



Office of  
Inspector  
General

# Work Plan

FISCAL YEAR  
**2012**



U.S. Department of Health & Human Services  
Office of Inspector General

# Introductory Message From the Office of Inspector General

**T**HE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) Office of Inspector General (OIG) *Work Plan for Fiscal Year 2012* (Work Plan) provides brief descriptions of new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations during the next 12 months and beyond. The introductory section outlines our responsibilities and values, organization, work planning process, accomplishments, and additional information about this edition.

The [Work Plan](#) is one of OIG's three core publications. The [Semiannual Report to Congress](#) summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

## What is our responsibility?

Our organization was created to protect the integrity of HHS programs and operations and the well-being of beneficiaries by detecting and preventing fraud, waste, and abuse; identifying opportunities to improve program economy, efficiency, and effectiveness; and holding accountable those who do not meet program requirements or who violate Federal laws. Our mission encompasses the more than 300 programs administered by HHS at agencies such as the Centers for Medicare & Medicaid Services, National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Administration for Children and Families.

As required by statute, the majority of our resources are directed toward safeguarding the integrity of the Medicare and Medicaid programs and the health and welfare of their beneficiaries. Consistent with our responsibility to oversee all departmental programs, we also focus considerable effort on HHS's other programs and management processes, including key issues, such as food and drug safety, child support enforcement, conflict-of-interest and financial disclosure policies governing HHS staff, and the integrity of departmental contracts and grants management processes and transactions. Our core organizational values are:

**Integrity:** Acting with independence and objectivity.

**Credibility:** Building on a tradition of excellence and accountability.

**Impact:** Yielding results that are tangible and relevant.

## How and where do we operate?

Our staff of more than 1,800 professionals are deployed throughout the Nation in regional and field offices and in Washington, DC, headquarters. We conduct audits, evaluations, and investigations; provide guidance to industry; and, when appropriate, impose civil monetary penalties (CMP), assessments, and administrative sanctions. We collaborate with HHS and its operating and staff divisions, the Department of Justice (DOJ) and other executive branch agencies, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds. The following are descriptions of our mission-based components.

- THE OFFICE OF AUDIT SERVICES (OAS) 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.
- THE OFFICE OF EVALUATION AND INSPECTIONS (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs. OEI reports also present practical recommendations for improving program operations.
- THE OFFICE OF INVESTIGATIONS (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in almost every State and the District of Columbia, OI actively coordinates 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.
- THE OFFICE OF COUNSEL TO THE INSPECTOR GENERAL (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the antikickback statute and other OIG enforcement authorities.

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

## How do we plan our work?

Work planning is a dynamic process, and adjustments are made throughout the year to meet priorities and to anticipate and respond to emerging issues with the resources available. We assess relative risks in the programs for which we have oversight authority to identify the areas most in

need of attention and, accordingly, to set priorities for the sequence and proportion of resources to be allocated. In evaluating work plan proposals, we consider a number of factors, including:

- mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget;
- top management and performance challenges facing HHS;
- work to be performed in collaboration with partner organizations;
- management's actions to implement our recommendations from previous reviews; and
- timeliness.

## What do we accomplish?

In fiscal year (FY) 2010, OIG's contributions to safeguarding HHS programs from threats of fraud, waste, and abuse and to promoting economy, efficiency, and effectiveness in HHS programs included:

- \$3.8 billion in expected investigative receivables that were court ordered or agreed to be paid through civil settlements that resulted from cases developed by OIG investigators;
- \$1.1 billion in audit receivables that were agreed to be pursued by HHS program managers as a result of OIG audit disallowance recommendations;
- a ratio of \$16.7 to \$1 expected return on investment measuring the efficiency of OIG's health care oversight efforts; and
- 120 quality and management improvement recommendations that HHS program managers accepted and agreed to implement.

(FY 2012 OIG Online Performance Appendix. [View the Online Performance Appendix.](#))

## What can you learn from our Work Plan?

The OIG *Work Plan* outlines our current focus areas and states the primary objectives of each review. It also provides the internal identification code (if assigned) for each review, the year in which we expect one or more reports to be issued as a result of the review, and indicates whether the work was in progress at the start of the FY or is planned as a new start. Typically, a review designated as "work in progress" will result in reports issued in FY 2012, but a review slated to begin in FY 2012 ("new start") could result in FY 2012 or FY 2013 reports, depending upon when the assignments are initiated during the year and the complexity and scope of the examinations. Because we make continuous adjustments to the Work Plan as appropriate, we do not provide status reports on the progress of the reviews. The updated Work Plan is published annually, usually during the first week of October.

The body of the Work Plan is presented in seven major parts followed by Appendix A that describes our reviews related to the Patient Protection and Affordable Care Act of 2010 and Appendix B that describes our oversight of the funding that HHS received under the American Recovery and

Reinvestment Act of 2009. Appendix C lists selected acronyms and abbreviations used in the Work Plan.

If you have questions about this publication, please contact our Office of External Affairs at (202) 619-1343.

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## FY 2012 Work Plan Major Parts and Appendixes

|             |                                    |
|-------------|------------------------------------|
| Part I:     | Medicare Part A and Part B         |
| Part II:    | Medicare Part C and Part D         |
| Part III:   | Medicaid Reviews                   |
| Part IV:    | Legal and Investigative Activities |
| Part V:     | Public Health Reviews              |
| Part VI:    | Human Services Reviews             |
| Part VII:   | Other HHS-Related Reviews          |
| Appendix A: | Affordable Care Act Reviews        |
| Appendix B: | Recovery Act Reviews               |
| Appendix C: | Acronyms and Abbreviations         |

Each major section (Part) of the Work Plan begins with page 1. The Part designation is included with the page number in the footers, e.g.: I-15, II-7, or VI-2.

# Part I: Medicare Part A and Part B

- Home Health Services ..... 1
  - States’ Survey and Certification of Home Health Agencies: Timeliness, Outcomes, Followup, and Medicare Oversight (New)..... 2
  - Medicare’s Oversight of Home Health Agencies’ Patient Outcome and Assessment Data.. 2
  - Missing or Incorrect Patient Outcome and Assessment Data (New)..... 2
  - Questionable Billing Characteristics of Home Health Services (New)..... 2
  - Home Health Agency Claims’ Compliance With Coverage and Coding Requirements ..... 3
  - Medicare Administrative Contractors’ Oversight of Home Health Agency Claims (New) .... 3
  - Wage Indexes Used To Calculate Home Health Payments (New)..... 3
  - Home Health Prospective Payment System Requirements..... 3
  - Home Health Agency Trends in Revenues and Expenses ..... 4
  
- Hospitals..... 4
  - Hospital Reporting for Adverse Events ..... 4
  - Reliability of Hospital-Reported Quality Measure Data..... 4
  - Hospital Admissions With Conditions Coded Present on Admission..... 4
  - Accuracy of Present-on-Admission Indicators Submitted on Medicare Claims (New)..... 5
  - Medicare Inpatient and Outpatient Payments to Acute Care Hospitals (New)..... 5
  - Hospital Inpatient Outlier Payments: Trends and Hospital Characteristics ..... 5
  - Medicare’s Reconciliations of Outlier Payments ..... 6
  - Hospital Claims With High or Excessive Payments ..... 6
  - Hospital Same-Day Readmissions..... 6
  - Acute-Care Hospital Inpatient Transfers to Inpatient Hospice Care (New) ..... 6
  - Medicare Payments for Beneficiaries With Other Insurance Coverage ..... 7
  - Duplicate Graduate Medical Education Payments..... 7
  - Hospital Occupational-Mix Data Used To Calculate Inpatient Hospital Wage Indexes..... 7
  - Inpatient Prospective Payment System: Hospital Payments for Nonphysician Outpatient Services..... 7
  - Noninpatient Prospective Payment System: Hospital Payments for Nonphysician Outpatient Services..... 7
  - Medicare Brachytherapy Reimbursement ..... 8

|  |           |
|--|-----------|
| Medicare Outpatient Dental Claims (New).....   | 8         |
| Medicare Inpatient and Outpatient Hospital Claims for the Replacement of Medical<br>Devices.....                             | 8         |
| Observation Services During Outpatient Visits.....   | 8         |
| Inpatient Rehabilitation Facility Transmission of Patient Assessment Instruments .....                                       | 9         |
| In-Patient Rehabilitation Facilities (New).....  | 9         |
| Critical Access Hospitals.....   | 9         |
| Critical Access Hospitals (New).....   | 9         |
| <b>Nursing Homes .....</b>   | <b>10</b> |
| Medicare Requirements for Quality of Care in Skilled Nursing Facilities .....  | 10        |
| Safety and Quality of Post-Acute Care for Medicare Beneficiaries (New) .....   | 10        |
| Nursing Home Compliance Plans (New) .....  | 10        |
| Oversight of Poorly Performing Nursing Homes .....   | 11        |
| Nursing Home Emergency Preparedness and Evacuations During Selected<br>Natural Disasters .....                               | 11        |
| Medicare Part A Payments to Skilled Nursing Facilities .....   | 11        |
| Hospitalizations and Rehospitalizations of Nursing Home Residents.....   | 11        |
| Questionable Billing Patterns During Non-Part A Nursing Home Stays (New).....  | 11        |
| <b>Hospices.....</b>   | <b>12</b> |
| Hospice Marketing Practices and Financial Relationships with Nursing Facilities (New) ....                                   | 12        |
| Medicare Hospice General Inpatient Care.....   | 12        |
| <b>Medical Equipment and Supplies .....</b>  | <b>12</b> |
| Medicare Enrollment and Monitoring for Suppliers of Durable Medical Equipment,<br>Prosthetics, Orthotics, and Supplies ..... | 13        |
| Medicare Qualifications of Orthotists and Prosthetists .....   | 13        |
| Medicare Supplier Acquisition Costs for Back Orthoses .....  | 13        |
| Medicare Payments for Various Categories of Durable Medical Equipment .....  | 13        |
| Frequency of Replacement of Supplies for Durable Medical Equipment .....   | 14        |
| Medicare Payments for Durable Medical Equipment Claims With Modifiers .....  | 14        |
| Medicare Pricing for Parenteral Nutrition.....   | 14        |
| Medicare Part B Payments for Home Blood Glucose Testing Supplies .....   | 14        |
| Effectiveness of Edits To Prevent Payments to Multiple Suppliers of Home<br>Blood-Glucose Testing Supplies (New).....        | 15        |



|  |           |
|--|-----------|
| Questionable Billing for Medicare Diabetic Testing Supplies (New).....   | 15        |
| Support Surface Pricing (New).....   | 15        |
| Collection of Surety Bonds for Overpayments Made to Suppliers of Durable Medical<br>Equipment (New).....   | 15        |
| Competitive Bidding Process for Medical Equipment and Supplies.....  | 16        |
| Medicare DMEPOS Competitive Bidding Program: Supplier Solicitation of Physician<br>Prescribing.....  | 16        |
| <b>Other Providers and Suppliers.....</b>  | <b>16</b> |
| Organ Procurement Organizations: Payments (New).....   | 16        |
| Ambulances: Comparison of Medicare Fee Schedule Amounts to Other Payers (New)....  | 16        |
| Ambulances: Questionable Billing for Ambulance Services (New).....   | 17        |
| Physicians and Suppliers: Compliance With Assignment Rules .....   | 17        |
| Physicians and Other Suppliers: High Cumulative Part B Payments (New).....   | 17        |
| Physician-Owned Distributors of Spinal Implants (New).....   | 17        |
| Physicians: Place-of-Service Errors.....   | 18        |
| Physicians: Incident-To Services (New).....  | 18        |
| Physicians: Impact of Opting Out of Medicare (New).....  | 18        |
| Chiropractors: Part B Payments for Services (New).....   | 18        |
| Ambulatory Surgical Centers: Payment System.....   | 19        |
| Ambulatory Surgical Centers and Hospital Outpatient Departments: Safety and<br>Quality of Surgery and Procedures (New).....                      | 19        |
| Evaluation and Management Services: Trends in Coding of Claims .....   | 19        |
| Evaluation and Management Services Provided During Global Surgery Periods .....  | 19        |
| Evaluation and Management Services: Use of Modifiers During the Global Surgery<br>Period (New) .....   | 20        |
| Evaluation and Management Services: Potentially Inappropriate Payments .....   | 20        |
| Part B Imaging Services: Medicare Payments.....  | 20        |
| Clinical Social Workers: Part B Billing for Services to Hospital Inpatients .....  | 20        |
| Partial Hospitalization Programs in Community Mental Health Centers: Questionable<br>Billing Characteristics and Contractor Oversight (New)..... | 20        |
| Partial Hospitalization Program Services in Hospital Outpatient Departments and<br>Community Mental Health Centers.....                          | 21        |
| Independent Therapists: Outpatient Physical Therapy Services .....   | 21        |
| Sleep Disorder Clinics: Medicare Payments for Sleep Testing .....  | 21        |
| Sleep Testing: Appropriateness of Medicare Payments for Polysomnography .....  | 22        |

|   |           |
|---|-----------|
| Diagnostic Radiology: Excessive Payments.....   | 22        |
| Laboratories: Part B Payments for Glycated Hemoglobin A1C Tests.....  | 22        |
| Laboratories: Trends in Laboratory Utilization.....   | 22        |
| Payments for Laboratory Tests—Comparing Medicare, State Medicaid, and Federal Employee Health Benefit Programs..... | 22        |
| Comprehensive Outpatient Rehabilitation Facilities.....   | 23        |
| End Stage Renal Disease: Payments for Beneficiaries Entitled to Medicare Under Special Provisions.....              | 23        |
| End Stage Renal Disease: Medicare’s Oversight of Dialysis Facilities (New).....                                     | 23        |
| End Stage Renal Disease: Bundled Prospective Payment System for Renal Dialysis Services (New).....                  | 23        |
| Medicare Payments for Part B Claims with G Modifiers.....   | 24        |
| Payments for Services Ordered or Referred by Excluded Providers.....  | 24        |
| Medical Claims Review at Selected Providers.....  | 24        |
| <b>Part B Payments for Prescription Drugs.....</b>  | <b>24</b> |
| Comparison of Average Sales Prices to Average Manufacturer Prices.....  | 25        |
| Comparison of Average Sales Prices to Widely Available Market Prices.....   | 25        |
| Costs and Payments for ESRD Drugs (New).....  | 25        |
| Billing for Immunosuppressive Drugs.....  | 25        |
| Payments for Off-Label Anticancer Pharmaceuticals and Biologicals.....  | 26        |
| Physician-Administered Drugs and Biologicals (New).....   | 26        |
| Off-Label and Off-Compendia Use of Medications in Government Prescription Drug Programs (New).....                  | 26        |
| Medicare Payments for the Drug Herceptin (New).....   | 26        |
| Acquisition Costs and Payments for Lucentis and Avastin Used in Treating Wet Age-Related Macular Degeneration.....  | 27        |
| Usage Patterns and Payments for Avastin and Lucentis in Treating Wet Age-Related Macular Degeneration.....          | 27        |
| Medicare Outpatient Payments for Drugs (New).....   | 27        |
| <b>Medicare Part A and Part B Contractor Operations.....</b>  | <b>28</b> |
| Contractor Error Rate Reduction Plans (New).....  | 28        |
| Preaward Reviews of Contract Proposals.....   | 28        |
| Contractors’ Administrative Costs.....  | 28        |
| Oversight of Medicare Administrative Contractors.....   | 28        |

|  |           |
|--|-----------|
| Zone Program Integrity Contractors’ Activities to Detect and Deter Potential Fraud and Abuse .....                           | 29        |
| Conflicts of Interest in the Zone Program Integrity Contracting Process .....  | 29        |
| Vulnerabilities Identified by Medicare Benefit Integrity Contractors.....  | 29        |
| Recovery Audit Contractors’ Performance and Identification and Recoupment of Improper Payments .....                         | 29        |
| Variation in Coverage of Services and Medicare Expenditures Due to Local Coverage Determinations .....                       | 29        |
| Performance of the National Supplier Clearinghouse.....  | 30        |
| Provider Education and Training: Medicare-Affiliated Contractors’ Progressive Correction Action .....                        | 30        |
| Pension Segmentation .....   | 30        |
| Pension Costs Claimed .....  | 30        |
| Unfunded Pension Costs .....   | 31        |
| Pension Segment Closing.....   | 31        |
| Postretirement Benefits and Supplemental Employee Retirement Plan Costs.....   | 31        |
| Medicare Annual Reports to Congress on Contractor Information Systems Security Programs .....                                | 31        |
| Medicare Contractor Information Technology Closeout Audits.....  | 31        |
| Medicare and Medicaid Security of Portable Devices Containing Personal Health Information at Contractors and Hospitals ..... | 32        |
| <b>Other Program-Related Reviews.....</b>  | <b>32</b> |
| Providers and Suppliers with Currently Not Collectible Debt .....  | 32        |
| First Level of the Medicare Appeals Process .....  | 32        |
| Medicare Administrative Law Judge Decisions .....  | 32        |
| Comprehensive Error Rate Testing Program: Fiscal Year 2011 Error Rate Oversight.....   | 33        |
| CMS Disclosure of Personally Identifiable Information (New) .....  | 33        |
| National Provider Identifier Enumeration and Medicare Provider Enrollment Data.....  | 33        |

