditures related to administration, outreach, and other child health assistance and initiatives. We will determine whether States have appropriately claimed administrative costs.

(OAS; W-00-09-31226; various reviews; expected issue date: FY 2010; new start)

### **Dually Enrolled Beneficiaries in a State**

We will review a State's claims for FFP under the State's SCHIP program for individuals who were enrolled in the State's Medicaid program to determine the appropriateness of these claims. Pursuant to the Social Security Act, § 2105(c)(6)(B), no payment shall be made to a State for expenditures for child health assistance provided for a targeted low-income child under its plan to the extent that payment has been made or can reasonably be expected to be made promptly under any other federally operated or financial health care insurance program. A previous OIG review of SCHIP eligibility in the State for the first 6 months of 2005 indicated that the State had made some SCHIP payments on behalf of individuals who were also enrolled in the Medicaid program.

(OAS; W-00-08-31314; A-04-08-03036; expected issue date: FY 2009; work in progress)

### **Medicaid and State Children's Health Insurance Program Payment Error Rate Measurement**

We will review CMS's Payment Error Rate Measurement (PERM) process to determine whether the PERM has produced valid and reliable error rate estimates for Medicaid and SCHIP fee-for-service, managed care, and eligibility. The IPIA and OMB's implementation of that act in memorandum M-06-23 require Federal agencies annually to develop statistically valid estimates of improper payments made under programs with a significant risk of erroneous payments. Medicaid and SCHIP have been identified as programs with significant risks and programs for which OMB has requested improper payment information. To comply with IPIA, CMS developed the PERM, which was to be fully implemented in FY 2008. The PERM process includes conducting fee-for-service, managed care, and eligibility reviews pursuant to 42 CFR

pt. 431, subpart Q. As part of OIG's oversight and monitoring responsibilities of CMS's error rate process, we will review CMS's implementation of the PERM process for Medicaid and SCHIP. We will also review the physical and data security of health information that is transmitted by States or contractors for use in the PERM process to assess compliance with OMB Memorandums M-06-16 and M-07-16, which provide guidance on protecting sensitive information and reporting incidents involving potential and confirmed breaches of personally identifiable information.

*(OAS; W-00-09-31141; various reviews; expected issue date: FY 2009; new start)*

### **Medicaid and State Children's Health Insurance Program Payment Error Rate for One State's Managed Care Program**

We will review the completeness of one State's Medicaid and SCHIP managed care programs' "pseudo claims" universe for the FY 2007 PERM program. The IPIA of 2002 and OMB's implementations of that act in memorandum M-06-23 require Federal agencies annually to develop statistically valid estimates of improper payments made under programs with significant risk of erroneous payments. The one State that we will review does not maintain paid claims databases at a beneficiary level for its Medicaid and SCHIP managed care programs.

Consequently, the State created pseudo claims universes for its Medicaid and SCHIP managed care programs to comply with CMS's PERM instructions to the States. The State created a pseudo claims universe by identifying beneficiaries recorded in the eligibility system as enrolled in the managed care plan to create a "pseudo payment record" for each beneficiary. OMB has requested that we conduct a review to determine whether this State's approach results in a complete universe for its Medicaid and SCHIP managed care programs to satisfy the PERM requirements.

*(OAS; W-00-09-40037; expected issue date: FY 2009; new start)*

## **Investigative and Legal Activities Related to Centers for Medicare & Medicaid Services Programs and Operations**

OIG conducts investigations of fraud and misconduct to safeguard HHS's programs and to protect the beneficiaries of those programs. Investigative activities are designed to detect and prevent waste, fraud, and abuse in HHS programs. Our investigations result in criminal prosecutions and program exclusions; recovery of damages and penalties through civil and administrative proceedings; and corrective management actions, regulations, or legislation.

Each year, thousands of complaints from various sources are brought to our attention for review, investigation, and appropriate resolution. The nature and volume of complaints cannot be predicted. Our Work Plan, however, identifies investigative focus areas on which we will concentrate our resources, subject to the demands of current complaint referrals. In addition to meeting our programmatic requirements, we will continue to review and investigate allegations of misconduct and wrongdoing within HHS. We carry out this responsibility to ensure that HHS personnel and contractors uphold the highest level of integrity.

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General (OCIG) coordinates our role in the resolution of civil and administrative health care fraud cases, including the litigation of program exclusions and CMPs and assessments. OCIG also negotiates and monitors CIAs. OCIG issues special fraud alerts, special advisory bulletins, and advisory opinions regarding the application of our sanction authorities and is responsible for developing OIG regulations, including new safe harbor regulations under the anti-kickback statute, and compliance program guidance.

Our health care investigations and legal activities span the Medicare and Medicaid programs. Following are some examples of where we will continue to focus attention.

### **Health Care Fraud**

OIG devotes significant resources to the investigation of fraud committed against the Medicare and Medicaid programs. We conduct numerous investigations in conjunction with other law enforcement agencies, such as the Federal Bureau of Investigation, the United States Postal Inspection Service, the Internal Revenue Service, and State Medicaid Fraud Control Units (MFCU).

We will investigate potentially illegal practices by suppliers and manufacturers who do not directly bill CMS's programs, as well as individuals, facilities, or entities that bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, and false claims submitted to obtain program funds. We will also investigate business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians.

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

OIG will also conduct investigations specifically related to the Medicare Part D drug benefit and assist CMS in identifying program vulnerabilities. We will continue to provide training to special agents and others on the intricacies and developing trends of the Part D benefit so that focused investigations can be conducted. We are investigating matters involving enrollment and marketing schemes, prescription shorting, and health care fraud.

OIG will apply lessons learned through our work related to fraudulent DME suppliers in South Florida to other areas of the Nation. The South Florida Initiative is a joint investigative and prosecutive effort against health care fraud in South Florida. In the first two phases of the initiative, infusion clinics and DME companies suspected of fraud were identified, investigated, and pursued for civil violations. The third phase, which is currently in effect, is a multiorganizational, multidisciplinary Task Force project that uses real-time analysis of Medicare billing data, as well as findings from earlier investigations, to identify, investigate, and prosecute individuals and companies that have committed DME fraud. By the end of July 2008, our efforts in South Florida had resulted in a cumulative \$144.6 million in health care fraud

investigative receivables and 92 health care fraud convictions. The operational model from the South Florida initiatives is also being applied to other high-risk areas with successful results.

We will continue to examine quality-of-care issues in nursing facilities and other care settings to detect and prevent fraud and abuse perpetrated against beneficiaries and the Medicare and Medicaid programs. We will investigate instances in which the programs may have been billed for medically unnecessary services or for services either not rendered or not rendered as prescribed or for substandard care that is so deficient that it constitutes a “failure of care.” We will expand our focus on these issues to additional institutions and community-based settings. We will also continue to investigate allegations of patient abuse or neglect and work jointly with the MFCUs to provide assistance in this area.

With regard to Medicaid specifically, OIG received additional funding under section 6035 of the DRA and the Supplemental Appropriations Act of 2008 to expand our Medicaid fraud and abuse control activities. We will continue to conduct investigations related to false claims submitted to Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, claims for substandard care provided to nursing home residents, and claims submitted to obtain program funds. We will use a portion of this funding to provide customized training to our special agents and our Federal, State, and local partners.

This customized training and education will enable us to better identify Medicaid program vulnerabilities, coordinate investigative activities and efforts, highlight successful Medicaid investigative accomplishments, illustrate new approaches to working cases, and hold information-sharing sessions to increase the efficiency and effectiveness of our efforts to protect the Medicaid program.

### **Exclusions From Program Participation**

OIG has authority to exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs to protect the programs and beneficiaries from providers that pose a risk. Providers are excluded for reasons that include program-related convictions, patient abuse or neglect convictions, and licensing board disciplinary actions. We impose exclusions based on referrals from various Federal and State agencies. We will continue to work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. In FY 2007, we excluded 3,308 individuals and entities from Federal health care programs and anticipate reviewing and implementing the exclusion of additional providers in FY 2009. As appropriate, the Office of Investigations and OIG expect to initiate program exclusions against individuals and entities that submitted false or fraudulent claims, failed to provide services that met professionally recognized standards of care, or otherwise engaged in conduct actionable under the Social Security Act, § 1128, or other statutes authorizing exclusions by OIG.

### **Provider Self-Disclosure**

OIG will continue to encourage health care providers to promptly self-disclose improper conduct that violates Federal health care program requirements. We have made a concerted effort to educate providers on the advantages of self-disclosure. In October 1998, we announced a self-disclosure protocol for use by all health care providers. The protocol offers health care providers specific steps, including a detailed audit methodology that they may use if they choose

to work openly and cooperatively with us. Numerous providers have been accepted under this protocol. These providers range from hospitals to laboratories and physicians. Both the Federal Government and the providers benefit from this program. In a 2006 Open Letter to Health Care Providers, we encouraged providers to disclose improper arrangements under the physician self-referral (Stark) law (42 U.S.C. § 1395nn) and committed, in appropriate cases, to settling liability under OIG's authorities, generally for an amount near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred. On April 15, 2008, we issued an additional open letter that discusses certain refinements and clarifications to OIG's policies to increase the efficiency of the self-disclosure protocol and benefit providers who self-disclose.