## Part II: Medicare Part C and Part D

|   |   |
|---|---|
| Part C (Medicare Advantage) .....   | 1 |
| Enhanced Payments to Plans for Certain Beneficiary Types .....  | 1 |
| Special Needs Plans: Enrollment of Medicare Beneficiaries With Chronic Conditions .....   | 1 |
| Medicare Advantage Risk Adjustment Data Submissions.....  | 2 |
| Medicare Advantage Risk Adjustment Data Validation.....   | 2 |
| Risk-Adjusted Payments to Medicare Advantage Organizations that Offer Prescription<br>Drug Plans.....                           | 2 |
| Duplicate Payments for Drugs by Part C and Part D for Beneficiaries Who Are<br>Institutionalized.....                           | 2 |
| Duplicate Payments to Cost-Based Health Maintenance Organization Plans Under<br>Capitation Agreements and Fee for Service ..... | 3 |
| Accuracy of Expenditures Claimed on Cost Reports by Health Care Prepayment<br>Plans (New) .....                                 | 3 |
| Quality-Based Bonus Payments to Unrated Plans in 2011 and 2012 (New).....   | 3 |
| Quality of the Part C Bid Review Process .....  | 3 |
| Medicare Advantage Organizations' Oversight of Contractors.....   | 4 |
| Medicare Advantage Plans Oversight of Durable Medical Equipment Suppliers .....   | 4 |
| Medicare Advantage Organizations' Identification of Potential Fraud and Abuse .....   | 4 |
| Medicare Advantage Organizations' Reporting Requirements.....   | 4 |
| Medicare Advantage Plans' Compensation of Field Marketing Organizations (New) .....   | 4 |
| Part D (Prescription Drug Program).....   | 5 |
| Part D Drug Pricing and Payment-Related Reviews .....   | 5 |
| Increase in Prices for Part D Brand Name Drugs (New) .....  | 5 |
| Medicare Part D Claims Duplicated in Part A and Part B .....  | 5 |
| Characteristics Associated With Part D Billing in 2009 .....  | 6 |
| Drug Costs Paid by Part D Sponsors Under Retail Discount Generic Programs.....  | 6 |
| Part D Payments for Drugs Dispensed at Retail Pharmacies With Discount Generic<br>Programs (New) .....                          | 6 |
| Duplicate Drug Claims for Hospice Beneficiaries .....   | 6 |
| Aberrant Part D Claims For Schedule II and Other Drugs.....   | 7 |
| Refills of Schedule II Drugs (New) .....  | 7 |

|  |           |
|--|-----------|
| Medicare Part D Expenditures for Revatio (New).....  | 7         |
| Questionable Part D Billing for HIV Drugs (New).....   | 7         |
| Prescription Drug Event Data Submitted for Incarcerated Individuals (New).....   | 7         |
| Part D Pharmaceutical Manufacturer Rebates .....   | 8         |
| Drug Pricing and Payments: Part D Payment Reconciliation Reopening (New).....  | 8         |
| Off-Formulary Drugs in Part D.....   | 8         |
| Part D Formulary Coverage Determinations and Beneficiary Appeals Process .....   | 8         |
| Utilization Management Controls in Medicare Part D (New) .....   | 9         |
| Medicare Part D Risk Sharing and Risk Corridors .....  | 9         |
| Sponsors’ and Plans’ Implementation of Supporting Systems at Small- and Medium-Size<br>Plans and Plans New to Medicare ..... | 9         |
| Accuracy of Sponsors’ Tracking of True Out-of-Pocket Costs .....   | 9         |
| Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts (New).....  | 9         |
| Quality of Sponsor Data Used in Calculating Coverage-Gap Rebates (New).....  | 10        |
| <b>Part D Administration and Program Integrity.....</b>  | <b>10</b> |
| Safety and Effectiveness of Part D Drugs.....  | 10        |
| Sponsors’ Documentation of Administrative Costs Included in Bid Proposals.....   | 10        |
| Sponsors’ Documentation of Investment Income Included in Bid Proposals.....  | 10        |
| Medicare’s Audits of Stand-Alone Part D Prescription Drug Plans .....  | 11        |
| Medicare’s Audits of Part D Sponsors’ Financial Records.....   | 11        |
| Medicare Prescription Drug Integrity Contractors’ Activities to Detect and Deter Fraud<br>and Abuse in Part D (New) .....    | 11        |
| Sponsors’ Internal Controls for Fraud, Waste, and Abuse .....  | 11        |
| Sponsors’ Audits of Pharmacies .....   | 11        |
| Sponsors’ Pharmacy and Therapeutics Committees: Potential Conflicts of Interest.....   | 12        |

# Part III: Medicaid Reviews

- Medicaid Prescription Drug Pricing, Reimbursement, and Rebates ..... 1
  - Calculation of Average Manufacturer Prices ..... 1
  - Recalculation of Base-Date Average Manufacturer Prices ..... 1
  - Federal Upper Payment Limit Drugs ..... 2
  - State Maximum Allowable Cost Programs ..... 2
  - Appropriateness of Federal Upper Limit Amounts (New) ..... 2
  - Update of Manufacturer Compliance With AMP Reporting Requirements (New) ..... 3
  - States’ Medicaid Drug Claims ..... 3
  - Compound Drug Claims ..... 3
  - Medicaid Claims for Drugs Purchased Under Retail Discount Generic Programs ..... 3
  - Impact of the Deficit Reduction Act of 2005 on Rebates for Authorized Generic Drugs ..... 4
  - Zero-Dollar Unit Rebate Amounts ..... 4
  - States’ Efforts and Experiences With Resolving Rebate Disputes ..... 4
  - States’ Collection of Rebates for Drugs Paid by Managed Care Organizations (New) ..... 5
  - Federal Share of Rebates (New) ..... 5
  - Rebates on New Formulations (New) ..... 5
- Home, Community, and Personal Care Services ..... 5
  - Home Health Services: Screenings of Health Care Workers ..... 6
  - Home Health Services: Agency Claims ..... 6
  - Home Health Services: Homebound Requirements (New) ..... 6
  - Home- and Community-Based Services: Federal and State Oversight of Quality of Care .... 6
  - Home- and Community-Based Services: Federal and State Oversight of Assisted-Living Facilities ..... 7
  - Home- and Community-Based Services: Vulnerabilities in Providing Services (New) ..... 7
  - Home- and Community-Based Services: Waiver Program Administrative Costs ..... 7
  - Home- and Community-Based Services: Adult Day Care Services for Elderly Individuals Who Have Chronic Functional Disabilities ..... 7
  - Community Residence Rehabilitation Services ..... 7
  - Continuing Day Treatment Providers ..... 8
  - Medicaid School-Based Services ..... 8

Personal Care Services ..... 8

**Other Medicaid Services and Payments..... 9**

Hospice Services: Compliance With Reimbursement Requirements ..... 9

Potentially Excessive Medicaid Payments for Inpatient and Outpatient Services ..... 9

Payments for Physical, Occupational, and Speech Therapy Services..... 9

Medicaid Medical Equipment..... 9

Medicaid Family Planning Services ..... 10

Payments for Transportation Services ..... 10

State-Operated Facilities: Reasonableness of Payment Rates (New)..... 10

Payments for Health-Care-Acquired Conditions (New)..... 10

Supplemental Payments to Private Hospitals..... 10

Supplemental Payments to Public Providers (New)..... 11

Medicaid Nursing Facility Incentive Payments..... 11

Emergency Payments by State Medicaid Agencies (New)..... 11

**Medicaid Integrity and Accountability ..... 12**

Early Results From Medicaid Integrity Contractors..... 12

Medicare and Medicaid Data Matching Project..... 12

Addressing Vulnerabilities Identified During Medicaid State Program Integrity Reviews  
(New) ..... 12

Claims With Inactive or Invalid Physician Identifier Numbers..... 13

Beneficiaries With Multiple Medicaid Identification Numbers ..... 13

State Medicaid Fraud Control Units Performance Standards ..... 13

State Agencies’ Terminations of Providers Terminated Under Medicare or by  
Other States (New) ..... 13

Federally Excluded Providers and Suppliers ..... 14

States’ Contingency Fee Payment Arrangements ..... 14

Federal Funds Generated Through Medicaid Provider Taxes (New)..... 14

Impact of Certified Public Expenditures..... 14

Overpayments: Medicaid Credit Balances..... 14

States’ Efforts To Improve Third-Party Liability Payment Collections in Medicaid..... 15

Proper Allocation of Medicaid Administrative Costs..... 15

Form CMS-64: Oversight of State Data Reporting..... 15

Form CMS-64: Pharmacy Prescription Drug Claims ..... 15

|  |           |
|--|-----------|
| Form CMS-64: Medicaid Monetary Drawdowns (New) .....   | 15        |
| Form CMS-64: Medicaid Overpayment Reporting and Collections (New).....   | 16        |
| Form CMS-64: Accuracy of Medicaid Collections and Federal Share (New) .....  | 16        |
| Payment Error Rate Measurement: Fiscal Year 2008 Error Rate .....  | 16        |
| Payment Error Rate Measurement Program: Error Rate Accuracy and<br>Health Information Security .....                                     | 16        |
| Payment Error Rate Measurement Program: Eligibility Determinations in One State .....  | 17        |
| <b>Program Administration, Information Systems, and Data Integrity .....</b>   | <b>17</b> |
| State Buy-In of Medicare Coverage .....  | 17        |
| Provider Enrollment: Collection and Verification of Provider Ownership Information by<br>State Medicaid Agencies.....                    | 17        |
| Beneficiary Eligibility: State Agencies’ Redeterminations of Medicaid Eligibility (New)....  | 18        |
| State Medicaid Plans’ Vaccines for Children Program: Storage and Management of<br>Vaccines .....   | 18        |
| Children’s Health Insurance Program: Dually Enrolled Beneficiaries in a State .....  | 18        |
| Children’s Health Insurance Program: State Compliance With Eligibility and Enrollment<br>Notification and Review Requirements .....      | 18        |
| Children’s Health Insurance Program Administrative Costs .....   | 19        |
| Medicaid Management Information System Costs .....   | 19        |
| States’ Use of the Public Assistance Reporting Information System To Reduce Medicaid<br>Benefits Received From More Than One State ..... | 19        |
| Medicaid National Correct Coding Initiative Effectiveness (New).....   | 19        |
| Medicaid Management Information Systems Business Associate Agreements.....   | 20        |
| CMS Oversight and Accuracy of Nursing Home Minimum Data Set Data .....   | 20        |
| Medicaid Security Controls Over State Web-Based Applications .....   | 20        |
| Medicaid Security Controls at the Mainframe Data Centers That Process States’<br>Claims Data .....                                       | 20        |
| <b>Medicaid Managed Care.....</b>  | <b>21</b> |
| Completeness and Accuracy of Managed Care Encounter Data (New).....  | 21        |
| Managed Care Entities’ Marketing Practices .....   | 21        |
| State Oversight of Provider Credentialing by Managed Care Entities.....  | 21        |
| Excluded Individuals Employed by in Managed Care Networks .....  | 21        |
| Managed Care Fraud and Abuse Safeguards .....  | 22        |
| Managed Care Organizations’ Use of Prepayment Review To Detect and Deter<br>Fraud and Abuse.....   | 22        |



Medicaid Managed Care Plans' Medical Loss Ratio..... 22

# Part IV: Legal and Investigative Activities Related to Medicare and Medicaid

|   |   |
|---|---|
| Legal Activities.....   | 1 |
| Exclusions From Program Participation .....   | 1 |
| Civil Monetary Penalties .....  | 1 |
| False Claims Act Cases and Corporate Integrity Agreements .....                     | 1 |
| Providers' Compliance With Corporate Integrity Agreements .....                     | 2 |
| Review of Entities That Do Not Enter Into Corporate Integrity Agreements (New)..... | 2 |
| Advisory Opinions and Other Industry Guidance.....                                  | 2 |
| Provider Compliance Training.....   | 2 |
| Provider Self-Disclosure .....  | 3 |
| Investigative Activities .....  | 3 |
| Medicare Strike Force Teams and Other Collaboration .....                           | 3 |

# Part V: Public Health Reviews

- Public Health Agencies ..... 1
- Agency for Healthcare Research and Quality ..... 2
  - Early Implementation of Patient Safety Organizations (New) ..... 2
- Centers for Disease Control and Prevention..... 2
  - Monitoring of Subrecipient Emergency Preparedness Expenditures ..... 2
  - States’ 24/7 Reporting Systems ..... 3
  - Radiological and Nuclear Preparedness: Assessing Selected Local Public Health  
Emergency Response Plans ..... 3
  - Prevention and Public Health Fund Recipient Capability Audits (New) ..... 3
  - Grantees’ Use of Funds From the Prevention and Public Health Fund (New)..... 3
  - Internal Controls for Awarding Affordable Care Act Grants (New)..... 4
  - Payment of Invoices for Affordable Care Act Purchases (New)..... 4
  - Contracting Activities Within CDC’s Procurement and Grants Office (New) ..... 4
  - CDC Oversight of High-Risk Grantees (New) ..... 4
- Food and Drug Administration ..... 5
  - Complaint Investigation Process ..... 5
  - Oversight of Food Safety Operations..... 5
  - Oversight of State Food Facility Inspections ..... 5
  - FDA Reportable Food Registry ..... 5
  - FDA’s Oversight of Investigational New Drug Applications..... 6
  - FDA’s Policies and Procedures for Resolving Scientific Disputes ..... 6
  - 510(k) Process for Device Approval ..... 6
  - The Food and Drug Administration's Implementation of the Risk Evaluation and  
Mitigation Strategies Program (New)..... 6
  - FDA Oversight of Claims Made on Dietary Supplement Labels (New)..... 7
- Health Resources and Services Administration ..... 7
  - Ryan White CARE Act Payer of Last Resort Provision ..... 7
  - Human Immunodeficiency Virus Testing in Health Centers ..... 7

|  |           |
|--|-----------|
| Community Health Centers’ Compliance With Affordable Care Act Grant Requirements (New).....                  | 7         |
| Community Health Center Limited-Scope Capability Audits (New) .....  | 8         |
| HRSA’s Monitoring of Recipients’ Fulfillment of National Health Services Corps’s Obligations (New) .....     | 8         |
| HRSA Oversight of High Risk Grantees (New).....  | 8         |
| <b>Indian Health Service.....</b>  | <b>8</b>  |
| IHS Medicaid Reimbursements.....   | 8         |
| Background Investigations To Protect Indian Children.....  | 9         |
| <b>National Institutes of Health.....</b>  | <b>9</b>  |
| Superfund Financial Activities for Fiscal Year 2010 .....  | 9         |
| Colleges’ and Universities’ Compliance With Cost Principles.....   | 9         |
| Review of Extra Service Compensation Payments Made by Educational Institutions.....                          | 9         |
| Recharge Centers at Colleges and Universities .....  | 10        |
| Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (New) .....  | 10        |
| Use of Data and Safety Monitoring Boards in Clinical Trials .....  | 10        |
| NIH Oversight of Grants Management Policy Implementation.....  | 10        |
| National Center for Research Resources’ Oversight of Clinical and Translational Science Awards.....          | 11        |
| Inappropriate Salary Draws From Multiple Universities (New).....   | 11        |
| Cost Sharing Claimed by Universities (New).....  | 11        |
| Awardee Eligibility for Small Business Innovation Research Awards (New) .....                                | 11        |
| <b>Substance Abuse and Mental Health Services Administration.....</b>  | <b>12</b> |
| Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program.....             | 12        |
| SAMHSA Oversight of Grantees .....   | 12        |
| SAMHSA Grantees’ Use of Funds From the Prevention and Public Health Fund (New).....                          | 12        |
| <b>Cross-Cutting and Other Public-Health-Related Reviews.....</b>  | <b>12</b> |
| Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation..... | 12        |
| HHS’ Federal Response Capabilities for Public Health and Medical Services Emergency Support (New).....       | 13        |
| Pandemic Influenza Planning.....   | 13        |

Public Health Legal Activities ..... 13

Public Health Investigations ..... 13

    Violations of Select Agent Requirements ..... 13

# Part VI: Human Services Reviews

- Human Services Agencies ..... 1
- Administration on Aging ..... 1
  - Performance Data for the Senior Medicare Patrol Projects ..... 1
  - State Long-Term-Care Ombudsman Programs: Efforts To Identify, Investigate, and Resolve Elder Abuse Cases (New)..... 2
- Administration for Children and Families ..... 2
  - Oversight of System Design of Statewide Automated Child Welfare Information Systems 2
  - Adoption Assistance Subsidies ..... 2
  - Foster Care and Adoption Assistance Training Costs and Administrative Costs ..... 2
  - Foster Care: Training Costs Charged by One County Probation Department ..... 3
  - Foster Care: Administrative Costs Charged by One County Probation Department ..... 3
  - Foster Care: Per Diem Rates..... 3
  - Foster Care: Group Home and Foster Family Agency Rate Classification..... 3
  - Foster Care: Claims for the Placement of Delinquent Children..... 3
  - Foster Care: Preplacement Candidacy Costs..... 4
  - Foster Care: Children Over 19 Years Old ..... 4
  - Foster Care: Program Collection and Reporting of Child-Support Payments ..... 4
  - Foster Care: Monitoring the Health and Safety of Foster Children ..... 4
  - Child Care and Development Fund: Integrity of Child Care Payments (New) ..... 4
  - Child Care and Development Fund: Monitoring of Licensing and Health and Safety Requirements for Childcare Providers ..... 5
  - Head Start and Child Care and Development Fund: Licensing Standards and Health and Safety Monitoring at Federally Funded Facilities ..... 5
  - Head Start: Oversight of Eligibility and Enrollment (New)..... 5
  - TANF Recipient Social Security Numbers ..... 6
  - TANF: Use of Smart Card Technology To Reduce Payment Errors ..... 6
  - TANF: ACF Oversight of Work Participation and Verification Requirements ..... 6
  - Refugee Resettlement: Services for Recently Arrived Refugees ..... 6
  - Community Action Agencies: Pension Costs Claimed on HHS-Funded Programs (New)..... 6
  - Low-Income Home Energy Assistance Program: Duplicate Payments (New) ..... 7

Child Support: Increasing Collections ..... 7  
Child Support: Investigations Under the Child-Support Enforcement Task Force Model .... 7

# Part VII: Other HHS-Related Reviews

- Cross-Cutting and Mandatory Work..... 1
- Financial Statement Audits ..... 1
  - Audits of Fiscal Years 2011 and 2012 Financial Statements ..... 1
  - Fiscal Year 2012 Statement on Standards for Attestation Engagements..... 2
  - Fiscal Years 2011 and 2012 Financial-Related Reviews..... 2
- Other Financial Accounting Reviews..... 3
  - The President’s Emergency Plan for AIDS Relief Funds ..... 3
  - Public Welfare Cost Allocation Plan..... 3
  - Annual Accounting of Drug Control Funds ..... 4
  - Use of Appropriated Funds in Program Support Center Contracting ..... 4
  - Reasonableness of Prime Contractor Fees ..... 4
  - Contracting Procedures ..... 4
  - Non-Federal Audits ..... 4
  - Reimbursable Audits ..... 5
  - Requested Audit Services ..... 5
  - Compliance With Executive Order 13520: Reducing Improper Payments ..... 5
- Automated Information Systems ..... 6
  - Information System Security Audits..... 6
  - Federal Information Security Management Act of 2002..... 6
  - Information Technology Systems’ General Controls..... 6
  - Fraud Vulnerabilities Presented by Electronic Health Records (NEW)..... 6
- Other Departmental Issues..... 6
  - State Protections for People in Residential Settings Who have Disabilities ..... 6
  - Classifications of Federal Pass-Through Funding Recipients ..... 7



# Appendix A: Affordable Care Act Reviews

- New Programs and Initiatives Created by the Affordable Care Act..... 1**
  - Pre-Existing Condition Insurance Plans, § 1101 .....2
    - Controls Over Pre-Existing Condition Insurance Plans and Collaborative Administration .... 2
  - Early Retiree Reinsurance Program, § 1102 .....2
    - CCIIO's Internal Control Structure for the Early Retiree Reinsurance Program (New)..... 3
    - CCIIO's Certification Procedures for Employment-Based Plans and Plan Sponsor's Use of Federal Funds ..... 3
    - CCIIO's System Security Controls Over Protected Health Information..... 3
    - CCIIO's Reimbursements to Plans ..... 3
    - Employment-Based Plans' Costs for Items and Services Reimbursed..... 3
    - Employment-Based Plan Sponsors' Use of Early Retiree Reinsurance Program Funds..... 3
  - Health Insurance Web Portal, § 1103..... 4
    - Oversight of Private Health Insurance Submissions to the Health Insurance Web Portal.... 4
  - Affordable Insurance Exchanges, § 1311 and 1413 ..... 4
    - States' Readiness To Comply With Exchange and Medicaid Eligibility and Enrollment System Requirements..... 5
  - National Background Check Program, § 6201 ..... 5
    - Program for National Background Checks for Long-Term-Care Employees ..... 5
  - Community Living Assistance Services and Supports Program, § 8002..... 6
    - Development of the Community Living Assistance Services and Supports Program ..... 6
- Existing Programs Related to Affordable Care Act Provisions ..... 7**
  - Medicare ..... 7
    - Reliability of Hospital-Reported Quality Measure Data..... 7
    - Accuracy of Present-on-Admission Indicators Submitted on Medicare Claims ..... 7
    - Hospital Same-Day Readmissions..... 7
    - Nursing Home Compliance Plans..... 7
    - Recovery Audit Contractors' Performance and Identification and Recoupment of Improper Payments ..... 7

|   |          |
|---|----------|
| Enhanced Payments to Plans for Certain Beneficiary Types .....                                    | 8        |
| Enrollment of Medicare Beneficiaries With Chronic Conditions in Special-Needs Plans .....         | 8        |
| Quality-Based Bonus Payments to Unrated Plans in 2011 and 2012 .....                              | 8        |
| Part D and Medicaid Payments for High-Volume Prescription Drugs.....                              | 8        |
| Quality of Sponsor Data Used in Calculating Coverage-Gap Rebates .....                            | 8        |
| Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts .....                          | 8        |
| <b>Medicaid.....</b>  | <b>8</b> |
| Appropriateness of Federal Upper Limit Amounts .....  | 8        |
| States’ Collection of Rebates for Drugs Paid by Managed Care Organizations.....                   | 8        |
| Federal Share of Rebates .....  | 9        |
| Rebates on New Formulations .....   | 9        |
| Payments for Health-Care-Acquired Conditions .....  | 9        |
| State Agencies’ Terminations of Providers Terminated Under Medicare or by Other States .....      | 9        |
| Medicaid National Correct Coding Initiative Effectiveness .....                                   | 9        |
| Completeness and Accuracy of Managed Care Encounter Data .....                                    | 9        |
| <b>Public Health .....</b>  | <b>9</b> |
| Prevention and Public Health Fund Recipient Capability Audits.....                                | 9        |
| CDC Grantees’ Use of Funds From the Prevention and Public Health Fund .....                       | 10       |
| Internal Controls for Awarding Affordable Care Act Grants .....                                   | 10       |
| Payment of Invoices for Affordable Care Act Purchases .....                                       | 10       |
| Community Health Centers’ Compliance With Affordable Care Act Grant Requirements..                | 10       |
| Community Health Center Limited-Scope Capability Audits .....                                     | 10       |
| HRSA’s Monitoring of Recipients’ Fulfillment of National Health Services Corps’s Obligations..... | 10       |
| SAMHSA Grantees’ Use of Funds From the Prevention and Public Health Fund .....                    | 10       |

# Appendix B: Recovery Act Reviews

- Appendix B..... 1**
- Recovery Act Reviews: Medicare and Medicaid ..... 1**
  - Medicare Part A and Part B..... 1
    - Medicare Incentive Payments for Electronic Health Records.....1
  - Medicaid Administration..... 1
    - Medicaid Incentive Payments for Electronic Health Records .....1
    - Reconciliation of Expenditure Reports to Claim Data ..... 2
  - Medicare and Medicaid Information Systems and Data Security .....2
    - Health Information Technology System Enhancements..... 2
    - Contractor System Enhancements ..... 2
    - Breaches and Medical Identity Theft Involving Medicare Identification Numbers ..... 2
    - OCR Oversight of the HIPAA Privacy Rule (New) ..... 3
    - OCR Oversight of the HITECH Breach Notification Rule (New)..... 3
- Recovery Act Reviews: Public Health Programs ..... 3**
  - Centers for Disease Control and Prevention..... 3
    - Recipient Compliance With Grant and Cooperative Agreement Requirements..... 3
  - Health Resources and Services Administration ..... 4
    - Limited-Scope Audits of Grantees’ Capacities ..... 4
    - Recovery Act Funding for Community Health Centers Infrastructure Development..... 4
    - Grant Award System for Health Information Technology Funds ..... 4
    - Community Health Centers Receiving Health Information Technology Funding ..... 5
    - HRSA Health Information Technology Grants (New)..... 5
  - Indian Health Service..... 5
    - Facilities Construction Bid Proposal Audits..... 5
    - Facilities Construction Contingency Fund Management Audits ..... 5
    - Internal Controls Over Equipment..... 5
    - Indian Health Service System Improvements ..... 6

- National Institutes of Health..... 6
  - Implementation of Internal Controls for Grantee Reporting ..... 6
  - Internal Controls for Extramural Construction and Shared Instrumentation..... 6
  - Intramural Construction Bid Proposal Audits ..... 6
  - Intramural Construction Contingency Fund Management ..... 6
  - College and University Indirect Costs Claimed as Direct Costs ..... 7
  - National Institutes of Health Grant System ..... 7
  
- Cross-Cutting Public Health Activities ..... 7
  - Recipient Compliance With Reporting Requirements..... 7
  - State Compliance With Grant Requirements ..... 7
  
- Recovery Act Reviews: Human Services Programs ..... 8**
  - Administration for Children and Families ..... 8
    - Head Start Agencies’ Use of Grant Funds ..... 8
    - Head Start Recipient Capability Audits..... 8
    - Administration for Children and Families Grant System..... 8
    - Administration for Children and Families Health Information Technology Grants..... 9
  
- Recovery Act Reviews: Departmentwide Issues..... 9**
  - Cross-Cutting Investigative Activities..... 9
    - Integrity of Recovery Act Expenditures ..... 9
    - Enforcement of Whistleblower Protections ..... 9
  
  - Information Systems Reviews ..... 9
    - Departmentwide Network Improvements ..... 9
    - Security Controls for Grants Web Site..... 10

Part I:

Medicare  
Part A and Part B

## Part I: Medicare Part A and Part B

Medicare Part A and Part B together are generally referred to as “traditional Medicare.” Part C (Medicare Advantage) and Part D (Medicare Prescription Drug benefit) are more recent innovations in the program.

Medicare Part A helps cover certain inpatient services in hospitals and skilled nursing facilities (SNF) and some home health services. Medicare Part B helps cover designated practitioners’ services, outpatient care, and certain other medical services, equipment, supplies, and drugs that Part A does not cover. Historically, Medicare contractors, known as fiscal intermediaries (FI) and carriers, have handled Medicare’s claims administration activities. Pursuant to Medicare’s contracting reform initiative, FIs and carriers are being replaced by Medicare Administrative Contractors (MAC).

- FIs have processed claims for Medicare Part A and Part B submitted by or on behalf of certain facility-based providers including hospitals and SNFs.
- Carriers have processed claims for Medicare Part B submitted by designated practitioners and other suppliers such as physicians, laboratories, and retail pharmacies. The Centers for Medicare & Medicaid Services (CMS) also engages contractors that perform specific fee-for-service (FFS) business functions.
- MACs process Part A and Part B claims. CMS is implementing the Medicare contracting reform initiative. The reform plan includes specialty MACs that service suppliers of durable medical equipment (DME). (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 911).

Descriptions of the Office of Inspector General’s (OIG) work in progress and planned reviews of Medicare Part A and Part B payments and services for fiscal year (FY) 2012 follow.

## Home Health Services

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

HHA—HOME HEALTH AGENCY

HHRG—HOME HEALTH RESOURCE GROUPS

MAC—MEDICARE ADMINISTRATIVE CONTRACTOR

MEDPAC—MEDICARE PAYMENT ADVISORY COMMISSION

OASIS—OUTCOME AND ASSESSMENT INFORMATION SET

PPS—PROSPECTIVE PAYMENT SYSTEM

**States' Survey and Certification of Home Health Agencies: Timeliness, Outcomes, Followup, and Medicare Oversight (New)**

We will review the timeliness of home health agency (HHA) standard and complaint surveys conducted by State Survey Agencies and Accreditation Organizations, the outcomes of those surveys, and the nature and followup of complaints against HHAs. We will also look at CMS oversight activities designed to monitor the timeliness and effectiveness of HHA surveys. CMS relies on the survey and certification process to ensure HHA compliance with Medicare Conditions of Participation (CoP). HHAs must be surveyed at least every 36 months. (Social Security Act, § 1891(c)(2).) Regulations on surveys to validate the accreditation process are at 42 CFR § 488.8, and instructions on surveys to monitor State Survey Agencies' performance are in CMS's *State Operations Manual*, §§ 4157 and 4158. See related information in OIG's [Compendium](#), March 2011, Part I, p. 1. (OEI; 06-11-00400; expected issue date: FY 2012; work in progress)

**Medicare's Oversight of Home Health Agencies' Patient Outcome and Assessment Data**

We will review CMS's oversight of Outcome and Assessment Information Set (OASIS) data submitted by Medicare-certified HHAs, including CMS's process for ensuring that HHAs submit accurate and complete OASIS data. Federal regulations require HHAs to conduct accurate comprehensive patient assessments that include OASIS data items and submit the data to CMS. (42 CFR § 484.55.) OASIS data reflect HHAs' performance in helping patients to regain or maintain their ability to function and perform activities of daily living. OASIS data also include measures of physical status and use of services, such as hospitalization or emergent care. CMS has used OASIS data for its HHA prospective payment system (PPS) since 2000. It began posting OASIS-based quality performance information on its Home Health Compare Web site in fall 2003 and conducted a home health pay-for-performance demonstration based on OASIS data during 2008 and 2009. (OEI; 01-10-00460; expected issue date: FY 2012; work in progress)

**Missing or Incorrect Patient Outcome and Assessment Data (New)**

We will review home health agencies OASIS data to identify payments for episodes for which OASIS data were not submitted or for which the billing code on the claim is inconsistent with OASIS data. OASIS data are electronically submitted to CMS, independent of the home health agency's claim for episode payment. Federal regulations require that HHAs submit OASIS data as a condition for payment. (42 CFR § 484.210(e).) HHAs receive prospective payments based on 60-day episodes of care. The OASIS is a standard set of data items used to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services and includes the billing code for the episode of care. (OAS; W-00-12-35600; various reviews; expected issue date: FY 2012; new start)

**Questionable Billing Characteristics of Home Health Services (New)**

We will review home health claims to identify home health agencies that exhibited questionable billing in 2010. Questionable billing refers to claims that exhibit certain characteristics that may indicate potential fraud. We will identify and review HHAs that had a high percentage of claims that meet at least one of the questionable billing characteristics. Medicare spending has increased 81 percent for HHA services since 2000. The home health benefit was originally intended for short-term, posthospital recovery for homebound beneficiaries, but it has been expanded to include other types of homebound beneficiaries. Home health services are authorized by Medicare Part A of the Social Security Act, §§ 1812(a)(3) and 1814(a)(2)(C) and by 42 CFR § 409 subpart E. Services for homebound beneficiaries on a part-time or intermittent basis are authorized in Part B of the Social

Security Act, §1832(a)(2)(A), and at 42 CFR § 410.80. (OEI; 04-11-00240; expected issue date: FY 2012; work in progress)

### **Home Health Agency Claims' Compliance With Coverage and Coding Requirements**

We will review Medicare claims submitted by HHAs to determine the extent to which the claims meet Medicare coverage requirements. We will assess the accuracy of resource group codes submitted for Medicare home health claims in 2008 and identify characteristics of miscoding. On a prospective basis, Medicare reimburses for home health episodes using a system that categorizes beneficiaries into groups based on care and resource needs and that are referred to as Home Health Resource Groups (HHRG). HHRGs are calculated using beneficiary assessment data collected by an HHA, and each HHRG has an assigned weight that affects the payment rate. Federal regulations provide that beneficiaries receiving home health services must be homebound; need intermittent skilled nursing care, physical or speech therapy, or occupational therapy; be under the care of a physician; and be under a plan of care that has been established and periodically reviewed by a physician. (42 CFR § 409.42.) The payment basis and reimbursement for claims submitted by HHAs are governed by the Social Security Act, § 1895. (OEI; 01-08-00390; expected issue date: FY 2012; work in progress)

### **Medicare Administrative Contractors' Oversight of Home Health Agency Claims (New)**

We will review fraud and abuse prevention and services performed by the home health benefit MACs. We will also review the reduction of payment errors by MACs. Medicare Payment Advisory Commission (MedPAC), OIG, CMS, and Government Accountability Office studies and reviews have reported vulnerabilities in the home health PPS. The pattern of utilization growth has not been related to clinical or patient characteristics. One of the purposes of MACs is to reduce payment errors by preventing initial payment of claims that are not compliant with Medicare's coverage, coding, payment, and billing policies. To detect and deter fraud, MACs may use a variety of methods such as, but not limited to, data analysis, prepayment claim reviews, postpayment claim reviews, extrapolation claim reviews, and medical reviews to target and identify claims and/or providers with suspicious characteristics. (OEI; 04-11-00220; expected issue date: FY 2012; work in progress)