The self-disclosure protocol is designed only for providers that believe a potential violation of the law has occurred. Matters exclusively involving overpayments or errors that do not indicate violations of the law should be brought directly to the attention of the entity responsible for claim processing and payment.

### **Resolution of False Claims Act Cases and Negotiation of Corporate Integrity Agreements**

OIG staff will continue to work closely with prosecutors from DOJ to develop and pursue Federal false claims cases against individuals and entities that defraud the Government, when adequate evidence of violations exists. Authorities relevant to this work come from the False Claims Amendments Act of 1986. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases. We also will continue to consider whether to invoke our exclusion authority based on these defendants' conduct. When appropriate and necessary, we will require these defendants to implement compliance measures, in the form of integrity agreements, aimed at ensuring future compliance with Federal health care program requirements.

### **Providers' Compliance With Corporate Integrity Agreements**

We will continue to assess the compliance of providers with the terms of CIAs (and settlements with integrity provisions) into which they entered as part of the settlement of fraud and abuse allegations. We will conduct site visits to entities that are subject to the integrity agreements to verify compliance efforts, to confirm information submitted by the entities to us, and to assist with compliance generally. Included in this monitoring process will be systems reviews to determine whether a provider's compliance mechanisms are appropriate and to identify any problem areas and establish a basis for corrective action. When warranted, we will continue to impose sanctions, in the form of stipulated penalties or exclusions, on providers that breach their integrity agreement obligations.

### **Advisory Opinions, Fraud Alerts, and Other Industry Guidance**

As part of our ongoing efforts to foster compliance efforts by providers and industry groups, we will respond to requests for formal advisory opinions on the application of the anti-kickback statute and other fraud and abuse statutes to particular business arrangements or practices. We will issue special fraud alerts and advisory bulletins, as warranted, to inform the health care industry more generally of particular practices that we determine are suspect. We will also review existing Compliance Program Guidances to identify those that should be revised or updated. In FY 2008, we initiated an update of the nursing home guidance issued in 2000.

### **Civil Monetary Penalties**

We will continue to pursue CMP cases, when supported by appropriate evidence, based on the submission of false or fraudulent claims; the offer, payment, solicitation, or receipt of remuneration (kickbacks) in violation of the Social Security Act; § 1128B(b), EMTALA; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

# Public Health and Human Service Programs and Departmentwide Issues

Based on our available resources each fiscal year (FY), we allocate about 20 percent of our appropriations to reviews of the Department of Health and Human Services's (HHS) approximately 300 public health and human service programs and to departmentwide issues that affect more than one program. Work Plan Part II describes our ongoing and planned activities in public health and human services, categorized by agency, followed by departmentwide issues.

## Public Health Programs

Public health activities and programs represent this 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. Public health agencies within HHS include the following:

- Centers for Disease Control and Prevention (CDC). CDC operates a system of health surveillance to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.
- Food and Drug Administration (FDA). FDA is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.
- Health Resources and Services Administration (HRSA). HRSA maintains a safety net of health services for people who are low income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.
- Indian Health Service (IHS). IHS provides or funds health care services for 1.6 million American Indians and Alaska Natives.
- National Institutes of Health (NIH). NIH supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).
- Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds services to improve the lives of people with or at risk for mental and substance abuse disorders.

In addition, the Agency for Healthcare Research and Quality sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access. Within the Office of the Secretary, issues related to public health are also addressed by several offices. For example, the Office of the Assistant Secretary for Preparedness and Response serves as the Secretary's principal advisor on matters related to Federal public health preparedness and response to public health emergencies. The Office of Human Research Protections oversees the protection of volunteers involved in research.

The following sections describe the reviews that are planned with regard to the Office of Inspector General's (OIG) oversight of public health programs.

## **Centers for Disease Control and Prevention**

### **Centers for Disease Control and Prevention's Implementation of Select Agent Regulations**

We will review CDC's implementation of select agent regulations at its own laboratories. Select agents regulated by CDC are biological agents or toxins that have the potential to pose a severe threat to public health and safety. This effort continues our previous reviews at university, State, and private laboratories, which generated recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR pt. 73, we will assess compliance with select agent Federal regulations regarding security plans, accountability for select agents, and access to select agents. *(OAS; W-00-07-58200; A-04-07-01051; expected issue date: FY 2009; work in progress and new start)*

### **Select Agent Transfers**

We will review laboratories' compliance with regulations regarding the transfer of select agents. Federal regulations at 42 CFR § 73.10(a) require that access to select agents, which are biological agents and toxins that have the potential to pose a severe threat to public health and safety, be restricted to persons approved by the Secretary of HHS (the Secretary) following a security risk assessment by the Attorney General. The Department of Transportation's hazardous materials regulations at 49 CFR pts. 171 to 180 govern how hazardous materials, such as select agents, are to be packaged, shipped, and transported. Prior OIG reviews found that unauthorized individuals had access to select agent shipments. Our review will focus on transfers at laboratories registered with CDC to possess and transfer select agents and will exclude laboratories operated by CDC itself. *(OAS; W-00-07-56150; A-02-07-02010; expected issue date: FY 2009; work in progress)*

### **Deemed Exports**

We will review CDC's compliance with Department of Commerce's (DOC) Export Administration Regulations at 15 CFR, Chapter VII, subchapter C, for foreign nationals working at CDC and having access to certain equipment. Release of covered goods and technologies to a foreign national constitutes a "deemed export" and requires a license in accordance with the Export Administration Act of 1979 and Executive Order 13222 (August 17, 2001). DOC controls the export of certain goods and technologies for reasons of national security. We will

determine whether CDC obtained the required licenses for foreign nationals who worked at CDC and had access to covered equipment.

*(OAS; W-00-09-58130; expected issue date: FY 2009; new start)*

### **Contracting Procedures**

We will review CDC's contracting procedures to determine whether applicable criteria and regulations have been followed. In its contracting activities, CDC is required to follow the Federal Acquisition Regulation (FAR) and the HHS Acquisition Regulation (HHSAR) at Title 48 of the CFR.

*(OAS; W-00-08-56033; expected issue date: FY 2009; work in progress)*

### **Monitoring of Subrecipient Emergency Preparedness Expenditures**

We will review the adequacy of a State's monitoring of subrecipient expenditures charged to the Public Health Emergency Preparedness Program. The purpose of this program is to upgrade and integrate State and local public health jurisdictions' preparedness for and response to terrorism and other public health emergencies. Pursuant to Office of Management and Budget (OMB) Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, App. B, § h(3) (codified in 2 CFR pt. 225), State grantees of the Public Health Emergency Preparedness Program are required to provide time and effort certifications for employees who are expected to work solely on that Federal award. Under 45 CFR § 92.40, grantees must also manage and monitor day-to-day operations of their subgrantees to assure compliance with Federal requirements. A prior review disclosed that one State was not able to provide the required certifications for its employees who charged 100 percent of their time and effort to the Public Health Emergency Preparedness Program. We will determine whether similar salary charges have been made at the subrecipient level and assess the adequacy of the State's subrecipient expenditure monitoring process.

*(OAS; W-00-09-52404; A-01-09-00000; expected issue date: FY 2009; new start)*

### **The CHEMPACK Project: Storage of Drugs To Treat Nerve Agent Exposure**

We will review the extent to which CHEMPACK drugs are stored in accordance with Federal temperature and humidity requirements and the extent to which CDC ensures that CHEMPACK drugs meet Federal requirements of the Shelf Life Extension Program (SLEP). In the CHEMPACK project, CDC assembles and distributes containers stocked with drugs to treat nerve agent exposure to selected locations throughout the country. The drugs must be stored in accordance with Federal regulations, including 21 CFR pt. 205, Guidelines for State and Licensing of Wholesale Prescription Drug Distributors; 21 CFR pt. 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; and 21 CFR pt. 211, Current Good Manufacturing Practice for Finished Pharmaceuticals. In addition, CDC participates in FDA's SLEP to extend the expiration dates of CHEMPACK drugs and defer drug replacement costs. CDC has reported that use of the SLEP program has resulted in significant cost savings for the program. In 2006, OIG issued a report on early CHEMPACK project implementation, focusing on drug deployment. As CDC shifts into the maintenance phase of the program, OIG will assess CDC's efforts to ensure that CHEMPACK drugs are stored in accordance with Federal regulations and meet SLEP requirements.