### **Wage Indexes Used To Calculate Home Health Payments (New)**

We will determine whether Medicare home health payments were calculated using incorrect wage indexes and evaluate the adequacy of controls to prevent such inaccuracies. To calculate an HHA's prospective payment, Federal regulations require that the national episode payment rate be adjusted to account for geographic differences in wage levels using the wage index that corresponds to the beneficiary's site of service. (42 CFR § 484.220(b).) (OAS; W-00-12-35601; various reviews; expected issue date: FY 2012; new start)

### **Home Health Prospective Payment System Requirements**

We will review compliance with various aspects of the home health PPS, including the documentation required in support of the claims paid by Medicare. Some beneficiaries who are confined to their homes are eligible to receive home health services. (Social Security Act, §§ 1835(a)(2)(A) and 1861(m).) Such services include part-time or intermittent skilled nursing care, as well as other skilled care services such as physical, occupational, and speech therapy; medical social work; and home health aide services. (OAS; W-00-11-35501; various reviews; expected issue date: FY 2012; new start)



## Home Health Agency Trends in Revenues and Expenses

We will review cost report data to analyze HHA revenue and expense trends under the home health PPS to determine whether the payment methodology should be adjusted. We will examine various Medicare and overall revenue and expense trends for freestanding and hospital-based HHAs. Since the home health PPS was implemented in October 2000, HHA expenditures have significantly increased. Home health services are paid under a PPS pursuant to the Social Security Act, § 1895, added by the Balanced Budget Act of 1997 (BBA), § 4603. (OAS; W-00-10-35428; various reviews; expected issue date: FY 2012; work in progress)

## Hospitals

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

|  |   |
|--|---|
| CAH—CRITICAL ACCESS HOSPITALS                  | HAC—HOSPITAL-ACQUIRED CONDITIONS            |
| CoP—CONDITIONS OF PARTICIPATION (IN MEDICARE)  | IPPS—INPATIENT PROSPECTIVE PAYMENT SYSTEM   |
| DGME—DIRECT GRADUATE MEDICAL EDUCATION (COSTS) | IRF—INPATIENT REHABILITATION FACILITIES     |
| DRA—DEFICIT REDUCTION ACT OF 2005              | IRIS—INTERN AND RESIDENT INFORMATION SYSTEM |
| FTE—FULL TIME EQUIVALENT                       | POA—PRESENT ON ADMISSION                    |
| GME—GRADUATE MEDICAL EDUCATION (PAYMENTS)      |   |

### Hospital Reporting for Adverse Events

We will review the type of information that hospitals' internal incident-reporting systems capture about adverse events and determine the extent to which hospital systems captured adverse events and reported the information to external patient-safety oversight entities. Most hospitals have incident-reporting systems that enable medical and hospital staff members to report information about patient safety incidents when they occur and to use reported information to prevent recurrence, hold staff members accountable, and notify families. We will use data collected for a 2010 OIG study examining the national incidence of adverse events among hospitalized Medicare beneficiaries. (OEI; 06-09-00091; expected issue date: FY 2012; work in progress)

### Reliability of Hospital-Reported Quality Measure Data

We will review hospitals' controls for ensuring the accuracy and validity of data related to quality of care that they submit to CMS for Medicare reimbursement. Hospitals must report quality measures for a set of 10 indicators established by the Secretary as of November 1, 2003. (The Social Security Act, § 1886(b)(3)(B)(vii).) A reduction in payments of 0.4 percent to hospitals that did not report quality measures to CMS was established by the MMA, § 501(b). The reduction was increased to 2 percent effective at the beginning of FY 2007. (Social Security Act, § 1886(b)(3)(viii), as added by the Deficit Reduction Act of 2005 (DRA), § 5001(a).) We note that the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) also expands the existing quality initiative. (OAS; W-00-11-35438; various reviews; expected issue date: FY 2012; new start; Affordable Care Act)

### Hospital Admissions With Conditions Coded Present on Admission

We will review Medicare claims to determine which types of facilities, such as SNF or rehabilitation facilities, are most frequently transferring patients with certain diagnoses that were coded as being present when patients were admitted (referred to as "present on admission" (POA)). We will also

determine whether specific providers transferred a high number of patients to hospitals with POA diagnoses. Medicare requires acute care hospitals to report on their claims which diagnoses were present when patients were admitted. (Social Security Act, § 1886(d)(4)(D), and CMS's *Change Request 5679*, Pub. 100-20, One-Time Notification, Transmittal 289.) For certain diagnoses specified by CMS, hospitals receive a lower payment if the specified diagnoses were acquired in the hospital. (OAS; W-00-10-35500; W-00-11-35500; various reviews; expected issue date: FY 2012; work in progress)

### **Accuracy of Present-on-Admission Indicators Submitted on Medicare Claims (New)**

We will review the accuracy of POA indicators submitted on inpatient claims submitted by hospitals nationally in October 2008. Hospitals do not receive additional payment for certain conditions that were not present when the patient was admitted. (DRA, § 501.) Beginning in FY 2008, CMS required hospitals to submit POA indicators with each diagnosis code on Medicare hospital inpatient claims. These indicators identify which diagnoses were present at the time of admission and those conditions that developed during the hospital stay. Recent law provides that hospitals with high rates of hospital-acquired conditions (HAC) will receive reduced payments. (Affordable Care Act, § 3008.) Accurate POA indicators are needed for CMS to implement the requirements in the DRA and the Affordable Care Act. We will use certified coders to review medical records and Medicare claims. (OEI; 06-09-00310; expected issue date: FY 2012; work in progress; Affordable Care Act)

### **Medicare Inpatient and Outpatient Payments to Acute Care Hospitals (New)**

We will review Medicare payments to hospitals to determine compliance with selected billing requirements. We will use the results of these reviews to recommend recovery of overpayments and identify providers that routinely submit improper claims. Prior OIG audits, investigations, and inspections have identified areas that are at risk for noncompliance with Medicare billing requirements. Based on computer matching and data mining techniques, we will select hospitals for focused reviews of claims that may be at risk for overpayments. Using the same data analysis techniques, we will identify hospitals that broadly rank as least risky across compliance areas and those that broadly rank as most risky. We will then review the hospitals' policies and procedures to compare the compliance practices of these two groups of hospitals. We will also survey or interview hospitals' leadership and compliance officers to provide contextual information related to hospitals' compliance programs. (OAS; W-00-11-35538; various reviews; expected issue date: FY 2012; work in progress; and OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Hospital Inpatient Outlier Payments: Trends and Hospital Characteristics**

We will review hospital inpatient outlier payments, examine trends of outlier payments nationally, and identify characteristics of hospitals with high or increasing rates of outlier payments. Medicare typically reimburses hospitals for inpatient services based on a predetermined per-discharge amount, regardless of the actual costs incurred. Medicare pays hospitals supplemental payments, called outliers, for patients incurring extraordinarily high costs. (Social Security Act, § 1886(d)(5)(A)(ii).) In 2009, outlier payments represented about 5 percent of total Medicare inpatient payments, or about \$6 billion per year. Recent whistleblower lawsuits have resulted in millions of dollars in settlements from hospitals charged with inflating Medicare claims to qualify for outlier payments. (OEI; 06-10-00520; expected issue date: FY 2012; work in progress)

### **Medicare's Reconciliations of Outlier Payments**

We will review Medicare outlier payments to determine whether CMS performed the necessary reconciliations in a timely manner so that Medicare contractors could perform final settlement of the associated cost reports submitted by providers. We will also examine whether MACs referred all providers that meet the criteria for reconciliations to CMS. Outliers are additional payments made for beneficiaries who incur unusually high costs. Outlier payment reconciliations must be based on the most recent cost-to-charge ratio from the cost report to properly determine outlier payments. (42 CFR § 412.84(i)(4).) Outlier payments also may be adjusted to reflect the time value of money for overpayments and underpayments. (OAS; W-00-11-35451; various reviews; expected issue date: FY 2012; new start)

### **Hospital Claims With High or Excessive Payments**

We will review Medicare hospital claims with high payments to determine whether they were appropriate. We will also review the effectiveness of the claims processing system edits used to identify excessive payments. Our prior work has shown that claims with unusually high payments may be incorrect for various reasons. Our work will include certain outpatient claims in which payments exceeded charges and selected Healthcare Common Procedure Coding System codes for which billings appear to be aberrant. Medicare requires hospitals to report units of service as the number of times a service or procedure was performed. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 4, § 20.4.) (OAS; W-00-10-35518; W-00-11-35518; various reviews; expected issue date: FY 2012; work in progress)

### **Hospital Same-Day Readmissions**

We will review Medicare claims to determine trends in the number of same-day hospital readmission cases. Based on prior OIG work, CMS implemented an edit (a special system control) in 2004 to reject subsequent claims on behalf of beneficiaries who were readmitted to the same hospital on the same day. If a same-day readmission occurs for symptoms related to or for evaluation or management of the prior stay's medical condition, the hospital is entitled to only one diagnosis-related group payment and should combine the original and subsequent stays into a single claim. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, § 40.2.5.) Providers are permitted to override the edit in certain situations. We will test the effectiveness of the edit. This work may also be helpful to CMS in implementing provisions of the Affordable Care Act. (OAS; W-00-10-35439; W-00-11-35439; various reviews; expected issue date: FY 2012; work in progress; Affordable Care Act)

### **Acute-Care Hospital Inpatient Transfers to Inpatient Hospice Care (New)**

We will review Medicare claims for inpatient stays for which the beneficiary was transferred to hospice care and examine the relationship, either financial or common ownership, between the acute-care hospital and the hospice provider and how Medicare treats reimbursement for similar transfers from the acute-care setting to other settings. Regulations at 42 CFR § 412.2 state that inpatient prospective payment system (IPPS) payments to hospitals for inpatient stays are payment in full for hospitals' operating costs. Regulations state that hospice payments can be made for a general inpatient care day. (42 CFR § 318.301(b)(4).) A general inpatient care day is one on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management that cannot be managed in other settings. (OAS; W-00-12-35602; various reviews; expected issue date: FY 2012; new start)

**Medicare Payments for Beneficiaries With Other Insurance Coverage**

We will review Medicare payments for services to beneficiaries who have certain types of other insurance coverage to assess the effectiveness of procedures in preventing inappropriate Medicare payments. (Social Security Act, § 1862(b).) This review 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 amounts. (OAS; W-00-11-35317; various reviews; expected issue date: FY 2012; new start)

**Duplicate Graduate Medical Education Payments**

We will review provider data from CMS's Intern and Resident Information System (IRIS) to determine whether duplicate or excessive graduate medical education (GME) payments have been claimed. We will also assess the effectiveness of IRIS in preventing providers from receiving payments for duplicate GME costs. Medicare pays teaching hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs. In the calculation of payments for DGME and IME costs, no intern or resident may be counted by Medicare as more than one full-time-equivalent (FTE) employee. (42 CFR §§ 413.78(b) and 412.105(f)(1)(iii).) The primary purpose of IRIS is to ensure that no intern or resident is counted as more than one FTE. If duplicate payments were claimed, we will determine which payment was appropriate. (OAS; W-00-09-35432; W-00-10-35432; W-00-11-35432; various reviews; expected issue date: FY 2012; work in progress)

**Hospital Occupational-Mix Data Used To Calculate Inpatient Hospital Wage Indexes**

We will determine whether hospitals reported occupational-mix data used to calculate inpatient wage indexes in compliance with Medicare regulations and the effect on Medicare of inaccurate reporting of occupational-mix data. Hospitals must accurately report data every 3 years on the occupational mix of their employees. (Social Security Act, § 1886 (d)(3)(E).) CMS uses data from the occupational-mix survey to construct an occupational-mix adjustment to its hospital wage indexes. Accurate wage indexes are essential elements of the PPS for hospitals. (OAS; W-00-11-35452; various reviews; expected issue date: FY 2012; new start)

**Inpatient Prospective Payment System: Hospital Payments for Nonphysician Outpatient Services**

We will review the appropriateness of payments for nonphysician outpatient services that were provided to beneficiaries shortly before or during Medicare Part A-covered stays at acute care hospitals. Prior OIG reviews in this area found significant numbers of improper claims. IPPS payments to hospitals for inpatient stays are payment in full for hospitals' operating costs, and hospitals generally receive no additional payments for nonphysician services. (Social Security Act, § 1886(a)(4), and 42 CFR § 412.2.) For nonphysician services provided to inpatients by entities under arrangements with the hospitals, submissions of any additional claims to Part B are prohibited. (Social Security Act, §§ 1862(a)(14) and 1861(w)(1), as interpreted by CMS in its FY 1983 IPPS final rule.) Section 1886(a)(4) prohibits separate payments for outpatient diagnostic services and admission-related nondiagnostic services rendered up to 3 days before the dates of admission. (OAS; W-00-10-35436; various reports; expected issue date: FY 2012; work in progress)

**Noninpatient Prospective Payment System: Hospital Payments for Nonphysician Outpatient Services**

We will review the appropriateness of payments for nonphysician outpatient services that were provided to beneficiaries shortly before or during Medicare Part A-covered stays at non-IPPS

hospitals. Payments to non-IPPS hospitals for inpatient claims should include diagnostic services and other services related to admission provided during 1 day immediately preceding the date of the patient's admission. (Social Security Act, § 1886(a)(4).) For nonphysician services provided to inpatients, CMS prohibits submissions of additional claims to Part B for outpatient diagnostic services and admission-related nondiagnostic services rendered up to 1 day before and on the date of admission. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, §§ 40.3 B and 40.3 C.) (OAS; W-00-11-35450; various reviews; expected issue date: FY 2012; new start)

### **Medicare Brachytherapy Reimbursement**

We will review payments for brachytherapy to determine whether the payments are in compliance with Medicare requirements. Brachytherapy is a form of radiotherapy in which a radiation source is placed inside or next to the area requiring treatment. Medicare pays for radioactive source devices used in treating certain forms of cancer. (Social Security Act, § 1833 (t)(16)(C), as amended by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 142.) (OAS; W-00-10-35520; W-00-11-35520; various reviews; expected issue date: FY 2012; work in progress)

### **Medicare Outpatient Dental Claims (New)**

We will review Medicare hospital outpatient payments for dental services to determine whether payments for dental services were made in accordance with Medicare requirements. Dental services are generally excluded from Medicare coverage, with a few exceptions. (Social Security Act, § 1862(a)(12).) For example, Medicare reimbursement is allowed for the extraction of teeth to prepare the jaw for radiation treatment (CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 150). Based on current OIG audits, providers received Medicare reimbursement for noncovered dental services that resulted in significant overpayments. (OAS; W-00-12-35603; various reviews; expected issue date: FY 2012; new start)

### **Medicare Inpatient and Outpatient Hospital Claims for the Replacement of Medical Devices**

We will determine whether hospitals submitted inpatient and outpatient claims that included procedures for the insertion of replacement medical devices in compliance with Medicare regulations. Medicare does not cover items or a services for which neither the beneficiary nor anyone on his or her behalf has an obligation to pay. (Social Security Act, §1862(a)(2).) Medicare is not responsible for the full cost of the replaced medical device if the hospital receives a partial or full credit from the manufacturer either because the manufacturer recalled the device or because the device is covered under warranty. Medicare requires hospitals to use modifiers on their inpatient and outpatient claims when they receive credit from the manufacturer of 50 percent or more for a replacement device. (OAS; W-00-10-35516; W-00-11-35516; various reviews; expected issue date: FY 2012; work in progress)

### **Observation Services During Outpatient Visits**

We will review Medicare payments for observation services provided by hospital outpatient departments to assess the appropriateness of the services and their effect on Medicare beneficiaries' out-of-pocket expenses for health care services. Part B coverage of hospital outpatient services and reimbursement for such services under the hospital outpatient prospective payment system are provided by the Social Security Act, §§ 1832(a) and 1833(t).) Observation care includes certain short-term services such as treatment, assessment, and reassessment that are furnished while a decision is being made regarding whether patients will require further treatment as

hospital inpatients or if they are able to be discharged from the hospital. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 4, § 290.) Improper use of observation services may subject beneficiaries to high cost sharing. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Inpatient Rehabilitation Facility Transmission of Patient Assessment Instruments**

We will determine whether inpatient rehabilitation facilities (IRF) received reduced payments for claims with patient assessment instruments that were transmitted to CMS's National Assessment Collection Database more than 27 days after the beneficiaries' discharges. The patient assessment instrument is used to gather data to determine payment for each Medicare patient admitted to an IRF. Federal regulations for IRF payments provide that such payments be reduced if patient assessments are not encoded and transmitted within defined time limits. (42 CFR § 412.614(d)(2).) If an IRF transmits the instrument more than 27 calendar days from (and including) the beneficiary's discharge date, the IRF's payment rate should be reduced by 25 percent. (OAS; W-00-10-35522; various reviews; expected issue date: FY 2012; work in progress)

### **In-Patient Rehabilitation Facilities (New)**

We will examine the appropriateness of admissions to IRFs. We will also examine the level of therapy being provided in IRFs and how much concurrent and group therapy IRFs are providing. IRFs provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and a multidisciplinary, coordinated team approach to improve their ability to function. Patients must undergo preadmission screening and evaluation to ensure that they are appropriate candidates for IRF care. (42 CFR §§ 412.622(a)(3)-(5).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Critical Access Hospitals**

We will examine the appropriateness of payments to Critical Access Hospitals (CAH). We will determine whether CAHs have met designation criteria and conditions of participation and whether payments to CAHs were in accordance with Medicare requirements. CAH designation criteria are in the Social Security Act, § 1820(c)(2)(B), and conditions of participation are at 42 CFR pt. 485, subpart F. CAHs are generally paid 101 percent of the reasonable costs of providing covered CAH services. (Social Security Act, §§ 1814(l)(1) and 1834(g).) (OAS; W-00-10-35101; W-00-11-35101; various reviews; expected issue date: FY 2012; work in progress)

### **Critical Access Hospitals (New)**

We will review CAHs to profile variations in size, services, and distance from other hospitals. We will also examine the numbers and types of patients that CAHs treat. To be designated as CAHs, hospitals must meet several criteria, such as being located in a rural area, furnishing 24-hour emergency care services, providing no more than 25 inpatient beds; and having an average annual length of stay of 96 hours or less. (Social Security Act, § 1820(c)(2)(B).) CAHs represent a separate provider type with their own Medicare (CoP) as well as a separate payment method. There are approximately 1,350 CAHs, but limited information exists about their structure and the type of services they provide. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

## Nursing Homes

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

IRF—INPATIENT REHABILITATION FACILITY  
LTCH—LONG-TERM-CARE HOSPITALS  
RAI—RESIDENT ASSESSMENT INSTRUMENTS

RUG—RESOURCE UTILIZATION GROUPS  
SNF—SKILLED NURSING FACILITIES

### **Medicare Requirements for Quality of Care in Skilled Nursing Facilities**

We will review how SNFs have addressed certain Federal requirements related to quality of care. We will determine the extent to which SNFs developed plans of care based on assessments of beneficiaries, provided services to beneficiaries in accordance with the plans of care, and planned for beneficiaries' discharges. We will also review SNFs' use of Resident Assessment Instruments (RAI) to develop nursing home residents' plans of care. Prior OIG reports revealed that about a quarter of residents' needs for care, as identified through RAIs, were not reflected in care plans and that nursing home residents did not receive all the psychosocial services identified in care plans. Federal laws require nursing homes participating in Medicare or Medicaid to use RAIs to assess each nursing home resident's strengths and needs. (Social Security Act, §§ 1819(b)(3) and 1919(b)(3).) (OEI; 02-09-00201; expected issue date: FY 2012; work in progress)

### **Safety and Quality of Post-Acute Care for Medicare Beneficiaries (New)**

We will review the quality of care and safety of Medicare beneficiaries transferred from acute-care hospitals to postacute care. We will evaluate the transfer process and also identify rates of adverse events and preventable hospital readmissions from post-acute-care settings. We will focus on three postacute settings: SNFs, IRFs and long-term-care hospitals. Average hospital stays for Medicare beneficiaries have fallen steadily over several decades, resulting in increased transfers to postacute-care facilities. Patients recovering in these facilities often require substantial clinical care, and the capabilities of the facilities to care for residents vary by facility type and access to appropriate equipment and staffing. The hospital discharge planning process and the degree of communication and collaboration between acute-care and postacute-care providers also affect a beneficiary's experience and the ability of providers to ensure a smooth and safe transition. (OEI; 06-11-00370; expected issue date: FY 2013; work in progress)

### **Nursing Home Compliance Plans (New)**

We will review Medicare- and Medicaid-certified nursing homes' implementation of compliance plans as part of their day-to-day operations and whether the plans contain elements identified in OIG's compliance program guidance. We will assess whether CMS has incorporated compliance requirements into Requirements of Participation and oversees provider implementation of plans. Section 6102 of the Affordable Care Act requires nursing homes to operate a compliance and ethics program, containing at least 8 components, to prevent and detect criminal, civil, and administrative violations and promote quality of care. The Affordable Care Act requires CMS to issue regulations by 2012 and SNFs to have plans that meet such requirements on or after 2013. OIG's compliance program guidance is at 65 Fed. Reg. 14289 and 73 Fed. Reg. 56832. (OEI; 00-00-00000; expected issue date: FY 2013; new start; Affordable Care Act)

### **Oversight of Poorly Performing Nursing Homes**

We will review CMS's and States' use of enforcement measures to determine their impact on improving the quality of care that beneficiaries received in poorly performing nursing homes and evaluate the performance of these nursing homes. We will also determine the extent to which CMS and States follow up to ensure that poorly performing nursing homes implement correction plans. Federal requirements include a survey-and-certification process, including an enforcement process, to ensure that nursing homes meet Federal standards for participation in Medicare and Medicaid. (Social Security Act, §§ 1819(g) and 1864.) We will examine enforcement decisions resulting from inspections and other oversight by CMS and States. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Nursing Home Emergency Preparedness and Evacuations During Selected Natural Disasters**

We will review nursing homes' emergency plans and emergency preparedness deficiencies cited by State surveyors to determine the sufficiency of the nursing homes' plans and their implementation of the plans. We will also describe the experiences of selected nursing homes, including challenges, successes, and lessons learned, when they implemented their plans during recent disasters, such as hurricanes, floods, and wildfires. Federal regulations require that Medicare- and Medicaid-certified nursing homes have plans and procedures to meet all potential emergencies and train all employees in emergency procedures. (42 CFR § 483.75(m).) In 2006, OIG reported that nursing homes in certain Gulf States had plans that lacked a number of features suggested by emergency preparedness experts and that staff members did not always follow plans during emergencies. (OEI; 06-09-00270; expected issue date: FY 2012; work in progress)

### **Medicare Part A Payments to Skilled Nursing Facilities**

We will review the extent to which payments to SNFs meet Medicare coverage requirements. We will conduct a medical review to determine whether claims were medically necessary, sufficiently documented, and coded correctly during calendar year (CY) 2009. The amount paid to SNFs for all covered services is established by the Social Security Act, § 1888(e). Medicare pays Part A SNF stays using a system that categorizes each beneficiary into a group according to care and resource needs. The groups are referred to as Resource Utilization Groups (RUG). In a prior report, OIG found that 26 percent of claims had RUGs that were not supported by patients' medical records. The percentage represented \$542 million in potential overpayments for FY 2002. (OEI; 02-09-00200; expected issue date: FY 2012; work in progress)

### **Hospitalizations and Rehospitalizations of Nursing Home Residents**

We will review the extent to which Medicare beneficiaries residing in nursing homes have been hospitalized and rehospitalized. We will also assess CMS's oversight of nursing homes whose residents have high rates of hospitalization. Hospitalizations and rehospitalizations of nursing home residents are costly to Medicare and may indicate quality-of-care problems at nursing homes. A 2007 OIG study found that 35 percent of hospitalizations during a SNF stay were caused by poor quality of care or unnecessary fragmentation of services. (OEI; 06-11-00040; expected issue date: FY 2012; work in progress)

### **Questionable Billing Patterns During Non-Part A Nursing Home Stays (New)**

We will identify questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to nursing home residents whose stays are not paid for under Medicare's



Part A SNF benefit. Part B services provided during a non-Part A stay must be billed directly by suppliers and other providers. (CMS's *Medicare Benefits Policy Manual*, Pub. 100-02, ch. 8, § 70.) Congress directed OIG to monitor these services for abuse. (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 313.) A series of studies will examine podiatry, ambulance, laboratory, and imaging services. (OEI; 06-11-00280; various reviews; expected issue dates: FY 2012, 2013; work in progress)

## Hospices

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

MEDPAC—MEDICARE PAYMENT ADVISORY COMMISSION

CoPs—(MEDICARE) CONDITIONS OF PARTICIPATION

### **Hospice Marketing Practices and Financial Relationships with Nursing Facilities (New)**

We will review hospices' marketing materials and practices and their financial relationships with nursing facilities. Medicare covers hospice services for eligible beneficiaries under Medicare Part A. (Social Security Act, § 1812(a).) In a recent report, OIG found that 82 percent of hospice claims for beneficiaries in nursing facilities did not meet Medicare coverage requirements. MedPAC, an independent congressional agency that advises Congress on issues affecting Medicare, has noted that hospices and nursing facilities may be involved in inappropriate enrollment and compensation. MedPAC has also highlighted instances in which hospices aggressively marketed their services to nursing facility residents. We will focus our review on hospices that have a high percentage of their beneficiaries in nursing facilities. (OEI; 02-10-00071; 02-10-00072; expected issue date: FY 2012; work in progress)

### **Medicare Hospice General Inpatient Care**

We will review the use of hospice general inpatient care from 2005 to 2010. We will assess the appropriateness of hospices' general inpatient care claims and hospice beneficiaries' drug claims billed under Part D. Federal regulations address Medicare CoPs for hospice at 42 CFR Part 418. We will review hospice medical records to address concerns that this level of hospice care is being misused and to determine the extent to which drugs are being inappropriately billed to Part D. (OEI; 02-10-00490; expected issue date: FY 2012; work in progress)

## Medical Equipment and Supplies

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

DME—DURABLE MEDICAL EQUIPEMENT

DMEPOS—DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS,  
AND SUPPLIES

DTS—DIABETIC TESTING SUPPLIES

LCD—LOCAL COVERAGE DETERMINATION

MAC—MEDICARE ADMINISTRATIVE CONTRACTOR

### **Medicare Enrollment and Monitoring for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**

We will review Medicare contractors' processes for enrolling and monitoring suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). We will assess their use of enrollment-screening mechanisms and post-enrollment monitoring activities to identify applicants that pose fraud risks to Medicare and the extent to which applicants omitted ownership information on enrollment applications. Medicare contractors must conduct prescreening, verification, validation, and final processing of Medicare provider enrollment applications. (CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 10, § 1.3.) A recent OIG study found that suppliers omitted or provided inaccurate information on enrollment applications, which resulted in improper enrollment. (OEI; 06-09-00230; expected issue date: FY 2012; work in progress)

### **Medicare Qualifications of Orthotists and Prosthetists**

We will review the credentials of a sample of providers submitting custom-fabricated orthotic and prosthetic claims to determine the extent to which Medicare paid unqualified practitioners in 2009 and the extent to which CMS provides oversight of credentialing of orthotists and prosthetists. We will also assess whether CMS provided guidance to State licensing boards and industry on how to define a "qualified practitioner" of orthotics and prosthetics. Pursuant to special payment rules for certain custom-fabricated prosthetics and custom-fabricated orthotics, no payment will be made for such items unless provided by a qualified practitioner as defined in the statute. (Social Security Act, § 1834(h)(1)(F).) Previous OIG work found that miscoded orthotics represented \$33 million in inappropriate Medicare payments in 1998 because the device did not meet the specifications billed, the device was not custom-fabricated, or the part billed was already included in the base code for a larger device. OIG concluded that the qualifications of orthotic suppliers varied, with noncertified suppliers most likely to provide inappropriate devices and services. (OEI; 07-10-00410; expected issue date: FY 2012; work in progress)

### **Medicare Supplier Acquisition Costs for Back Orthoses**

We will compare supplier acquisition costs to the Medicare reimbursement amount for the back orthosis procedure code L0631. Medicare beneficiaries receive their L0631 back orthoses from suppliers that bill Medicare for reimbursement. Back orthoses are covered by Social Security Act, § 1832(a)(2), and are supplied by Medicare DMEPOS suppliers, who purchase back orthoses from wholesalers or directly from orthotics manufacturers. For 2011, the median Medicare reimbursement amount for a L0631 back brace is \$929. OIG has encountered suppliers who can purchase these back orthoses for prices significantly lower than Medicare reimbursement rates. Internet retail prices for this type of orthoses are also significantly lower. (OEI; 03-11-00600; expected issue date: FY 2012; work in progress)

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

We will review the appropriateness of Medicare Part B payments to suppliers of power mobility devices and other DME items to determine whether payments were in accordance with Medicare requirements. Prior OIG reviews have identified issues such as Medicare payments 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 for power mobility devices (e.g., scooters), hospital beds and accessories, oxygen concentrators, and enteral/parenteral nutrition. 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.” (Social Security Act, §§ 1862(a)(1)(A) and 1833(e).) (OAS; W-00-10-35223; W-00-11-35223; various reviews; expected issue date: FY 2012; work in progress)

### **Frequency of Replacement of Supplies for Durable Medical Equipment**

We will review the compliance of suppliers of DMEPOS with Medicare requirements for frequently replaced DME supplies to determine whether payments for such supplies met Medicare requirements. Preliminary OIG work showed that suppliers automatically shipped continuous positive airway pressure system and respiratory-assist device supplies when no physician order for refills was in effect. We will select a sample of claims for frequently replaced supplies. For DME supplies and accessories used on a periodic basis, the order or Certificate of Medical Necessity must specify the type of supplies needed and the frequency with which they must be replaced, used, or consumed. (CMS’s *Medicare Program Integrity Manual*, Pub. 100-08, ch. 5, §§ 2.3 and 5.9.)

A beneficiary or a beneficiary’s caregiver must specifically request refills of repetitive services and/or supplies before a supplier dispenses them. (CMS’s *Medicare Claims Processing Manual*, Pub. 100-04, ch. 20, § 200.) Also, a supplier may not initiate a refill of an order and a supplier must not automatically dispense a quantity of supplies on a predetermined regular basis. Medicare does not pay for items or services that are “not reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-12-35240; various reviews; expected issue date: FY 2012; 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 certain modifier codes and determine whether payments to the suppliers met Medicare requirements. Payments to any service provider are precluded unless the provider has furnished the information necessary to determine the amounts due. (Social Security Act, § 1833(e).) For certain items to be covered by Medicare, DME suppliers must use modifiers to indicate that they have the appropriate documentation on file and provide, upon request, the documentation to support their claims for payment. Reviews of suppliers conducted by several of CMS’s DME MACs found that suppliers had little or no documentation to support their claims, suggesting that many of the claims submitted may have been invalid and should not have been paid by Medicare. (OAS; W-00-10-35305; W-00-11-35305; various reviews; expected issue date: FY 2012; work in progress)

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

We will compare Medicare’s fee schedule for parenteral nutrition with fees paid by other sources of reimbursement. We will identify reimbursement amounts paid by public and private payers for parenteral nutrition services. Parenteral nutrition is the practice of feeding a person intravenously to replace the function of a permanently inoperative or malfunctioning internal organ and is covered under the prosthetic device benefit of the Social Security Act, § 1861(s)(8). In 2009, Medicare paid more than \$137 million for parenteral nutrition supplies. 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. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

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

We will review Medicare Part B payments for home blood glucose test strips and lancet supplies to determine their appropriateness. The local coverage determinations (LCD) 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 LCDs require that the supplier add a modifier code to identify when a patient is treated with insulin or not treated with insulin. The amount of supplies allowable for Medicare reimbursement differs depending on the applicable modifier. Medicare does not pay for items or services that are not “reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-11-35407; various reviews; expected issue date: FY 2012; work in progress)

### **Effectiveness of Edits To Prevent Payments to Multiple Suppliers of Home Blood-Glucose Testing Supplies (New)**

We will review the the DME MACs’ claims processing edits (special system controls) designed to prevent payments to multiple suppliers of home blood-glucose test strips and lancets and determine whether they are effective in preventing inappropriate payments. The LCDs issued by the four DME MACs states that the DME supplier may not dispense test strips and lancets until a beneficiary has nearly exhausted the previously dispensed supplies. The LCDs also require that a beneficiary or a caregiver must specifically request the refill of test strips and lancets before the DME supplier dispenses them to a beneficiary. Prior OIG reports identified inappropriate payments to multiple DME suppliers for test strips and lancets dispensed to the same beneficiary with overlapping service dates. Medicare does not pay for items or services that are not “reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-12-35604; various reviews; expected issue date: FY 2012; new start)

### **Questionable Billing for Medicare Diabetic Testing Supplies (New)**

We will review Medicare claims for diabetic testing strips and lancets (diabetic testing supplies) to identify questionable billing. We will also identify characteristics that may be indicative of fraud, waste, and abuse. Medicare has utilization guidelines for the amount of diabetic testing supplies (DTS) that beneficiaries may receive. To receive reimbursement from Medicare, suppliers must maintain documentation demonstrating that their DTS claims meet all Medicare coverage, coding, and medical necessity requirements. DTS claims with certain characteristics (e.g., DTS provided to a beneficiary at irregular intervals) may indicate improper supplier billing. (OEI; 04-11-00330; expected issue date: FY 2012; work in progress)

### **Support Surface Pricing (New)**

We will review supplier acquisition costs for support surfaces as compared to Medicare payment rates. We will also review whether competitive bidding rates have affected Medicare patients’ access to appropriate supplies and services. Support surfaces are a type of DME covered under Part B as a medical or other health service pursuant to the Social Security Act, § 1861(s)(6). We will review costs for low-air-loss and alternating-pressure seat cushions. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Collection of Surety Bonds for Overpayments Made to Suppliers of Durable Medical Equipment (New)**