*(OEI; 04-08-00040; expected issue date: FY 2009; work in progress)*

### **State 24/7 Reporting Systems**

We will review the status of States' systems for receiving urgent reports of bioterrorism agents and other public health emergencies. Pursuant to authority granted under 42 U.S.C. §§ 247d-3 and 247d-3a, CDC funds Public Health Emergency Preparedness Cooperative Agreements that include critical tasks that States must accomplish to improve the timeliness and accuracy of communications regarding threats to the public's health and to decrease the time needed to classify health events, such as terrorism or naturally occurring disasters. The State must operate urgent disease and public health emergency reporting systems 24 hours per day, 7 days per week (24/7 systems). These 24/7 systems enable health care providers to report to or consult with State or local health department staff at any time regarding suspected or confirmed diseases that require urgent reporting. We will evaluate State 24/7 systems to assess State preparedness for receiving urgent reports and the functionality of these systems.  
(OEI; 00-00-00000; expected issue date: FY 2010; new start)

### **Fraud and Abuse Safeguards for the Vaccines for Children Program**

We will review Vaccines for Children (VFC) grantees' compliance with CDC's fraud and abuse program safeguard requirements. The Social Security Act, § 1902(a)(62), requires that a program for vaccinating eligible children be included in each State's Medicaid eligibility plan. The Social Security Act, § 1928, provides for the Federal Government to purchase vaccines on behalf of States as part of the vaccination program. CDC requires VFC grantees to develop and implement comprehensive fraud and abuse policies. Specifically, grantees must submit written fraud and abuse policies to CDC annually. We will also review the adequacy of CDC's oversight of VFC grantees' fraud and abuse activities.  
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **Community Health Center Adoption of Recommendations for Human Immunodeficiency Virus Testing in Health Care Settings**

We will review the extent to which health care providers in Community Health Centers have received and adopted CDC's recommendations for HIV testing in health care settings. Each year, 40,000 people in the United States become infected with HIV. CDC's recommendations, issued on September 22, 2006, aim to make HIV testing a routine part of medical and prenatal care and are a key strategy in CDC's effort to reduce the number of new HIV infections in the United States by 50 percent. Intended for all health care providers in the public and private sectors, CDC's recommendations include the following: HIV screening for all patients ages 13 to 64 in a health care setting; inclusion of screening in the routine panel of prenatal tests for all pregnant women, unless the patient declines; and incorporation of HIV screening into the general consent for medical care rather than requiring a separate consent. We will also review activities CDC has undertaken to encourage Community Health Centers to adopt CDC's HIV guidelines.  
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

### **State and Local Preparedness for Pandemic Influenza: Mass Prophylaxis and Medical Surge**

We will review the extent to which selected States and localities met the preparedness goals outlined in CDC's Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II (the Guidance). The Guidance describes preparedness goals for States and localities for 2006 and 2007, including five target

capabilities: medical surge, mass prophylaxis, isolation and quarantine, planning, and communications. The Guidance also defines critical tasks for each of these target capabilities. Using criteria that include these critical tasks, we will examine how selected States and localities have prepared for a medical surge in response to a pandemic influenza. We will also review the extent to which States and localities have plans and resources to distribute and dispense pandemic influenza clinical countermeasures.

*(OEI; 02-08-00210; 04-08-00260; various reviews; expected issue date: FY 2009; work in progress)*

## **Food and Drug Administration**

### **Food and Drug Administration's Implementation of Select Agent Regulations**

We will review FDA's implementation of Federal select agent regulations at its laboratories. This effort continues our previous work at university, State, and private laboratories, which generated recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR pt. 73, we will assess compliance with Federal select agent regulations regarding security plans, accountability for select agents, and access to select agents.

*(OAS; W-00-08-51001; A-02-08-02009; expected issue date: FY 2009; work in progress)*

### **Oversight of Food Safety Operations**

We will review FDA's oversight and operations related to three broad areas: imported foods, imported pet food and feed products, and recall procedures for human food and pet food. These various reviews are being conducted in response to a congressional request. For each of the three areas, we will review the extent of FDA's enforcement authorities, its procedures to implement those authorities, how FDA is carrying out the activities called for in its procedures, and the sufficiency of the authorities. In the area of imported foods, we will review FDA's policies and procedures to determine whether and how FDA determines that foreign countries' food safety standards and inspections meet U.S. food safety requirements (or whether their food products exported to the United States are in compliance with requirements), whether and how FDA determines that foreign measures are equivalent to U.S. food safety measures, and how frequently FDA evaluates companies that export food products to the United States. In the area of imported pet food and feed products, we will review FDA's policies and procedures to determine whether it requires imported pet food and feed to be produced under the same safety standards as those under which they are produced in the United States. We will also determine whether FDA samples imported pet food and feed for chemicals and microbial pathogens. If FDA is not sampling food and feed products, OIG will determine why. In the area of human food and pet food recall procedures, we will review FDA's policies and procedures and specifically determine whether FDA conducted tests for melamine in human food immediately after melamine was found in pet food.

*(OAS; W-00-08-51002; expected issue date: FY 2009; work in progress)*

### **Complaint Investigation Process**

We will review the adequacy of FDA's complaint investigation process, upon which the agency relies in its efforts to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Specifically, we will

determine whether complaints are properly recorded in the Consumer Complaint System and investigated in an expeditious manner as required by FDA's "Investigations Operation Manual," Chapter 8, § 8.2. In addition, we will review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries. (OAS; W-00-09-52406; expected issue date: FY 2009; new start)

### **FDA's Oversight of Postmarketing Surveillance Studies of Medical Devices**

We will review FDA's oversight of medical device postmarketing surveillance studies. Under section 522 of the Food and Drug Administration Modernization Act of 1997, FDA may require sponsors of medical devices to complete postmarketing surveillance for any moderate to high-risk medical device (Class II or III) that has a reasonable likelihood of serious adverse health outcomes. A 2006 OIG study of FDA's oversight of postmarketing study commitments for drugs found that FDA could not readily identify whether or how timely such postmarketing study commitments were progressing toward completion, in part because some information submitted by drug applicants was missing and incomplete. This review will examine the extent to which FDA has required postmarketing studies of medical devices, the level of compliance among sponsors that have been required to perform such studies, and FDA's oversight of sponsors' study commitments. We will also identify trends and challenges associated with postmarketing surveillance studies.

(OAS; 00-09-52407; expected issue date: FY 2009; new start; OEI-00-00-00000; expected issue date: FY 2010; new start)

### **Adverse Event Reporting for Medical Devices**

We will review FDA's adverse-event-reporting system for medical devices. Medical device manufacturers are required under 21 CFR pt. 803 to report deaths, serious injuries, and device malfunctions to FDA within 30 calendar days or within 5 working days if the event requires remedial action to prevent substantial harm to the public. Adverse event reporting is a key part of FDA's oversight of new medical devices, providing an early warning of problems with devices after they reach the market. We will evaluate the extent to which FDA ensures compliance with adverse-event-reporting requirements. We will also examine how FDA uses medical device adverse-event-reports to identify and address safety concerns.

(OEI; 01-08-00110; expected issue date: FY 2009; work in progress)

### **Food Facility Inspections**

We will review FDA's food facility inspection process and its methods for selecting facilities for inspection. FDA monitors the safety of domestic food primarily through inspections of farms, warehouses, manufacturers, packers, and other types of food establishments. Section 704(a) of the Food, Drug, and Cosmetic Act of 1938 (FDCA) authorizes FDA to conduct inspections to enforce the provisions of that statute and other applicable laws. Under this authority, FDA carries out surveillance inspections to gauge overall industry compliance with manufacturing practices and compliance inspections based on known or suspected problems with specific manufacturers. FDA's district offices, with guidance from FDA headquarters, determine the number, type, and specific facilities to be inspected. We will identify trends in the number of FDA facility inspections.

(OEI; 02-08-00080; expected issue date: FY 2009; new start)

## **Compliance With Food Registry Requirements**

We will review food facilities' compliance with Federal registration requirements. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), food facilities are required to register with FDA. Facility registration allows FDA to identify and locate food facilities implicated in a deliberate or accidental contamination of the food supply. Recent instances of food contaminations have highlighted food safety as a critical public health concern. We will assess the extent to which selected facilities have registered with FDA.

*(OEI; 02-08-00060; expected issue date: FY 2009; work in progress)*

## **Traceability in the United States Food Supply Chain**

We will review FDA's ability to trace selected food products back through the U.S. food supply chain. In the event of a food emergency, FDA is responsible for finding the source of the contamination and helping to remove the food products from the food supply chain. Section 306 of the Bioterrorism Act and FDA's regulation at 21 CFR pt. 1, subpart J, require persons who manufacture, process, pack, hold, transport, distribute, receive, or import food under FDA's jurisdiction to maintain records that identify the immediate previous sources and immediate subsequent recipients of food that they receive or release. Compliance with this requirement is intended to enable FDA to trace back through the supply chain any food FDA believes may pose a serious health threat and to trace forward through the food chain to alert facilities of potentially contaminated food. We will determine the extent to which selected food facilities can provide information required by FDA in the event of a food emergency.

*(OEI; 02-06-00210; expected issue date: FY 2009; work in progress)*

## **Oversight of Human Cells, Tissues, and Cellular- and Tissue-Based Products Establishments**

We will review the effectiveness of FDA's oversight of human cells, tissues, and cellular- and tissue-based products (HCT/P) establishments. These establishments process bones, ligaments, skin, tendons, reproductive tissues, heart valves, and other human cellular products for use in a variety of medical treatments. Section 361 of the Public Health Service Act (PHS Act), authorizes FDA to make and enforce regulations necessary to prevent the spread of communicable diseases within the United States, including dangers posed by transplanting HCT/Ps. Subsequent to a 2001 OIG report that identified limitations in FDA's oversight of tissue establishments, FDA promulgated new regulations at 21 CFR pt. 1271. These regulations strengthened FDA's oversight of HCT/Ps and increased the number of inspections of HCT/P establishments that it conducts annually. As part of this follow-up review, we will assess FDA's inspection process for HCT/P establishments.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Foreign Clinical Trials**

We will review the extent to which drug manufacturers use foreign clinical trials to support new drug applications (NDA) submitted to FDA. Section 505(i) of the FDCA and regulations at 21 CFR pt. 312 provide for FDA oversight of clinical trials of new drugs. Sponsors may submit data from foreign clinical trials provided that they meet criteria set forth in 21 CFR § 312.120 related to the qualifications of clinical investigators and participating sites. FDA is prohibited from disqualifying foreign trial data if the trials are conducted in accordance with ethical principles acceptable to the world community. FDA officials interviewed for a 2007 OIG report

estimated that 20 to 30 percent of data used in NDAs come from foreign clinical trials and stated that FDA is often unaware that foreign trials have been conducted until after the results are submitted in NDAs. We will review trends associated with use of foreign clinical trial data in the past 5 years and the number of NDAs supported solely by foreign trial data.  
(OEI-01-08-00510; expected issue date: FY 2009; work in progress)

### **Management of Information Technology Contracts at the Center for Drug Evaluation and Research**

We will review the FDA's Center for Drug Evaluation and Research (CDER) process for selecting information technology (IT) contractors. CDER is involved in new drug development and reviews of new, generic, and over-the-counter drugs, and postapproval activities. Other mission-related activities concern the safety and effectiveness of orphan drugs, the drug registration and listing system, women's health, and pediatric initiatives. As in all HHS agencies, IT is part of CDER's mission critical support infrastructure. In addition to the contractor selection process, we will also review CDER's oversight of the performance of its IT contractors. Requirements in 48 CFR § 302.1 govern FDA's contracting practices.  
(OEI; 01-07-00450; expected issue date: FY 2009; work in progress)

### **Renal Dialysis Facilities' Dosing Guidelines for Erythropoiesis Stimulating Agents**

We will review whether dosing guidelines used by renal dialysis facilities for erythropoiesis-stimulating agents (ESA) adhere to FDA labeling recommendations. In response to research published in 2007, FDA approved revised labeling for ESAs, including a "black box" warning recommending that ESAs be dosed to maintain a hemoglobin value of less than 12 g/dL. According to the revised labeling for ESAs, maintaining hemoglobin levels above 12 g/dL can adversely affect a patient's health, possibly resulting in death. There are concerns that dialysis facilities may be using dosing guidelines, standards, and protocols that are not consistent with the revised labeling recommendations. We will determine the extent to which renal dialysis facilities' dosing guidelines for ESAs are consistent with FDA labeling recommendations.  
(OEI; 00-00-00000; expected issue date: FY 2009; new start)

## **Health Resources and Services Administration**

### **Ryan White Care Act Payer of Last Resort Provision**

We will review States' compliance with the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (Ryan White CARE Act) payer of last resort requirement in the administration of the AIDS Drugs Assistance Program (ADAP) funds. Title II of the Ryan White CARE Act stipulates that grant funds not be used to make payments for items or services that are eligible for coverage by any other Federal or State program or by any health insurance policy. This requirement, commonly referred to as the payer of last resort provision, is outlined in section 2617(b)(7)(F) of the PHS Act. In FY 2006, ADAP grant awards totaled more than \$750 million. A previous OIG report indicated that a significant percentage of payments made for ADAP medications in one State should have been paid by parties other than the ADAP.

(OAS; W-00-08-54260; expected issue date: FY 2009; work in progress)

## **Oversight of the Ryan White Core Medical Services Requirement**

We will review HRSA's oversight of the core medical services requirement of the Ryan White HIV/AIDS Treatment Modernization Act of 2006. Pursuant to this Act, grantees must spend at least 75 percent of funds for Ryan White Parts A–C on “core medical services,” such as outpatient health services, medications, and mental health care. HHS may waive this requirement for a grantee requesting a waiver if there is no ADAP waiting list and if core medical services are otherwise available to all those identified and eligible under this Act. Grantees seeking a waiver self-certify that core medical services are otherwise available. We will assess HRSA's oversight of grantee compliance with the 75-percent requirement, grantees' processes for self-certifying availability of core medical services, and HRSA's oversight of self-certification.

*(OEI; 07-08-00240; expected issue date: FY 2009; work in progress)*

## **Oversight of Health Centers**

We will review health centers' quality assurance activities as well as HRSA's oversight of these activities. Pursuant to 42 CFR § 51c.303(c), health centers receiving HRSA grants are required to have ongoing quality assurance programs. In FY 2002, Congress appropriated for the President's Health Initiative an additional \$780 million over 5 years to expand the Nation's health center network and manage quality improvement activities at health centers. We will examine the quality assurance programs and periodic assessments of a random sample of health centers. We will also use this sample to determine the extent to which HRSA performance reviews have assessed health centers' quality assurance programs and quality of care.

*(OEI; 09-06-00420; expected issue date: FY 2009; work in progress)*

## **Reporting Adverse Actions to the Healthcare Integrity and Protection Data Bank**

We will review the extent to which HHS agencies have reported adverse actions to the Healthcare Integrity and Protection Data Bank (HIPDB). The Health Insurance Portability and Accountability Act of 1996 directed the Secretary, acting through OIG and the Attorney General, to create HIPDB to help combat fraud and abuse in health care delivery. The HIPDB, operated by HRSA under a memorandum of agreement with OIG, is a national data bank containing “adverse actions” taken against health care practitioners and suppliers, including OIG exclusions, criminal convictions, and civil judgments related to health care. As such, adverse actions taken by the Centers for Medicare & Medicaid Services (CMS), FDA, IHS, HRSA, NIH, and OIG are required to be reported to the HIPDB. We will determine whether the HIPDB contains all HHS-imposed actions and whether there are any impediments to reporting such actions.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

## **Indian Health Service**

### **Contract Health Services**

We will review the extent to which IHS pays providers more than the Medicare rate for contract health services. IHS provides health care through a combination of direct care provided onsite at IHS-funded facilities and contract health services, which are purchased pursuant to 42 CFR pt. 136, subpart C, from other public and private providers. A 1999 OIG study found that IHS could save money and serve more patients if it paid no more than the Medicare rate for contract

health services. Pursuant to section 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, hospitals that provide inpatient services payable under Medicare must participate in the IHS Contract Health Service program and accept rates established by HHS as payment in full. In effect, regulations at 42 CFR § 136.30 base the payment rate for contract health services on the Medicare PPS rate. We will determine whether IHS paid providers at or below the Medicare rate for contract health services.

*(OEI; 05-08-00410; expected issue date: FY 2009; work in progress)*

### **Provision of Dialysis and Mental Health Services**

We will assess the provision of dialysis and mental health services at IHS facilities. Mortality rates for many illnesses, including alcoholism, diabetes, and suicide, are significantly higher among American Indians and Alaska Natives than among other Americans. Provision of dialysis and mental health services poses particular challenges due to the need for specialized equipment and/or staff. If services are not provided at a local IHS facility, patients may need to travel a significant distance to receive services. Additionally, when services are not provided at an IHS facility, patients may rely on contract health services, which are purchased pursuant to 42 CFR pt. 136, subpart C, from other public and private providers. Funding for contract health services is limited and may be exhausted before the end of each year. We will determine the availability of dialysis and mental health services at IHS facilities as well as the distance patients must travel for these services.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Accounting for Medication Inventory**

We will review IHS's accounting for medication inventory. OMB Circular A-123, Management's Responsibility for Internal Control, Section II, requires Federal managers to implement controls to provide reasonable assurance that assets are safeguarded against waste, loss, unauthorized use, or misappropriation. Although IHS is required to implement inventory procedures for drugs controlled by the Drug Enforcement Administration (DEA), there is no commensurate Federal requirement for inventories of non-DEA-controlled drug products, which account for most of the drugs on hand. We will determine whether pharmacies in IHS facilities have implemented controls to ensure accountability for their medication inventories.

*(OAS; W-00-08-55060; various reviews; expected issue date: FY 2009; work in progress)*

### **Background Investigations To Protect Indian Children**

We will review the handling of background investigations required by the Indian Child Protection and Family Violence Prevention Act. This law requires that all IHS employees and contractors with regular contact with, or control over, Indian children be investigated for any history of certain criminal acts. Previous OIG work found inconsistent practices regarding staff background investigations. We will determine whether IHS and tribal organizations have completed required background investigations.

*(OAS; W-00-08-55010; various reviews; expected issue date: FY 2009; work in progress)*

### **Indian Health Service Loan and Repayment Programs**

We will review the internal controls that IHS has in place for its scholarship and loan repayment programs. The Indian Health Care Improvement Act of 1976 authorizes IHS funding to recruit and retain health professionals who provide health care services to the Indian population.