We will review CMS’s use of surety bonds to recover overpayments made to DMEPOS suppliers. We will determine the amount of overpayments CMS sought and recouped through DMEPOS surety bonds, and also identify barriers to surety bond collection. Certain DMEPOS suppliers must provide and maintain a surety bond of no less than \$50,000. (BBA, § 4312(a)(16).) By requiring DMEPOS surety bonds, CMS aims to limit fraud risk to Medicare by ensuring only legitimate suppliers are

enrolled and to recoup overpayments resulting from fraudulent or abusive billing practices. (OEI; 03-11-00350; expected issue date: FY 2012; work in progress)

### **Competitive Bidding Process for Medical Equipment and Supplies**

We will review the process CMS used to conduct competitive bidding and subsequent pricing determinations for certain DMEPOS items and services in selected competitive bidding areas under rounds 1 and 2 of the competitive bidding program. Federal law requires OIG to conduct postaward audits to assess this process. (MIPPA, § 154(a)(1)(E).) (OAS; W-00-11-35241; various reviews; expected issued date: FY 2012; new start)

### **Medicare DMEPOS Competitive Bidding Program: Supplier Solicitation of Physician Prescribing**

We will interview prescribing physicians to determine the extent to which suppliers participating in the competitive bidding program are soliciting physicians to prescribe certain brands or modes of delivery of covered items that are more profitable to suppliers. We will also examine billing patterns to identify changes resulting from competitive bidding. Federal law requires Medicare to establish a competitive bidding process for the purchase of selected DME items. Congress subsequently delayed implementation until 2011. (Social Security Act, § 1847.) The same section of law requires that OIG conduct reviews (including this evaluation) examining the competitive bidding process. (OEI; 06-11-00081; expected issue date: FY 2012; work in progress)

## Other Providers and Suppliers

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CERT—COMPREHENSIVE ERROR RATE TESTING (PROGRAM)  
 CMHC—COMMUNITY MENTAL HEALTH CENTER  
 CORF—COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY  
 E/M—EVALUATION AND MANAGEMENT (SERVICES)  
 ESRD—END STAGE RENAL DISEASE

HOPD—HOSPITAL OUTPATIENT DEPARTMENT  
 IDTF—INDEPENDENT DIAGNOSTIC TESTING FACILITY  
 OPO—ORGAN PROCUREMENT ORGANIZATION  
 PHP—PARTIAL HOSPITALIZATION PROGRAM  
 PPS—PROSPECTIVE PAYMENT SYSTEM

### **Organ Procurement Organizations: Payments (New)**

We will review Medicare payments to organ procurement organizations (OPO) to determine whether payments were correct and supported by documentation, including whether OPOs correctly reported organ statistics for purposes of proper allocation of costs in their cost reports. 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 forth at 42 CFR § 413. (OAS; W-00-11-35568; various reviews; expected issue date: FY 2012; work in progress)

### **Ambulances: Comparison of Medicare Fee Schedule Amounts to Other Payers (New)**

We will compare reimbursements by other payers for ambulance services to Medicare fee schedule amounts for similar services to determine whether Medicare amounts exceed the reimbursements by other payers. Medicare payments are based on the lesser of the actual charge or the applicable fee schedule amount. (42 CFR § 414.610(a).) We will examine reimbursements made by Medicare

Advantage (MA) plans, State Medicaid programs, and the Federal Employees Health Benefits Plan (FEHB). (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Ambulances: Questionable Billing for Ambulance Services (New)**

We will examine Medicare claims data to identify questionable billing for ambulance services such as transports that were potentially not medically reasonable and necessary and potentially unnecessary billing for Advanced Life Support Services and speciality care transport. We will also examine relationships between ambulance companies and other providers. Medicare pays for emergency and nonemergency ambulance services when a beneficiary's medical condition at the time of transport is such that other means of transportation are contraindicated (i.e., would endanger the beneficiary). (Social Security Act, § 1861(s)(7).) Medicare pays for different levels of ambulance service, including Basic Life Support and Advanced Life Support as well as specialty care transport. (42 CFR § 410.40(b).) (OEI; 00-00-00000; expected issue date: FY 2012; new start; and OAS; W-00-11-35574; various reviews; expected issue date: FY 2012; work in progress)

### **Physicians and Suppliers: Compliance With Assignment Rules**

We will review the extent to which providers comply with assignment rules and determine to what extent beneficiaries are inappropriately billed in excess of amounts allowed by Medicare. We will also assess beneficiaries' awareness of their rights and responsibilities regarding potential billing violations and Medicare coverage guidelines. Physicians participating in Medicare agree to accept payment on an "assignment" for all items and services furnished to individuals enrolled in Medicare. (Social Security Act, § 1842(h)(1).) CMS defines "assignment" as a written agreement between beneficiaries, their physicians or other suppliers, and Medicare. The beneficiary agrees to allow the physician or other supplier to request direct payment from Medicare for covered Part B services, equipment, and supplies by assigning the claim to the physician or supplier. The physician or other supplier in return agrees to accept the Medicare-allowed amount indicated by the carrier as the full charge for the items or services provided. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Physicians and Other Suppliers: High Cumulative Part B Payments (New)**

We will review payment systems controls that identify high cumulative Medicare Part B payments to physicians and suppliers. We will determine whether payment system controls are in place to identify such payments and assess the effectiveness of those controls. Medicare Part B services must be reasonable and necessary (Social Security Act, § 1862(a)(1)(A)), adequately documented (§ 1833(e)), and provided consistent with Federal regulations (42 CFR, § 410). A high cumulative payment is an unusually high payment made to an individual physician or supplier, or on behalf of an individual beneficiary, over a specified period. Prior OIG work has shown that unusually high Medicare payments may indicate incorrect billing or fraud and abuse. (OAS; W-00-12-35605; various reviews; expected issue date: FY 2012; new start)

### **Physician-Owned Distributors of Spinal Implants (New)**

We will determine the extent to which physician-owned distributors (POD) provide spinal implants purchased by hospitals. We will also analyze Medicare claims data to determine whether PODs we identify in our review are associated with high use of spinal implants. PODs are business arrangements involving physician ownership of medical device companies and distributorships. PODs are focused primarily in the surgical arena and are currently primarily involve orthopedic implants such as spine and total joints. However, PODs appear to be quickly growing into other

areas such as cardiac implants. Congress has expressed concern that PODs could create conflicts of interest and safety concerns for patients. (OEI; 01-11-00660; expected issue date: FY 2012; work in progress)

### **Physicians: Place-of-Service Errors**

We will review physicians' coding on Medicare Part B claims for services performed in ambulatory surgical centers and hospital outpatient departments to determine whether they properly coded the places of service. Federal regulations provide for different levels of payments to physicians depending on where services are performed. (42 CFR § 414.32.) Medicare pays a physician a higher amount when a service is performed in a nonfacility setting, such as a physician's office, than it does when the service is performed in a hospital outpatient department or, with certain exceptions, in an ambulatory surgical center. (OAS; W-00-10-35113; W-00-11-35113; various reviews; expected issue date: FY 2012; work in progress)

### **Physicians: Incident-To Services (New)**

We will review physician billing for "incident-to" services to determine whether payment for such services had a higher error rate than that for non-incident-to services. We will also assess CMS's ability to monitor services billed as "incident-to." Medicare Part B pays for certain services billed by physicians that are performed by nonphysicians incident to a physician office visit. A 2009 OIG review found that when Medicare allowed physicians' billings for more than 24 hours of services in a day, half of the services were not performed by a physician. We also found that unqualified nonphysicians performed 21 percent of the services that physicians did not perform personally. Incident-to services represent a program vulnerability in that they do not appear in claims data and can be identified only by reviewing the medical record. They may also be vulnerable to overutilization and expose Medicare beneficiaries to care that does not meet professional standards of quality. Medicare's Part B coverage of services and supplies that are performed incident to the professional services of a physician is in the Social Security Act, § 1861(s)(2)(A). Medicare requires providers to furnish such information as may be necessary to determine the amounts due to receive payment. (Social Security Act, § 1833(e).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Physicians: Impact of Opting Out of Medicare (New)**

We will review the extent to which physicians are opting out of Medicare and determine whether physicians who have opted out of Medicare are submitting claims to Medicare. We will also examine whether specific areas of the country have seen higher numbers of physicians opting out and its potential impact on beneficiaries. Physicians are permitted to enter into private contracts with Medicare beneficiaries. (Social Security Act, § 1802(b).) As a result of entering into private contracts, physicians must commit that they will not submit a claim to Medicare for any Medicare beneficiary. (OEI; 07-11-00340; expected issue date: FY 2012; work in progress)

### **Chiropractors: Part B Payments for Services (New)**

We will review Medicare Part B payments for chiropractic services to determine whether such payments were in accordance with Medicare requirements. Prior OIG work identified inappropriate payments for chiropractic services furnished during CY 2006. Medicare chiropractors' services include only treatment by means of manual manipulation of the spine. (42 CFR § 440.60.) Chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. (CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 30.5B.)

Medicare will not pay for items or services that are “not reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-12-35606; various reviews; expected issue date: FY 2012; new start)

### **Ambulatory Surgical Centers: Payment System**

We will review the appropriateness of Medicare’s methodology for setting ambulatory surgical center payment rates under the revised payment system. Federal law requires the Secretary to implement a revised payment system for payment of surgical services furnished in such centers. (MMA, § 626.) (OAS; W-00-10-35423; W-00-11-35423; various reviews; expected issue date: FY 2012; work in progress)

### **Ambulatory Surgical Centers and Hospital Outpatient Departments: Safety and Quality of Surgery and Procedures (New)**

We will review the safety and quality of care for Medicare beneficiaries having surgeries and procedures in ambulatory surgical centers and Hospital Outpatient Departments (HOPD). We will assess care in preparation for and provided during surgeries and procedures in both settings. We will identify adverse events in both settings. CMS and stakeholders have expressed interest in the comparative safety and quality of care provided by ambulatory surgical centers and HOPDs. When Medicare beneficiaries require certain surgeries or procedures that do not require hospitalization, physicians generally have the option to perform such surgeries or procedures in an ambulatory surgical center, HOPD, or other health care setting such as a physician’s office. Site determinations are typically made based on the type of surgery or procedure, as well as the patient’s health status and comorbidities. The proportion of surgeries and procedures performed in ambulatory surgical centers has risen substantially over the past decade. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Evaluation and Management Services: Trends in Coding of Claims**

We will review evaluation and management (E/M) claims to identify trends in the coding of E/M services from 2000-2009. We will also identify providers that exhibited questionable billing for E/M services in 2009. Medicare paid \$32 billion for E/M services in 2009, representing 19 percent of all Medicare Part B payments. Providers are responsible for ensuring that the codes they submit accurately reflect the services they provide. (CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 30.6.1.) E/M codes represent the type, setting, and complexity of services provided and the patient status, such as new or established. (OEI; 04-10-00180; expected issue date: FY 2012; work in progress)

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

We will review industry practices related to the number of E/M services provided by physicians and reimbursed as part of the global surgery fee to determine whether the practices have changed since the global surgery fee concept was developed in 1992. Under the global surgery fee concept, physicians bill a single fee for all of their services that are usually associated with a surgical procedure and related E/M services provided during the global surgery period. The criteria for global surgery policy are in CMS’s *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 40. (OAS; W-00-09-35207; various reviews; expected issue date: FY 2012; work in progress)



**Evaluation and Management Services: Use of Modifiers During the Global Surgery Period (New)**

We will review the appropriateness of the use of certain claims modifier codes during the global surgery period and determine whether Medicare payments for claims with modifiers used during the global surgery period were in accordance with Medicare requirements. Prior OIG work has shown that improper use of modifiers during the global surgery period resulted in inappropriate payments. The global surgery payment includes a surgical service and related preoperative and postoperative E/M services provided during the global surgery period. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 40.1.) Guidance for the use of modifiers for global surgeries is in CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 30. (OAS; W-00-12-35607; various reviews; expected issue date: FY 2012; new start)

**Evaluation and Management Services: Potentially Inappropriate Payments**

We will assess the extent to which CMS made potentially inappropriate payments for E/M services and the consistency of E/M medical review determinations. We will also review multiple E/M services for the same providers and beneficiaries to identify electronic health records (EHR) documentation practices associated with potentially improper payments. Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service based upon the content of the service and have documentation to support the level of service reported. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 30.6.1.) (OEI; 04-10-00181; 04-10-00182; expected issue date: FY 2013; work in progress)

**Part B Imaging Services: Medicare Payments**

We will review Medicare payments for Part B imaging services to determine whether they reflect the expenses incurred and whether the utilization rates reflect industry practices. Physicians are paid for services pursuant to the Medicare physician fee schedule, which covers the major categories of costs, including the physician professional cost component, malpractice costs, and practice expense. Practice expenses are those such as office rent, wages of personnel, and equipment. (Social Security Act, § 1848(c)(1)(B).) For selected imaging services, we will focus on the practice expense components, including the equipment utilization rate. (OAS; W-00-11-35219; various reviews; expected issue date: FY 2012; new start)

**Clinical Social Workers: Part B Billing for Services to Hospital Inpatients**

We will review services furnished by clinical social workers to inpatients of Medicare participating hospitals or SNFs to determine whether the services were separately billed to Medicare Part B. We will examine Medicare Part A and Part B claims with overlapping dates of service. Federal regulations describe services performed by clinical social workers that may not be billed as clinical social worker services under Medicare Part B when provided to inpatients of certain facilities. (42 CFR § 410.73(b)(2).) (OAS; W-00-11-35405; various reviews; expected issue date: FY 2012; new start)

**Partial Hospitalization Programs in Community Mental Health Centers: Questionable Billing Characteristics and Contractor Oversight (New)**

We will identify questionable billing characteristics associated with partial hospitalization program (PHP) claims submitted by community mental health centers (CMHC). We will also assess fraud prevention and detection activities by relevant CMS contractors and the level of coordination

between CMS and the contractors. Medicare Part B covers PHP services if they are reasonable and necessary for the diagnosis or treatment of an individual's condition, are reasonably expected to improve a beneficiary's condition, and will prevent relapse or hospitalization. Past OIG work has identified vulnerabilities in Medicare payments to CMHCs for PHPs, finding weaknesses in the fraud detection and investigation activities of Medicare program integrity contractors and in CMS's oversight thereof. (OEI; 04-11-00100 and 04-11-00101; various reviews; expected issue date: FY 2012; work in progress)

### **Partial Hospitalization Program Services in Hospital Outpatient Departments and Community Mental Health Centers**

We will review the appropriateness of Medicare payments for PHP psychiatric services in hospital outpatient departments and freestanding community mental health centers. We will determine whether the payments met Medicare requirements. A PHP is an intensive outpatient program of psychiatric services that hospitals may provide to individuals in lieu of inpatient psychiatric care. The program provides individuals who have mental health conditions with an individualized, coordinated, comprehensive, and multidisciplinary treatment involving nurses, psychiatrists, psychologists, and social workers. Medicare spending for PHP services has increased over the years. This review focuses on whether payments met Medicare requirements based on documentation supporting the services, including patient plans of care and physician supervision and certification requirements. Medicare coverage of PHP services is provided by the Social Security Act, § 1832(a)(2)(J), and conditions for payment are in CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 4, § 260, and at 42 CFR §§ 410.43 and 424.24(e). (OAS; W-00-11-35453; various reviews; expected issue date: FY 2012; new start)

### **Independent Therapists: Outpatient Physical Therapy Services**

We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. Previous OIG work has identified claims for therapy services provided by independent physical therapists that were not reasonable, medically necessary, or properly documented. Our focus is on independent therapists who have a high utilization rate for outpatient physical therapy services. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Documentation requirements for therapy services are in CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 220.3. (OAS; W-00-11-35220; various reviews; expected issue date: FY 2012; new start)

### **Sleep Disorder Clinics: Medicare Payments for Sleep Testing**

We will review the appropriateness of Medicare payments for sleep test procedures provided at sleep disorder clinics and determine whether they were in accordance with Medicare requirements. A preliminary OIG review identified improper payments when certain modifier codes are not reported with sleep test procedures. We will examine Medicare payments to physicians and independent diagnostic testing facilities for sleep test procedures. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Requirements for coverage of sleep tests under Part B are in CMS's *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 15, § 70. (OAS; W-00-10-35521; various reviews; expected issue date: FY 2012; work in progress)

**Sleep Testing: Appropriateness of Medicare Payments for Polysomnography**

We will review the appropriateness of Medicare payments for sleep studies. We will also examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements. Medicare payments for polysomnography increased from \$62 million in 2001 to \$235 million in 2009, and coverage was also recently expanded. Sleep studies are reimbursable for patients who have symptoms such as sleep apnea, narcolepsy, or parasomnia in accordance with the CMS's *Medicare Benefit Policy Manual*, Pub. 102, ch. 15, § 70. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

**Diagnostic Radiology: Excessive Payments**

We will review Medicare payments for high-cost diagnostic radiology tests to determine whether they were medically necessary and the extent to which the same diagnostic tests are ordered for a beneficiary by primary care physicians and physician specialists for the same treatment. Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862 (a)(1)(A).) (OAS; W-00-11-35454; various reviews; expected issue date: FY 2012; new start)