Several of these programs require that the recipients of these funds enter into contracts with the IHS whereby they are required to fulfill service obligations or repay the funds if the obligations are not fulfilled. We will determine whether IHS has adequate internal controls to monitor recipients' compliance with their scholarship and loan repayment program requirements. (OAS; W-00-09-57208; *expected issue date: FY 2010; new start*)

## **National Institutes of Health**

### **Superfund Financial Activities for Fiscal Year 2008**

We will review the payments, obligations, reimbursements, and other uses of Superfund monies by NIH's National Institute of Environmental Health Sciences (Institute). A provision of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, codified at 42 U.S.C. § 9611(k), requires that OIG conduct an annual audit of the Institute's Superfund activities, carried out by its own staff and through cooperative agreements, which include training for people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals.

(OAS; W-00-09-57201; *expected issue date: FY 2009; new start*)

### **National Institutes of Health's Implementation of Select Agent Regulations**

We will review NIH's implementation of select agent regulations at its laboratories. This effort continues our previous work at university, State, and private laboratories, which led to OIG recommendations aimed at strengthening control of select agents. Pursuant to 42 CFR pt. 73, we will assess compliance with Federal select agent regulations regarding security plans, accountability for select agents, and access to select agents.

(OAS; W-00-08-56031; *various reviews; expected issue date: FY 2009; work in progress*)

### **National Institute of Environmental Health Science's Grant Process**

We will review issues related to grants made by the Institute to determine whether it complies with the HHS "Grants Administration Manual" and whether FY 2005 to 2007 expenses incurred by its Director's office were in accordance with NIH policies. This review is being conducted in response to a congressional request.

(OAS; W-00-09-57203; *expected issue date: FY 2009; new start*)

### **Financial Conflicts of Interest in Research Funded by the National Institutes of Health**

We will review NIH's oversight of grantees' compliance with financial conflicts-of-interest requirements. Eighty percent of NIH funding is allocated through extramural research grants. Federal regulations at 42 CFR pt. 50, subpart F, establish standards to ensure that research is not biased by financial conflicts of interest and require grantee institutions to have written policies for identifying financial conflicts of interest and ensuring that conflicts are managed, reduced, or eliminated. We will review NIH's processes for reviewing the nature and management of financial conflicts of interest reported by grantee institutions during FY 2006.

(OEI; 03-07-00700; *expected issue date: FY 2009; work in progress*).

## **Colleges' and Universities' Compliance With Cost Principles**

We will review colleges' and universities' compliance with selected cost principles governed by OMB Circular A-21, Cost Principles for Educational Institutions. We will conduct reviews at selected schools based on the dollar value of Federal grants received and on input from HHS' operating divisions and the offices of the Assistant Secretary for Budget, Technology, and Finance and the Assistant Secretary for Administration and Management.

*(OAS; W-00-09-57204; expected issue date: FY 2009; new start)*

## **Use of Data and Safety Monitoring Boards in Clinical Trials**

We will review the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. A DSMB is a group of individuals with pertinent expertise that regularly reviews accumulated data from one or more ongoing clinical trials to ensure the safety of participants in the trials and the validity and integrity of the scientific data generated. The NIH Policy for Data and Safety Monitoring, set forth in June 1998, requires that all NIH-funded clinical trials establish data- and safety-monitoring plans. A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial. This requirement sets minimum responsibilities that sponsoring Institutes and Centers must meet to ensure and oversee data and safety monitoring. We will also determine how and to what extent NIH is ensuring that grantees comply with the NIH policy for DSMBs in multisite clinical trials.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

## **Clinical and Translational Science Awards**

We will review the National Center for Research Resources' (NCRR) process for overseeing Clinical and Translational Science Award (CTSA) grantees. The CTSA program began in 2006 to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at various medical colleges and universities. The CTSA program awards 5-year grants to 12 academic health centers annually. When fully implemented in 2012, the CTSA program will consist of a consortium of 60 institutions that facilitates the creation of translational science networks and biomedical informatics tools. NCRR oversees this program and its milestones for compliance with CTSA program objectives and HHS grant administration requirements at 45 CFR pt. 74. Congress awarded over \$300 million during the first 2 years of this program, with funding of the full CTSA initiative expected to exceed \$500 million annually by 2012. We will also examine the types of innovative information sharing techniques developed through the CTSA program.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

# **Substance Abuse and Mental Health Services Administration**

## **Substance Abuse Prevention and Treatment Block Grants**

We will review one State's expenditures of SAMHSA-funded Prevention and Treatment Block Grants (SAPTBG) for State FYs 2003 through 2007. The State's SAPTBG expenditures have exceeded its awards for the past several years. SAMHSA requested that OIG perform this review to determine whether the State's proposed plan for addressing the deficit will meet applicable Federal requirements specified in 42 U.S.C. § 300x-30 and 45 CFR § 96.134.

*(OAS; W-00-09-57205; expected issue date: FY 2009; new start)*

## **Cross-Cutting Public Health Activities**

### **Oversight of Federal Advisory Committee Special Government Employee Conflicts of Interest**

We will review HHS officials monitoring of conflicts of interest reported by special Government employees who serve on Federal advisory committees. Pursuant to 5 CFR pt. 2634, the HHS Designated Agency Ethics Official and Deputy Ethics Counselors oversee submission and review of financial reports required of all employees in HHS, including special Government employees. For Federal advisory committees' advice, recommendations, and guidance to be credible, it is important that special Government employees be free from conflicts of interest that may impair their independence. We will also assess HHS's documentation of required ethics training for special Government employees.

*(OEI; 04-07-00260; various reviews; expected issue date: FY 2009; work in progress and new start)*

### **Use of Public Health Preparedness and Response for Bioterrorism Program Funds in Gulf Coast States**

We will review the use of Public Health Preparedness and Response for Bioterrorism program funds in five Gulf Coast States that were affected by the 2005 hurricanes. The funding, authorized under sections 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2 of the PHS Act, is to be used to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. We will determine whether funding recipients used program funds for approved purposes and assess the extent to which program funds contributed to hurricane response and recovery efforts.

*(OAS; W-00-07-58201; various reviews; expected issue date: FY 2009; work in progress and new start)*

### **Pandemic Influenza Expenditures**

We will review pandemic influenza spending in three States. CDC awards Federal grant funds to States to develop an effective national response to a possible influenza outbreak of pandemic proportions. States' use of these funds is governed and regulated by OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, and the award terms specified in Cooperative Agreement AA154, which explains the funding and provides specific criteria for our audit testing. We will determine whether these States have complied with these requirements in using pandemic influenza grant funds.

*(OAS; W-00-09-58131; expected issue date: FY 2009; new start)*

### **Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation**

We will review States' use of the Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. The program, authorized under sections 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2 of the PHS Act, provides funding to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. States may not use Federal funds to compensate State employees for non-Federal services that States have provided in the immediately prior years. We will

determine whether States have inappropriately used program funding to compensate State employees.

*(OAS; W-00-09-57207; various reviews; expected issue date: FY 2009; new start)*

## **Investigations**

### **Violations of Select Agent Requirements**

OIG continues to receive requests for information and investigations of alleged terrorist and bioterrorist activities relating to select agents. On March 18, 2005, HHS issued a final regulation at 42 CFR pt. 73 on Possession, Use, and Transfer of Select Agents and Toxins, which applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. The rule authorizes OIG to conduct investigations and to impose civil monetary penalties (CMP) against individuals or entities for violations of these select agent and toxin requirements. As of May 2008, OIG had settled 11 cases involving violations of the select agent regulations and had collected a total of \$887,000 in CMPs. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of the statute governing the registration, storage, and transfer of select agents and toxins.

## **Legal Activities**

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General (OCIG) coordinates OIG's role in the resolution of civil and administrative fraud cases and promotes compliance measures by recipients of HHS grant funding. In the public health area, OCIG will continue to work closely with OIG investigators and auditors and with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal False Claims Act cases against institutions that receive grant funds from NIH and other public health service agencies. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases.

## **Human Service Programs**

Several HHS agencies support human services to assist vulnerable individuals of all ages, including the Administration on Aging, which supports programs that provide 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; and the Administration for Children and Families (ACF), which operates over 30 programs that promote the economic and social well-being of children, families, and communities, including Temporary Assistance for Needy Families (TANF); the national child support enforcement (CSE) system; the Head Start program for preschool children; and assistance for child care; foster care; and adoption services.

Our planned reviews of human service programs follow.

## Administration on Aging

### Aging Programs in One State

We will review one State's aging program grants. Pursuant to Title III of the Older Americans Act of 1965, HHS awards funds to States to develop systems for support services through designated State agencies. These grants also seek to maximize support to enable senior citizens to remain in their homes and communities and to support nutrition services. Non-Federal audits have identified problems in accounting for funds, unspent funds, and inadequately documented matching contributions. We will determine whether aging program grants in a State complied with Federal requirements.