**Laboratories: Part B Payments for Glycated Hemoglobin A1C Tests**

We will review Medicare contractors' procedures for screening the frequency of clinical laboratory claims for glycated hemoglobin A1C tests and determine the appropriateness of Medicare payments for these tests. Preliminary OIG work at two Medicare contractors showed variations in the contractors' procedures for screening the frequency of these tests. It is not considered reasonable and necessary to perform a glycated hemoglobin test more often than every 3 months on a controlled diabetic patient unless documentation supports the medical necessity of testing in excess of national coverage determinations guidelines. (CMS's *Medicare National Coverage Determinations Manual*, Pub. 100-03, Ch. 1, pt. 3, § 190.21.) (OAS; W-00-12-35455; various reviews; expected issue date: FY 2012; new start)

**Laboratories: Trends in Laboratory Utilization**

We will review trends in laboratory utilization under Medicare, such as in the types of laboratory tests and the number of tests ordered. We will also examine how physician specialty, diagnosis, and geographic differences in the practice of medicine affect physicians' laboratory test ordering. In 2008, Medicare paid about \$7 billion for clinical laboratory services, which represents a 92 percent increase from 1998. Much of the growth in laboratory spending was the result of increased volume of ordered services. Medicare pays only for those laboratory tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary. (42 CFR § 410.32(a).) (OEI; 03-11-00730; expected issue date: FY 2012; work in progress)

**Payments for Laboratory Tests—Comparing Medicare, State Medicaid, and Federal Employee Health Benefit Programs**

We will determine how the methods for establishing Medicare laboratory test payment rates vary from State Medicaid and Federal Employee Health Benefits (FEHB) programs. We will identify 2011 Medicare, State Medicaid, and FEHB plan payment rates for selected laboratory tests and the extent to which Medicare payment rates differ from Medicaid and FEHB. Excessive payment rates for laboratory tests can be costly for Medicare. In 2009, Medicare paid nearly \$10 billion for lab tests. We will compare Medicare laboratory payment rates for 20 lab tests, representing the most frequently ordered and most costly tests in terms of total dollars paid, with those of other public

payers, including State Medicaid programs and the Federal Employee Health Benefit plans. (OEI; 07-11-00010; expected issue date: FY 2012; work in progress)

### **Comprehensive Outpatient Rehabilitation Facilities**

We will review national Medicare utilization patterns for Comprehensive Outpatient Rehabilitation Facility (CORF) services, identify CORFs in high-utilization areas, and determine whether they meet basic Medicare requirements. Medicare paid about \$61 million for 35,000 beneficiaries who received CORF services in 2009. Previous OIG work identified CORF services that did not meet Medicare reimbursement standards because they were not medically necessary or lacked documentation that they were provided. OIG has also raised concern about potentially inappropriate rental arrangements between physician landlords and CORFs. Federal regulations require that CORFs maintain locations that provide safe and sufficient space for the scope of all services offered. (42 CFR § 485.62.) We will conduct site visits of CORFs. (OEI; 05-10-00090; expected issue date: FY 2012; work in progress)

### **End Stage Renal Disease: Payments for Beneficiaries Entitled to Medicare Under Special Provisions**

We will review claims for end stage renal disease (ESRD) beneficiaries who are entitled to Medicare coverage only because of special circumstances to determine the extent to which they continue to obtain those benefits after their coverage should have ended. Individuals who are medically determined to have ESRD may become eligible for Medicare benefits regardless of age. Our preliminary analysis identified ESRD-eligible beneficiaries who were still receiving Medicare benefits beyond the allowed timeframe. Medicare coverage is limited to the 36th month after the month in which such individual receives a kidney transplant or, in the case of an individual who has not received a kidney transplant and no longer requires a regular course of dialysis, the 12th month after the month in which such course of dialysis is terminated. (Social Security Act, § 226A(b)(2).) (OAS; W-00-12-35456; various reviews; expected issue date: FY 2012; new start)

### **End Stage Renal Disease: Medicare's Oversight of Dialysis Facilities (New)**

We will assess Medicare's oversight of facilities that provide outpatient maintenance dialysis services to Medicare beneficiaries with ESRD. We will assess the performance of oversight functions as well as how CMS holds State survey and certification agencies and ESRD Networks accountable. Dialysis facilities must meet specific conditions to participate in Medicare. (Social Security Act, § 1881(b)(1), and 42 CFR Part 494.) CMS monitors the quality of care delivered to dialysis patients. (BBA, § 4558(b).) CMS contracts with State survey and certification agencies and ESRD Networks to conduct on-site inspections of dialysis facilities and initiate corrective actions. State agencies and ESRD Networks also respond to and resolve complaints and adverse events, and utilize data for dialysis facility oversight. (OEI; 01-11-00550; expected issue date: FY 2012; work in progress)

### **End Stage Renal Disease: Bundled Prospective Payment System for Renal Dialysis Services (New)**

We will review Medicare pricing and utilization related to renal dialysis services under the new bundled ESRD PPS for renal dialysis services. We will also determine whether Medicare payments under the new ESRD PPS were made in accordance with Medicare requirements. CMS was to establish a case-mix adjusted bundled PPS for renal dialysis services beginning January 1, 2011. (Social Security Act, § 1881(b)(14).) The ESRD PPS, to be phased in over 4 years, will replace the basic case-mix adjusted composite payment system and the methodologies for reimbursement of

separately billable outpatient ESRD services, and combines the payments for composite rate and separately billable services into a single payment. (OAS; W-00-12-35608; various reviews; expected issue date: FY 2012; new start)

### **Medicare Payments for Part B Claims with G Modifiers**

We will review Medicare payments made from 2002 to 2010 for claims on which providers used certain modifier codes indicating that Medicare denial was expected. We will determine the extent to which Medicare paid claims having such modifiers. We will also identify providers and suppliers with atypically high billing related to the modifiers. Providers may use GA or GZ modifiers on claims they expect Medicare to deny as not reasonable and necessary. (CMS's *Claims Processing Manual*.) They may use GX or GY modifiers for items or services that are statutorily excluded. A recent OIG review found that Medicare paid for 72 percent of pressure-reducing support surface claims with GA or GZ modifiers, amounting to \$4 million in potentially inappropriate payments. (OEI; 02-10-00160; expected issue date: FY 2012; work in progress)

### **Payments for Services Ordered or Referred by Excluded Providers**

We will review the nature and extent of Medicare payments for services ordered or referred by excluded providers (those who have been barred from billing Federal health care programs) and examine CMS's oversight mechanisms to identify and prevent payments for such services. No payments shall be made for any items or services furnished, ordered, or prescribed by excluded individuals or entities. (Social Security Act, §§ 1128 and 1156, and 42 CFR § 1001.1901.) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medical Claims Review at Selected Providers**

We will review Medicare Part A and Part B claims submitted by error-prone providers to determine their validity, project our results to each provider's population of claims, and recommend that CMS request refunds on projected overpayments. Previous OIG work illustrated a methodology for identifying error-prone providers using CMS's Comprehensive Error Rate Testing (CERT) Program data. Using this methodology, we identified providers that consistently submitted claims found to be in error in a 4-year period. In this review, we will select the top error-prone providers based on expected dollar error amounts and match selected providers against the National Claims History file to determine the total dollar amount of claims paid. We will then conduct a medical review on a sample of claims. Providers must submit accurate claims for services provided to Medicare beneficiaries. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04.) (OAS; W-00-11-35565; various reviews; expected issue date: FY 2012; new start)

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

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

AMD—WET AGE-RELATED MACULAR DEGENERATION  
AMP—AVERAGE MANUFACTURER PRICE  
ASP—AVERAGE SALES PRICE

LCD—LOCAL COVERAGE DETERMINATIONS  
WAMP—WIDELY AVAILABLE MARKET PRICES

### **Comparison of Average Sales Prices to Average Manufacturer Prices**

We will periodically review Medicare Part B drug prices by comparing average sales prices (ASP) to average manufacturer prices (AMP) and identify drug prices that exceed a designated threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Federal law requires OIG to 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. (Social Security Act, § 1847A(d).) (OEI; 00-00-00000; various studies; expected issue date: FY 2012; new start)

### **Comparison of Average Sales Prices to Widely Available Market Prices**

We will periodically review widely available market prices (WAMP) for selected prescription drugs covered by Part B and compare them to ASPs for those drugs to identify a designated payment-related threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. Federal law requires OIG to conduct studies that compare ASPs to WAMPs for Part B-covered drugs. (Social Security Act, § 1847A(d).) If OIG finds that the ASP of a drug exceeds the WAMP by a certain threshold (now 5 percent), Medicare is to base payment for the drug on the lesser of the WAMP or 103 percent of the AMP. (OEI; 00-00-00000; various studies; expected issue date: FY 2012; new start)

### **Costs and Payments for ESRD Drugs (New)**

We will review payments for ESRD drugs under the new bundled rate system. We will compare facility acquisition costs for certain drugs to inflation-adjusted cost estimates, and determine how costs for the drugs have changed since our last review. Effective January 1, 2011, CMS was to implement a new system that bundles all costs related to ESRD care (including drugs that were previously separately billable) into a single per-treatment payment. (Social Security Act, § 1881(b)(14)(A)(i).) The bundled rate must be updated annually to reflect changes in the price of goods and services used in ESRD care. CMS has based price updates on wage and price proxy data from the Bureau of Labor Statistics. (75 Fed. Reg. 49030 at page 49151 (Aug. 12, 2010).) Previous OIG work found that data from the Bureau did not accurately measure changes in facility acquisition costs for high-dollar ESRD drugs. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Billing for Immunosuppressive Drugs**

We will review Medicare Part B immunosuppressive drug claims to determine whether they were billed according to their Food and Drug Administration (FDA)-approved labels. We will also determine whether Medicare paid for immunosuppressive drugs that should not have been used in combination with other immunosuppressive drugs. Medicare Part B covers drugs that are not usually self-administered and are furnished incident to physicians' services, such as immunosuppressive drugs. (Social Security Act, § 1832(a)(2), and CMS's *Medicare Benefits Policy Manual*, Pub. No. 100-02, ch. 15, § 50.) The manual also states that use of such drugs must be safe and effective and otherwise reasonable and necessary and that drugs or biologicals approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Several FDA-approved labels for immunosuppressive drugs state that the drugs should not be used in combination with other immunosuppressive drugs. (OAS; W-00-12-35434; various reviews; expected issue date: FY 2012; new start)

### **Payments for Off-Label Anticancer Pharmaceuticals and Biologicals**

We will review Medicare payments for drugs and biologicals used on an off-label basis (prescribed for a condition that is not listed on the product's label) in anticancer chemotherapeutic regimens to determine whether patients with particular indications were prescribed anticancer drugs approved by FDA for such indications before resorting to anticancer drugs not approved for those indications. If so, we will determine whether there were improvements in the patients' medical conditions before the use of off-label drugs. If the beneficiaries' medical conditions improved before the use of off-label drugs, we will determine how much Medicare could have saved had the previously administered anticancer drugs continued to be used. Medicare covers FDA-approved drugs used for off-label indications in anticancer chemotherapeutic regimens when such uses are supported in authoritative compendia identified by the Secretary of HHS. (Social Security Act, § 1861(t)(2).) Federal regulations established a process for identifying authoritative sources of information. (CFR § 414.930(b).) The DrugDex, a compendium, defines drugs in the class we will review as being medically accepted even though the given tests or treatments are indicated in only some cases and even where evidence and/or expert opinions argue against efficacy. In CY 2007, Medicare payments for anticancer drugs totaled about \$2.7 billion. (OAS; W-00-11-35504; various reviews; expected issue date: FY 2012; new start)

### **Physician-Administered Drugs and Biologicals (New)**

We will compare Medicare and Medicaid payments for commonly used physician-administered drugs and biologicals to determine whether changes in the reimbursement methodologies for the Part B drug program would result in significant savings. Medicare Part B covers drugs and biologicals that are usually administered by nonphysicians during a visit to a physician's office. Medicare Part B pays for most covered drugs and biologicals based on the reimbursement methodology of ASP plus 6 percent. (Social Security Act, § 1847A.) Medicaid also covers physician-administered drugs and biologicals. However, under Medicaid, States have flexibility in determining reimbursement for covered drugs and biologicals as long as the ingredient cost approximates an estimated acquisition cost. In addition, manufacturers must provide rebates for Medicaid-covered drugs. (Social Security Act, § 1927(a)(1).) (OAS; W-00-12-35609; various reviews; expected issue date: FY 2012; new start)

### **Off-Label and Off-Compendia Use of Medications in Government Prescription Drug Programs (New)**

We will review the extent of off-label (prescribed for a condition that is not listed on the product's label) and off-compendia use of Medicare- and Medicaid-funded prescription drugs, and the extent to which specified compendia provide support for coverage. We will also determine CMS oversight mechanisms related to off-label use of drugs. For prescription drugs to be covered, Federal law generally requires that they are prescribed according to medically accepted indications, such as those approved by the FDA or supported in one or more of the authoritative drug compendia identified by the Secretary of HHS. Therefore, most drugs are covered when used off-label as long as one of the designated compendia has determined that there is sufficient evidence that the drug is safe and effective for treating the condition. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medicare Payments for the Drug Herceptin (New)**

We will review payments associated with Medicare claims for the drug Herceptin to determine whether they were appropriate. For drug claims involving a single-use vial or package, if a provider must discard the remainder of a single-use vial or package after administering a dose/quantity of the

drug or biological, Medicare provides payment for the amount discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. However, multiuse vials such as those used for supplying Herceptin are not subject to payment for discarded amounts of a drug or biological (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 17, § 40). Providers must bill accurately and completely for services provided. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) (OAS; W-00-10-35325; various reviews; expected issue date: FY 2012; work in progress)

### **Acquisition Costs and Payments for Lucentis and Avastin Used in Treating Wet Age-Related Macular Degeneration**

We will review how physicians' acquisition costs compare to Medicare Part B payments for two drugs used to treat wet age-related macular degeneration (AMD), the leading cause of blindness in the elderly. Lucentis is a drug specifically approved by FDA to treat wet AMD, and Avastin is approved to treat cancer. However, eye doctors have been using smaller doses of Avastin off-label as a treatment for wet AMD. CMS recently enacted and then reversed its decision to pay a lower amount for Avastin when used to treat wet AMD after physicians claimed that the new payments were too low and would require them to prescribe the higher-priced Lucentis. Medicare may subsequently be paying substantially more than the acquisition cost for Avastin when it is used to treat wet AMD. The smaller Avastin dose used to treat wet AMD must be prepared in a sterile environment through a process known as compounding. We will also examine the additional compounding cost for Avastin. (OEI; 03-10-00360; expected issue date: FY 2012; work in progress)

### **Usage Patterns and Payments for Avastin and Lucentis in Treating Wet Age-Related Macular Degeneration**

We will review National Claims History data to identify nationwide usage patterns and payments for two drugs (Avastin and Lucentis) used to treat wet AMD. We will determine whether significant savings can be recognized if either one drug or the other is used more by ophthalmologists. Avastin, approved by FDA as a colorectal cancer drug, is also used off-label (prescribed for a condition that is not listed on the product's label) to treat wet AMD. The FDA has approved the use of Lucentis for AMD. Both drugs are physician administered and are covered under Medicare Part B. MACs have issued LCDs allowing for reimbursement for Avastin use off-label to treat wet AMD. Initial results of the Comparison of Age-Related Macular Degeneration Treatments Trials study that compares the safety and efficacy of the two drugs from the National Eye Institute of the National Institutes of Health (NIH) are expected in late 2010 or early 2011. Medicare Part B may cover drugs that are used for indications other than those listed on the official label if the Medicare contractor determines the use to be medically accepted. (Social Security Act § 1861(t)(2), CMS's *Medicare Benefits Policy Manual*, Pub No. 100-02, ch. 15, § 50.4.2.) (OAS; W-00-10-35535; various reviews; expected issue date: FY 2012; work in progress)

### **Medicare Outpatient Payments for Drugs (New)**

We will review Medicare outpatient payments to providers for certain drugs and the administration of those drugs (e.g., chemotherapy) to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. Prior OIG reviews have identified certain drugs, particularly chemotherapy drugs, as vulnerable to incorrect coding. Providers must bill accurately and completely for services provided. (CMS's *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) Further, providers must report units of service as the number of times that a



service or procedure was performed (ch. 5, § 20.2, and ch. 26, § 10.4.). (OAS; W-00-11-35576; various reviews; expected issue date: FY 2012; work in progress)

## Medicare Part A and Part B Contractor Operations

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

|  |   |
|--|---|
| CAS—COST ACCOUNTING STANDARDS  | MAC—MEDICARE ADMINISTRATIVE CONTRACTOR                              |
| DME—DURABLE MEDICAL EQUIPMENT  | MEDIC—MEDICARE DRUG INTEGRITY CONTRACTOR                            |
| DMEPOS—DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES | MSP—MEDICARE SECONDARY PAYER  |
| DMERC—DURABLE MEDICAL EQUIPMENT REGIONAL CARRIERS                      | NSC—NATIONAL SUPPLIER CLEARINGHOUSE                                 |
| FAR—FEDERAL ACQUISITION REGULATION                                     | PCA—PROGRESSIVE CORRECTIVE ACTION (PROVIDER EDUCATION AND TRAINING) |
| FI—FISCAL INTERMEDIARY   | QASP—QUALITY ASSURANCE SURVEILLANCE PLAN                            |
| LCD—LOCAL COVERAGE DETERMINATION                                       | RAC—RECOVERY AUDIT CONTRACTOR                                       |
|  | ZPIC—ZONE PROGRAM INTEGRITY CONTRACTOR                              |