*(OAS; W-00-08-26002; expected issue date: FY 2009; work in progress)*

## Administration for Children and Families

### Foster Care and Adoption Assistance Training and Administrative Costs

We will review foster care and adoption assistance training and other administrative costs claimed under Title IV-E of the Social Security Act. The Social Security Act, §§ 474(a)(3)(A)-(B) and 474(a)(3)(E), provides for Federal reimbursement of training and administrative costs, respectively. Title IV-E training and other administrative costs have increased dramatically in relation to maintenance payments in recent years. Prior OIG reviews in three States found that unallowable costs were claimed, costs were improperly allocated, and/or costs were otherwise unsupported. We will determine whether current and retroactive claims were allowable and reasonable and were supported in accordance with laws and regulations and States' cost allocation plans.

*(OAS; W-00-08-24100; various reviews; expected issue date: FY 2009; work in progress)*

### Foster Care Per Diem Rates

We will review foster care maintenance payments claimed under Title IV-E of the Social Security Act on behalf of children. The Social Security Act, § 475(4)(A), defines foster care maintenance payments as payments to cover the cost of food, clothing, shelter, daily supervision, school supplies, a child's personal incidentals, liability insurance with respect to a child, and reasonable travel to the child's home for visitation. A prior OIG review found that some services included in per diem rates were not eligible for Title IV-E foster care maintenance payments. We will determine whether State agencies claimed Title IV-E maintenance and associated administrative costs in accordance with Federal requirements.

*(OAS; W-00-08-24101; expected issue date: FY 2009; work in progress)*

### Costs Billed by Child-Placing Agencies

We will review child-placing agencies' maintenance payments and administrative costs claimed under Title IV-E of the Social Security Act. Under the Social Security Act, § 475(4)(A), foster care maintenance payments cover a child's basic needs, such as food, clothing, shelter, and personal incidentals. In the case of institutional care, maintenance costs also include the costs of administration and operation of the institution. Preliminary work in one State showed that even though the administrative costs for child-placing agencies were included in the maintenance payments, these costs were also being billed to the State as additional administrative costs.

We will determine whether and to what extent States have received duplicate reimbursement for the administrative costs of child-placing agencies.

*(OAS; W-00-09-25024; expected issue date: FY 2009; new start)*

### **Group Home and Foster Family Agency Rate Classification**

We will review one State's foster care payment rates made for group homes and/or foster family agency treatment programs. Federal regulations at 45 CFR §§ 1356.60(a)(1)(i) and 1356.71(d)(2) provide that Federal financial participation is available for allowable costs of foster care maintenance payments and that States must review the amount of the payments to ensure the continued appropriateness of the amounts. The auditee State's Code provides that rates be established by classifying each group home program and applying the standardized schedule of rates. The foster care payment amount correlates with the rate classification level. Payments are initially established at a provisional rate; the State subsequently conducts audits to establish the actual rate classification level. We will determine whether foster care payment rates made for group homes and/or foster family agency treatment programs in the State were accurate.

*(OAS; W-00-09-25205; expected issue date: FY 2009; new start)*

### **Adoption Assistance Subsidies**

We will review States' claims for Federal reimbursement of adoption assistance subsidies to determine compliance with eligibility requirements. The Social Security Act, §§ 473(a) and 473(c), establishes adoption assistance eligibility requirements. Federal subsidy payments are provided to families to ensure that they have the necessary services and financial resources to meet the special needs of some adopted children. A previous OIG review of one State's adoption assistance subsidies identified payments to families that did not meet eligibility requirements.

*(OAS; W-00-08-24009; expected issued date: FY 2009; work in progress )*

### **Foster Care Claims for the Placement of Delinquent Children**

We will review foster care maintenance costs claimed by several States under Title IV-E of the Social Security Act for the placement of delinquent children. Pursuant to the Social Security Act, § 475(4)(A), maintenance costs include room and board payments to licensed foster parents, group homes, and residential child care facilities for children who meet Title IV-E program requirements. A prior OIG review found that claims were submitted for ineligible children, that some services were not provided, and some services were ineligible. We will determine whether foster care maintenance costs under Title IV-E for the placement of delinquent children were claimed in compliance with applicable Federal requirements.

*(OAS; W-00-06-25023; various reviews; expected issue date: FY 2009; work in progress and new start)*

### **Foster Care Preplacement/Candidacy Costs**

We will review State claims for foster care candidate costs. The Social Security Act, § 472(i)(2), allows States to claim administrative costs for allowable preplacement activities on behalf of foster care candidates. A candidate for foster care is a child who is at imminent risk of removal from his/her home. Under 45 CFR § 1356.60(c)(2), administrative costs cover staff activities, such as case management and supervision of children placed in foster care and children

considered to be candidates under Title IV-E of the Social Security Act. In several States, we will determine whether costs for candidates were properly claimed.  
(OAS; W-00-09-25026; expected issue date: FY 2009; new start)

### **Foster Children Over 19 Years Old**

We will review foster care maintenance payments made on behalf of children over the age of 19. Children over 19 years old are ineligible for foster care maintenance payments. The Social Security Act, § 472, limits Title IV-E eligibility to children under age 18, or over age 18 but under age 19 if full-time students (Title IV-A State plan option). The Adoption and Foster Care Analysis and Reporting System database, maintained by ACF, listed more than 9,900 of 513,000 children who were over 19 years old as of September 30, 2005. We will determine whether foster care maintenance payments were made on behalf of children over the age of 19.  
(OAS; W-00-09-25027; expected issue date: FY 2009; new start)

### **Oversight of System Design of Statewide Automated Child Welfare Information Systems**

We will review ACF's oversight, guidance, and assistance to States directed to ensuring that States' new Statewide Automated Child Welfare Information System (SACWIS) initiatives are appropriately focused and successfully implemented with potential risks minimized. Federal regulations at 45 CFR § 95.621 require that ACF continually review, assess, and inspect the planning, design, and operation of SACWIS systems to determine how such systems meet the requirements imposed by law, regulations, and guidelines. Pursuant to 45 CFR § 1355.52, States may receive 50-percent FFP for the costs of planning, design, development, and installation of a statewide child welfare information system. In addition, we will determine whether the costs claimed by States for the systems are allowable.  
(OAS; W-00-09-25028; expected issue date: FY 2009; new start)

### **Foster Care Programs Collection and Reporting of Child Support Payments**

We will review and reconcile States' records of children in foster care with corresponding States' collections of child support. Federal regulations at 45 CFR 302.52 require that States' collections of child support payments for children in foster care be used to offset Foster Care program costs instead of being sent to individuals who no longer have custody of the children. To facilitate offsets, Foster Care program agencies are required to report identifying information for children in foster care to States' CSE agencies. We will determine the extent to which prompt and accurate reporting takes place, reconcile the reports with corresponding offsets, and identify the causes of any discrepancies.  
(OAS; W-00-09-25029; expected issue date: FY 2009; new start)

### **Temporary Assistance for Needy Families Improper Payment Rate**

We will review TANF basic assistance payments to determine the extent to which State agencies made payments to individuals who did not meet Federal and State eligibility requirements. The Improper Payments Information Act of 2002 requires Federal agencies to estimate improper payments. HHS and OMB have requested that OIG review State TANF programs to establish a statistically valid estimate of improper payments. We will review TANF basic assistance expenditures for a 1-year period ending March 31, 2007, in one State. We will establish an improper payment rate for the State reviewed and incorporate the data into the results from other

States we are currently reviewing to develop a nationwide TANF improper payment rate. (OAS; W-00-08-20016; various reviews; expected issue date: FY 2009; work in progress and new start)

### **Services for Recently Arrived Refugees**

We will review grantee compliance with terms and conditions for grants and contracts awarded under section 412(c) of the Refugee Act of 1980. Section 412(c) allows the Director of Refugee Resettlement to make grants to, and enter into contracts with, public or private nonprofit agencies for projects specifically designed to assist refugees in obtaining the skills necessary for economic self-sufficiency; to provide training in English where necessary; and to provide health, social, educational, and other services. We will determine whether agencies have met the terms and conditions of their respective grants and contracts.

(OAS; W-00-09-25030; expected issue date: FY 2009; new start)

### **Head Start Matching Costs**

We will review Head Start matching claims to determine whether grantees met the 20-percent match of total costs required for Federal Head Start funding. Regional ACF officials have indicated to us that grantees might not be meeting the Head Start matching requirement. Federal regulations at 45 CFR §§ 74.23 and 1301.20 establish which costs a grantee can consider to satisfy the required match. We will also identify any challenges facing grantees in meeting the matching requirement.

(OAS; W-00-08-24014; expected issue date: FY 2009; work in progress)

### **Head Start Agencies' Use of Grant Funds**

We will review the use of funds received by Head Start agencies. Recipients of Head Start funds are required to ensure that these funds are used for authorized purposes, as required by 45 CFR § 92.20(b)(3). We will determine whether funds were properly used for the purposes outlined in Federal award letters and approved Head Start agency grant applications and program requirements.

(OAS; W-00-09-25031; various reviews; expected issue date: FY 2009; new start)

### **Licensing Standards and Health and Safety Monitoring at Child Care Facilities**

We will review licensing, health, and safety standards at selected child care facilities that received Federal Head Start funding and/or Federal funding from the Child Care and Development Fund (CCDF). Federal regulations for the CCDF at 45 CFR § 98.15(b)(4)-(6) require States to certify that they have licensing and health and safety requirements applicable to child care services in accordance with 45 CFR §§ 98.40 and 98.41. A previous OIG review of one Head Start grantee that also provided CCDF day care services found several instances in which child care facilities did not comply with the applicable health and safety requirements. Federal Head Start Performance Standards at 45 CFR §§ 1304 and 1308 require that Head Start facilities comply with State and local child care licensing requirements. If States do not have licensing requirements, or the States' requirements are less stringent than Federal standards, the facilities must comply with the Head Start health and safety requirements found at 45 CFR §1304.53(a). We will determine the extent to which Head Start grantees and States have

demonstrated that child care facilities receiving Federal funding have complied with applicable requirements.

*(OAS; W-00-09-25032; various reviews; expected issue date: FY 2009; new start. OEI; 00-00-0000; expected issue date: FY 2010; new start.*

### **Use of Financial Institution Data Match To Collect Child Support**

We will review the effectiveness of States' use of the Financial Institution Data Match (FIDM) to collect payment of arrears and ongoing support obligations. The Social Security Act, § 466(a)(17), requires States to establish procedures under which States' CSE agencies enter into agreements with financial institutions doing business in the States to develop and operate the FIDM for purposes of securing information leading to the enforcement of child support orders. Since its inception in 1999, the FIDM has assisted in the collection of billions of dollars in past-due and current support. As an enforcement tool, the FIDM is targeted primarily at increasing the collection of arrears. Payment of arrears through the FIDM may also reestablish contact between States and noncustodial parents and result in increases in ongoing support. We will identify any existing factors that may limit the effectiveness of the FIDM in increasing collections and reducing arrears.

*(OEI; 00-00-00000; expected issue date: FY 2010; new start)*

### **Federal Employers' Payment Submissions to Child Support State Disbursement Units**

We will assess the procedural accuracy of Federal employers' payment submissions to Child Support State Disbursement Units. In a 2000 OIG review of State Disbursement Units, managers of these units reported that child support payments from Federal agencies were often labeled poorly or delivered incorrectly, which caused delays in States' disbursement of payments to families. OIG recommended that the Office of Child Support Enforcement work with Federal employers to improve payment practices. This follow-up review will determine whether these problems have been corrected. Specifically, we will determine if Federal payers accurately label and submit payments, identify barriers to proper labeling and submission, and assess the impact on agencies and families of deficient practices on the part of Federal payers.

*(OEI; 00-00-00000; expected issue date: FY 2009; new start)*

### **Undistributable Child Support Collections**

We will review undistributable child support collections and program income reported by States. In accordance with Federal regulations at 45 CFR § 304.50, undistributable child support collections that are retained by a State must be counted as program income and used to reduce program expenditures under Title IV-D of the Social Security Act. Historically, States have had difficulty in distributing sizable amounts of support payments because certain identifiers, such as custodial parents' addresses, were not current or the case numbers were omitted from collection receipts. Prior OIG reviews have identified several States that did not recognize or report as program income undistributable child support collections or interest earned on these balances. We will determine whether the Federal Government received its share of any program income earned in interest-bearing accounts or for undistributed balances written off by States.

*(OAS; W-00-08-23080; various reviews; expected issue date: FY 2009; work in progress)*

### **Child Support Incentive Payments**

We will review child support incentive payments made to States. States are eligible to receive child support incentive payments after meeting certain performance measures. The Social Security Act, § 458(f), requires States receiving child support incentive payments to reinvest the payments into their CSE programs or use the funds for other approved activities that will improve their CSE programs. We will determine whether States properly used child support incentive payments.

*(OAS; W-00-09-23150; expected issue date: FY 2009; new start)*

### **Interest Earned on Child Support Enforcement Funds**

We will review interest earned by local government entities that receive CSE funds. Pursuant to 45 CFR § 92.21(i), interest earned on advances, except for interest earned on advances of funds exempt under the Intergovernmental Cooperation Act of 1968, must be remitted to the Federal Government at least quarterly. A prior OIG review found that Federal funds that a county received for administering the CSE program were commingled with other county funds and that the interest earned on the commingled funds was considered general-purpose revenue and used to support countywide operations. We will determine whether the Federal Government received credit for the income received on invested funds and whether Federal program funds were drawn down and disbursed before the funds were needed.

*(OAS; W-00-09-23151; expected issue date: FY 2009; new start)*

### **Increasing Child Support Collections**

We will review States' procedures for collecting child support from self-employed noncustodial parents. A prior review in one State disclosed that the State increased child support collection by more than \$1 million as a result of enacting legislation to identify earnings from self-employed noncustodial parents. We will determine the adequacy of procedures for and extent of increases in child support collections by States that have implemented the necessary legislation to identify earnings and collect child support from self-employed individuals whose families are receiving TANF.

*(OAS; W-00-09-25033; expected issue date: FY 2009; new start)*

### **Followup to Noncustodial Parents' Contributions Toward Medicaid Premiums**

We will review ACF's and CMS's implementation of our recommendations requiring noncustodial parents to contribute to their children's Medicaid costs. In a prior review of eight States, we found that noncustodial parents could have contributed over a 1-year period an estimated \$99 million in Medicaid costs for children in foster care as set forth under Title IV-D of the Social Security Act. We will determine whether cost savings have been achieved or can be achieved if noncustodial parents are required to contribute toward their children's Medicaid costs.

*(OAS; W-00-09-25034; expected issue date: FY 2009; new start)*

### **Investigations Under the Child Support Enforcement Task Force Model**

Project Save Our Children is a coordinated effort to identify, investigate, and prosecute individuals who fail to meet their court-ordered support obligations. This project brings together OIG, the U.S. Marshals Service, DOJ, State and local law enforcement, local prosecutors, State child support agencies, and other interested parties to enforce Federal and

State criminal child support statutes. For FY 2007, OIG reported, as part of Project Save Our Children, 98 criminal convictions and approximately \$6.6 million in court-ordered fines, penalties, and restitution. In FY 2009, we plan to continue our efforts to encourage and coordinate the efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases.

## Departmentwide Issues

Certain financial, performance, and investigative issues cut across HHS programs. Our ongoing and planned work addresses departmentwide issues, such as financial statement audits; financial accounting; information systems management; and other departmental issues, including discounted airfares, travel cards, and purchase cards.

We have discretion in allocating most of our non-Medicare and non-Medicaid resources; a portion, however, is used for mandatory reviews. These include financial statement audits conducted pursuant to section 405(b) of the Government Management Reform Act of 1994 (GMRA) and the Chief Financial Officers Act of 1990 (CFO Act) and information systems reviews required by the Federal Information Security Management Act of 2002 (FISMA).

The GMRA seeks to ensure that Federal managers have at their disposal the financial information and flexibility necessary to make sound policy decisions and manage scarce resources. The GMRA broadened the CFO Act by requiring annual audited financial statements for all accounts and associated activities of HHS and other Federal agencies.

## Financial Statement Audits

### Audits of Fiscal Years 2008 and 2009 Financial Statements

We will review the independent auditor's workpapers to determine whether financial statement audits of HHS and its components were conducted in accordance with applicable laws and regulations. The purpose of a financial statement audit is to determine whether the financial statements present fairly, in all material respects, the financial position of the audited entity for the specified time period. The audited consolidated HHS FY 2008 financial statements are due to OMB by November 17, 2008; for FY 2009, they are due by November 16, 2009.

The following FY 2008 financial statement audits will be completed and reports will be issued during FY 2009:

Consolidated HHS – This audit incorporates all operating divisions, including those that will receive separate audit reports (listed below).  
(OAS; W-00-08-40009; A-17-08-00001)

CMS (OAS; W-00-08-40008; A-17-08-02008)

The following FY 2009 financial statement audits will be completed and reports will be issued during FY 2010:

Consolidated HHS – This audit will incorporate all operating divisions, including those that will receive separate audit reports (listed below). (OAS; W-00-09-40009)

CMS (OAS; W-00-09-40008)

### **Fiscal Year 2009 Statement on Auditing Standards 70 Examinations**

We will review the independent auditor's workpapers to determine whether the Statement on Auditing Standards (SAS) 70 examinations of HHS's service organizations were conducted in accordance with applicable laws and regulations. An SAS 70 examination reports on the controls of a service organization that may be relevant to the user organization's internal control structures. The following SAS 70 examinations of HHS service organizations will support FY 2009 financial statement audits and will be issued during FY 2009:

Center for Information Technology (NIH Computer Center)  
(OAS; W-00-09-40012)

Program Support Center and Major Administrative Support Services  
(OAS; W-00-09-40012)

Payment Management System  
(OAS; W-00-09-40012)

### **Fiscal Years 2008 and 2009 Financial-Related Reviews**

The purpose of the financial-related reviews is to fulfill requirements in OMB Bulletin No. 07-04, "Audit Requirements for Federal Financial Statements," §§ 11 and 13.

FY 2008 financial-related reviews:

Closing-Package Audit Reports for the Governmentwide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports.

(OAS; W-00-08-40009; A-17-08-00006)

Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the DOD OIG in performing the OMB Bulletin 07-04, "Audit Requirements for Federal Financial Statements," § 11, Agreed-Upon Procedures.

(OAS; W-00-08-40009)

FY 2009 financial-related reviews:

Closing-Package Audit Reports for the Governmentwide Financial Report System. These audit reports are intended to support the preparation of governmentwide financial statements and reports.

*(OAS; W-00-09-40009)*

Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the DOD OIG in performing the OMB Bulletin 07-04, "Audit Requirements for Federal Financial Statements," § 11, Agreed-Upon Procedures.

*(OAS; W-00-09-40009)*

## **Other Financial Accounting Reviews**

### **Expired Appropriations**

We will determine whether HHS should retain the expired appropriations on its financial statements for the mandatory 5-year period. In accordance with 31 U.S.C. §§ 1551 through 1555, HHS is required to retain the expired appropriations on its financial statements for 5 years, after which any remaining balances would be returned to the Department of the Treasury (Treasury). New legislation would need to be enacted to authorize HHS to return the funds to Treasury in less than 5 years.

*(OAS; W-00-08-40030; expected issue date: FY 2009; work in progress)*

### **President's Emergency Plan for Relief Funds**

We will review the effectiveness of HHS's accounting for and control of funds received under the President's Emergency Plan for AIDS Relief (PEPFAR) program. HHS received PEPFAR funds from both the annual HHS/Labor appropriation and the Foreign Operations appropriation. PEPFAR funds support international programs for AIDS prevention, treatment, and care.

*(OAS; W-00-08-52300; expected issue date: FY 2009; work in progress)*

### **Public Welfare Cost Allocation Plan**

We will review the cost allocation plan submitted by one State. The State contracted to have its cost allocation plan prepared. ACF has informed us that the plan may be unsupported and that the State has been required to revise it. Federal regulations at 45 CFR pt. 95, subpart E require that cost allocation plans conform to the accounting principles and standards in OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments. We will determine whether State agency costs have been allocated correctly among various Federal programs and whether claims submitted by the State based on the cost allocation plan were supported and claimed in accordance with Federal criteria pertinent to the State agency.

*(OAS; W-00-09-40029; expected issue date: FY 2009; new start)*

### **Annual Accounting of Drug Control Funds**

We will review HHS agencies' compliance with the requirement at 21 U.S.C. § 1704 that agencies expending funds on National Drug Control Program activities submit to the Office of National Drug Control Policy (ONDCP) an annual accounting of the expenditure of drug control

funds. ONDCP policy also requires that an agency submit with its annual accounting an authentication by the agency's OIG, in which OIG expresses a conclusion on the reliability of the agency's assertions in its accounting. We will make this authentication with respect to HHS's FY 2007 annual accounting.

*(OAS; W-00-09-40040; expected issue date: FY 2009; new start)*

### **Use of Appropriated Funds in Program Support Center Contracting**

We will review the appropriateness of the Program Support Center's obligation of appropriated funds for services it secures through contracts to ensure that appropriated funds were used only during their period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and were used only for a bona fide need arising in the FY for which the appropriation was made. Key provisions of the Anti-Deficiency Act prohibit the Government from obligating or expending funds in advance of an appropriation unless authorized by law (31 U.S.C. § 1341(a)(1)). In addition, appropriations may be used only for bona fide needs arising in the FY for which the appropriation was made (31 U.S.C. § 1502). We will review contracts and contract modifications issued by the Program Support Center during FYs 2004 through 2008 to determine whether appropriate funds were used in accordance with the Anti-Deficiency Act.

*(OAS; W-00-09-40041; expected issue date: FY 2009; new start)*

### **Contracting Procedures**

We will review HHS's contracting procedures by performing a risk assessment. HHS's contracting procedures are subject to the FAR and the HHSAR. We will determine the scope of HHS contracting for goods and services and determine whether there are risks in this process that would require reviews by OIG.

*(OAS; W-00-09-40042; various reviews; expected issue date: FY 2009; new start)*

### **Non-Federal Audits**

We will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations. State, local, and Indian tribal governments; colleges and universities; and nonprofit organizations receiving Federal awards are required to have annual organizationwide audits of all Federal money that they receive. Our reviews ensure that the audits and reports meet applicable standards, identify any follow-up work needed, and identify issues that may require management attention. We also provide upfront technical assistance to non-Federal auditors to ensure that they understand Federal audit requirements and to promote effective audit work. In addition, we analyze and record electronically the audit findings reported by non-Federal auditors for use by HHS managers. Our reviews provide HHS managers with assurance 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.

### **Reimbursable Audits**

We will conduct a series of audits as part of HHS's cognizant responsibility under OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations. To ensure a coordinated Federal approach to audits of colleges, universities, and States, this Circular

establishes audit cognizance, that is, designates which Federal agency has lead responsibility for audit of all Federal funds the entity receives. HHS OIG has audit cognizance over all State governments and most major research colleges and universities. Agreements have been reached among many OIG offices to reimburse the cognizant agencies for audits performed at their request or the request of their program offices.

*(OAS; W-00-09-50012; various reviews; expected issue date: FY 2009; new start)*

### **Requested Audit Services**

Throughout the year, Congress, HHS, and other Federal organizations request that we perform a variety of audit services. These services include:

- recipient capability audits,
- contract and grant closeouts,
- indirect cost audits,
- bid proposal audits, and
- other reviews designed to provide specific information requested by management.

We will evaluate these requests as we receive them, considering such factors as why the audit is being requested, how the results will be used, when the results are needed, and whether the work is cost beneficial.

## **Automated Information Systems**

### **Information System Security Audits**

We will review the reliability of the Information System Security Program at several operating divisions. HHS and its components are responsible for administering and implementing this security program in compliance with the FISMA and directives issued by OMB and the National Institute of Standards and Technology. To date, several reviews have been conducted to determine compliance with HHS-mandated security program requirements.

*(OAS; W-00-09-42020; expected issue date: FY 2009; new start)*

### **Federal Information Security Management Act of 2002 and Critical Infrastructure Protection**

We will review various operating divisions' compliance with the FISMA and critical infrastructure protection requirements. The FISMA and OMB Circular A-130, Management of Federal Information Resources, App. III, require that agencies and their contractors maintain programs that provide adequate security for all information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. As part of our review, we will follow up on the unresolved findings from prior reviews of information systems controls.

*(OAS; W-00-09-42010; various reviews; expected issue date: FY 2009; new start)*

## Other Departmental Issues

### Use of Discounted Airfares by Employees

We will review HHS employees' use of discounted airfares. Under a General Services Administration (GSA) agreement negotiated with airlines, Government employees traveling on Government business may be eligible for discounted airfares, known as a City Pair With Capacity Limits. Section 301-10.106 of the Federal Travel Regulation (FTR) requires Federal travelers to use a GSA contract carrier when available. Based on the results of a prior review, capacity-controlled coach-class fare may not be used as often as mandated by the FTR. We will determine the extent to which HHS's travelers obtain discount airfares and whether there are opportunities to increase the use of the discount airfares.

*(OAS; W-00-09-58120; expected issue date: FY 2009; new start)*

### State Protections for Persons With Disabilities in Residential Settings

We will review actions taken by CMS, ACF, SAMHSA, and FDA on OIG recommendations to work cooperatively to provide information and technical assistance to States for strengthening State protections for persons with disabilities in residential settings. Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid, CMS has established conditions of participation. For facilities not subject to CMS oversight, there are limited Federal standards, partly because of HHS's limited statutory authority.

*(OAS; W-00-09-58121; expected issue date: FY 2009; new start)*

### Purchase Cards

We will review the use of HHS Purchase Cards by one HHS operating division. To reduce the burden in procuring items under the simplified acquisition threshold, GSA's Federal Supply Service awarded a contract in February 1998 for Governmentwide Commercial Purchase Card Services to four banks under the GSA SmartPay Program. The use of the purchase credit card is a simplified acquisition mechanism that is subject to the simplified acquisition provisions established in the FAR and the HHSAR. The purchase card is designed to reduce procurement lead time and the cost of processing purchase orders; streamline payment procedures and reduce paperwork; improve cash management practices, such as forecasting and consolidating payments; and provide procedural checks and feedback to improve management control and decisionmaking. We will identify improper uses of the purchase cards.

*(OAS; W-00-09-58122; expected issue date: FY 2009; new start)*

### Travel Cards

We will review HHS's compliance with requirements for the use of travel cards. Such cards are to be used for official Government travel. Chapter 9 of the "HHS Travel Manual" governs employees' use of the travel card. The Government Accountability Office conducted a review of the Federal Government travel card program using FY 2001 data and found cases of unauthorized use, including personal purchases. It also found that HHS's process for monitoring the travel card program focused primarily on identifying and addressing existing delinquencies rather than preventing or detecting unauthorized use. We will examine HHS's processes for monitoring the card program to minimize delinquency rates, writeoffs, and unauthorized use of

the card. We will also determine the extent of travel card purchases that do not comply with departmental guidance.

*(OEI; 07-07-00480; expected issue date: FY 2009; work in progress)*