### Contractor Error Rate Reduction Plans (New)

We will examine the extent to which Medicare contractors have error rate reduction plans in place and the extent to which the plans have resulted in lower error rates for contractors. We will also assess CMS's oversight of the process and the extent to which it affects overall contractor evaluation. Error rate reduction plans describe the corrective actions that contractors plan to take to lower the CERT paid-claims error rate and provider-compliance error rate in their jurisdictions. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### Preaward Reviews of Contract Proposals

We will review the cost proposals of various bidders for Medicare contracts. The reports produced by these reviews assist CMS in negotiating favorable and cost-beneficial contract awards. Criteria are in OMB Circular A-122, *Cost Principles for Non-Profit Organizations*. (OAS; W-00-11-35002; various reviews; expected issue date: FY 2012; 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. We will coordinate with CMS the selection of the contractors we will review with. Criteria include Appendix B of the Medicare contract with CMS, and the Federal Acquisition Regulation (FAR) at 48 CFR pt. 31. (OAS; W-00-09-35005; W-00-10-35005; W-00-11-35005; various reviews; expected issue date: FY 2012; work in progress)

### Oversight of Medicare Administrative Contractors

We will review Quality Assurance Surveillance Plan (QASP) performance evaluation reports of MACs to determine whether the reports address the results of activities performed by the MACs. We will also determine how CMS addressed any deficiencies identified by the QASP reports. Federal law requires the Secretary to administer Medicare Part A and Part B through contracts with MACs and to develop specific performance requirements and standards for measuring the extent to which MACs meet such requirements. (MMA, § 911.) To assist in its oversight, CMS developed the QASP review process for use in monitoring and evaluating MACs' performance. Each fiscal year, CMS prepares a

QASP report of contractor performance that summarizes the results of oversight activities that occurred during the year. (OEI; 03-11-00740; expected issue date: FY 2012; work in progress)

### **Zone Program Integrity Contractors' Activities to Detect and Deter Potential Fraud and Abuse**

We will describe the extent to which Zone Program Integrity Contractors (ZPIC) performed program integrity activities including investigations, case referrals, requests for information, and administrative actions; determine any barriers ZPICs encountered in performing their program integrity activities; and determine any barriers affecting CMS oversight of ZPICs. As a result of contracting reform under section 911 of the MMA, CMS is in the process of replacing the Program Safeguard Contractors (PSC), who perform program integrity work in Medicare Parts A and B, with ZPICs. (OEI; 03-09-00520; expected issue date: FY 2012; work in progress)

### **Conflicts of Interest in the Zone Program Integrity Contracting Process**

We will review CMS's process for overseeing contractors' organizational conflicts of interest during the ZPIC award process and throughout the period of performance. We will determine the extent to which ZPICs disclosed conflicts of interest, examine how they resolved them, and determine how CMS addresses personal conflicts of interest among members of the Technical Evaluation Panel used during the awards process. Federal regulations and other authorities prescribe responsibilities, general rules, and procedures to identify, evaluate, and resolve organizational conflicts of interest. (The FAR (48 CFR subpart 9.5), the *Health and Human Services Acquisition Regulation*, and other authorities.) (OEI; 03-10-00300; expected issue date: FY 2012; work in progress)

### **Vulnerabilities Identified by Medicare Benefit Integrity Contractors**

We will review how CMS addresses vulnerabilities identified by PSCs, ZPICs, and Medicare Drug Integrity Contractors (MEDIC) and determine the numbers and types of actions CMS took to address such vulnerabilities. CMS requires PSCs and ZPICs, whose responsibilities include preventing, detecting, and deterring fraud and abuse, to report vulnerabilities on monthly cost reports and on quarterly vulnerability reports. (CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 4, § 4.31). Medicare MEDICs also submit quarterly vulnerability reports. (Section 8.2.12 of the MEDIC Statement of Work.) (OEI; 03-10-00500; expected issue date: FY 2012; work in progress)

### **Recovery Audit Contractors' Performance and Identification and Recoupment of Improper Payments**

We will review the performance of the Recovery Audit Contractor (RAC) program and CMS's oversight of the program. The RACs conduct postpayment reviews to identify overpayments and underpayments and attempt to recoup any overpayments they identify. On completion of a 3-year demonstration project, Congress mandated nationwide implementation of a permanent RAC program for Medicare Part A and Part B. (Tax Relief and Health Care Act of 2006, § 302.) Subsequently, Congress expanded the RAC program, giving it additional responsibilities to address improper payments in Medicare (including Part C and Part D), and Medicaid. (Affordable Care Act, § 6411.) (OEI; 04-11-00680; expected issue date: FY 2012; work in progress; Affordable Care Act)

### **Variation in Coverage of Services and Medicare Expenditures Due to Local Coverage Determinations**

We will review variation in Medicare spending and coverage of services due to LCDs and the evidence Medicare contractors use to develop LCDs. We will also assess CMS's monitoring and

oversight of LCDs. A contractor may establish an LCD to enforce its decision about whether a particular item or service is considered reasonable and necessary and is therefore covered under Medicare. (BIPA § 521 and Social Security Act, § 1862(a)(1)(A).) These coverage decisions are not national, meaning Medicare could pay for a service for a beneficiary in one location, but deny payment for that service to a beneficiary elsewhere. Over 2,800 LCDs are in effect, but it is not possible to readily calculate the number of claims and the amount of Medicare spending associated with LCDs because claims do not indicate whether an LCD is involved. (OEI; 01-11-00500; expected issue date: FY 2012; work in progress)

### **Performance of the National Supplier Clearinghouse**

We will review performance evaluation reports submitted to CMS by the National Supplier Clearinghouse (NSC) to determine whether the NSC performs all contractually required activities and to assess the results of those activities. We will also assess CMS's oversight of the NSC. CMS, through its contract with the NSC, verifies DMEPOS suppliers' initial and continuing compliance with conditions of payment. Federal regulations require DMEPOS suppliers to comply with the conditions of payment, which include, among other things, requirements relating to provider enrollment. (42 CFR pt. 424, subpart P, and 42 CFR § 424.57.) OIG work in 2007 and 2008 found that fraudulent suppliers continue to enroll and participate in Medicare. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Provider Education and Training: Medicare-Affiliated Contractors' Progressive Correction Action**

We will review the progressive corrective action (PCA) provider education and training programs conducted by Medicare-affiliated contractors to determine whether such programs have reduced billing and payment error rates and noncompliance. We will also assess CMS's processes for overseeing the education and training programs of affiliated contractors. PCA is a medical review tool used by Medicare contractors. In FY 2000, CMS included PCA as a strategy for conducting medical reviews and provider education and training. (*Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 3.) The Secretary coordinates educational activities provided through Medicare contractors to maximize the effectiveness of Federal education efforts for providers and oversee contractors' education and training programs. (MMA, § 921(d).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **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-00-10-35094; W-00-11-35094; various reviews; expected issue date: FY 2012; 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 CAS. We will also determine whether the costs claimed were allocable and allowable under the Medicare contracts. Criteria for compliance are in the FAR at 48 CFR § 31.205; CAS 412 and 413; and the Medicare contract,

Appendix B, section XVI. (OAS; W-00-10-35067; W-00-11-3-35067; various reviews; expected issue date: FY 2012; work in progress)

### **Unfunded Pension Costs**

We will review whether Medicare contractors identified and eliminated unallowable costs when computing pension costs charged to Medicare. 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; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI. (OAS; W-00-11-35148; various reviews; expected issue date: FY 2012; work in progress)

### **Pension Segment Closing**

We will review Medicare carriers and FIs whose Medicare contracts have been terminated, resulting in the closing of the Medicare segments of their pension plans. We will determine the amount of any excess pension assets related to each Medicare segment as of the segment closing date. Pension gains that occur when a Medicare segment closes are credited to Medicare. (The FAR at 48 CFR § 31.205; CAS 412 and 413; and the Medicare contract, Appendix B, section XVI.) (OAS; W-00-11-35067; various reviews; expected issue date: FY 2012; 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. Criteria are in the FAR at 48 CFR §§ 31.201 through 31.205. (OAS; W-00-11-35095; various reviews; expected issue date: FY 2012; work in progress)

### **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. We will report to Congress on our assessment of the scope and sufficiency of the independent evaluations and summarize the results of those evaluations. Federal law requires independent evaluations of the security programs of FIs, carriers, and MACs and requires OIG to assess such evaluations and report the results of its assessments to Congress. (MMA, § 912.) (OAS; W-00-12-41010; expected issue date: FY 2012; work in progress and new start)

### **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 FY 2007 and 2008. We will assess compliance with applicable Federal requirements. Federal law requires the Secretary to submit to Congress a plan outlining a strategy for accomplishing the replacement of FIs and carriers with MACs no later than 2011. (MMA, § 911.) The plan the Secretary submitted to Congress calls for the establishment of 23 new administrative contracts. 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 Common Working File system, and Medicare banking records need to be terminated as soon as the contractors' performance periods end. (OAS; W-00-12-41011; various reviews; expected issue date: FY 2012; 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. We will assess and test contractors' and hospitals' policies and procedures for electronic health information protections, access, storage, and transport. The Office of Management and Budget (OMB) 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. (OMB Memorandum M-06-16, issued June 23, 2006.) (OAS; W-00-11-41014; various reviews; expected issue date: FY 2012; new start)

## Other Program-Related Reviews

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

ALJ—ADMINISTRATIVE LAW JUDGE

CERT—COMPREHENSIVE ERROR RATE TESTING (PROGRAM)

FFS—FEE FOR SERVICE

NPI—NATIONAL PROVIDER IDENTIFIER

PECOS—PROVIDER ENROLLMENT, CHAIN, AND OWNERSHIP SYSTEM

PSC—PROGRAM SAFEGUARD CONTRACTOR

### **Providers and Suppliers with Currently Not Collectible Debt**

We will review the number and dollar value of Medicare Parts A and B overpayments that CMS deemed as currently not collectible (CNC) and review CMS's actions to reduce and recover CNC debt. We will also determine whether CNC debtors are closely associated with other businesses that continue to receive Medicare payment. CMS defines a CNC debt as a Medicare overpayment that remains uncollected 210 days after the provider or supplier is notified of the debt and for which recovery attempts by CMS contractors have failed. In 2006, the amount of DMEPOS supplier debt deemed CNC was \$402 million. An OIG report found that overpayments referred for collection by PSC in 2007 did not result in substantial recoveries to Medicare. (OEI; 03-11-00670; expected issue date: FY 2012; work in progress)

### **First Level of the Medicare Appeals Process**

We will review the timeliness of Medicare contractors in making determinations on requests for reconsideration at the first level of Medicare appeals. We will also review the processes that Medicare contractors use to conduct first-level Medicare appeals. Medicare contractors have 60 days to conclude a redetermination regarding a denied claim. (Social Security Act, § 1869(a)(3)(C)(ii).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medicare Administrative Law Judge Decisions**

We will review the characteristics of cases decided by Medicare administrative law judges (ALJ) in FY 2010 and describe how Medicare ALJs review and decide cases. We will also describe the extent

to which CMS and its contractors participate in ALJ hearings. There are four levels of the Medicare administrative appeals process within HHS. The third level of appeals consists of ALJ hearings. (Social Security Act, § 1869(d).) The process is administered by the HHS Office of Medicare Hearings and Appeals (OMHA). We will review case files from recent ALJ hearings as well as interview relevant OMHA and CMS officials. (OEI; 02-10-00340; expected issue date: FY 2012; work in progress)

### **Comprehensive Error Rate Testing Program: Fiscal Year 2011 Error Rate Oversight**

We will review certain aspects of the CERT Program to evaluate CMS's efforts to ensure the accuracy of the FY 2011 error rate and to reduce improper payments. Through CERT, national, contractor-specific, and service-type error rates are computed. The CERT program's national estimated improper payments for FY 2010 were \$34.3 billion (10.5 percent error rate). The Improper Payments Elimination and Recovery Act of 2010 (IPERA) requires the head of a Federal agency with any program or activity that may be susceptible to significant improper payments to report to Congress the agency's estimate of improper payments. For any program or activity with estimated improper payments exceeding \$10 million, the agency must report to Congress the actions that the agency is taking to reduce those payments. OMB identified CMS as an agency with high-profile programs that are susceptible to significant improper payments. In November 2003, CMS assumed responsibility for estimating and reporting improper Medicare FFS payments and national error rates. The CERT Program was established by CMS to meet the requirements of the IPERA and to monitor the accuracy with which Medicare claims are billed and paid. (CMS's *Medicare Program Integrity Manual*, Pub. 100-08, ch. 12.) Effective August 1, 2008, the CERT program also samples inpatient records replacing the Hospital Payment Monitoring Program. (OAS; W-00-11-40048; various reviews; expected issue date: FY 2012; new start)

### **CMS Disclosure of Personally Identifiable Information (New)**

We will determine whether CMS's disclosures of individuals' records are in accordance with the Privacy Act of 1974 (Privacy Act). We will also determine whether CMS is accounting for the disclosures in accordance with the Privacy Act and describe CMS's policies and practices for implementing safeguards that protect individuals' records. A "record" means any item, collection, or grouping of information about an individual maintained by an agency, including, but not limited to, financial transactions and medical history, which contains a name or identifying information. The Privacy Act allows limited disclosure of individuals' records for routine uses necessary to accomplish an agency activity. The law's requirements include keeping an accurate accounting of the name or agency to which the records were disclosed, and the date, nature, and purpose of each disclosure. (Privacy Act, 5 U.S.C. § 552a(c).) (OEI; 09-11-00430; expected issue date: FY 2012; work in progress)

### **National Provider Identifier Enumeration and Medicare Provider Enrollment Data**

We will review the extent to which national provider identifier (NPI) enumeration data and Medicare Provider Enrollment, Chain, and Ownership System (PECOS) data are complete, consistent, and accurate and assess CMS's supporting processes. Federal law requires the Secretary of HHS to establish a standard unique identifier for each health care provider, health care organization, and health plan for use in the health care system. (Health Insurance Portability and Accountability Act of 1996. The Secretary established the NPI to address this requirement. Separately, Federal regulations require providers to enroll to receive payment from Medicare. (42 CFR § 424.505.) PECOS is the system CMS uses to complete the enrollments online. (OEI; 07-09-00440; expected issue date: FY 2012; work in progress)

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The [Work Plan](#) is one of OIG's three core publications. The [Semiannual Report to Congress](#) summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

Part II:

Medicare  
Part C and Part D



## Part II: Medicare Part C and Part D

Beneficiaries must be enrolled in both Part A and Part B to join one of the Part C Medicare Advantage (MA) plans, which are administered by MA organizations. MA organizations are public or private organizations licensed by States as risk-bearing entities that are under contract with the Centers for Medicare & Medicaid Services (CMS) to provide covered services. MA organizations may offer one or more plans.

Medicare's optional outpatient prescription drug benefit, known as Medicare Part D, took effect on January 1, 2006. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).) This is a voluntary benefit available to Medicare beneficiaries.

### Part C (Medicare Advantage)

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES

DME—DURABLE MEDICAL EQUIPMENT

FFS—FEE FOR SERVICE

FMO—FIELD MARKETING ORGANIZATIONS

HCPP—HEALTH CARE PREPAYMENT PLAN

HMO—HEALTH MAINTENANCE ORGANIZATION

MA—MEDICARE ADVANTAGE

QIO—QUALITY IMPROVEMENT ORGANIZATIONS

SNF—SKILLED NURSING FACILITY

SNP—SPECIAL NEEDS PLANS

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

Descriptions of the Office of Inspector General's (OIG) continuing and planned reviews of Medicare Part C in fiscal year (FY) 2012 follow.

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

We will review the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, end stage renal disease, or Medicaid eligible. We will determine the impact of inaccurate or invalid classification of beneficiaries on Medicare payments to MA plans. CMS adjusts payments to MA organizations for risk factors, including disability status, institutional status, and such other factors as deemed appropriate. (Social Security Act, § 1853(a)(1)(c), as amended by the Affordable Care Act, § 3205.) (OAS; W-00-11-35227; various reviews; expected issue date: FY 2012; work in progress; Affordable Care Act)

#### **Special Needs Plans: Enrollment of Medicare Beneficiaries With Chronic Conditions**

We will review Special-Needs Plans' compliance with chronic condition enrollment requirements. We will also assess CMS's oversight of plans' enrollment practices. Medicare requires Special-Needs

Plans to restrict enrollment to chronic or disabling conditions. In 2010, the Secretary identified 15 conditions for 2010 that meet the requirements of being severe or disabling and needing specialized care management. (Medicare Improvements for Patients and Providers Act of 2008, § 164.) The Affordable Care Act extended Special-Needs Plans through 2014. (Affordable Care Act, § 3205.) (OEI; 00-00-00000; expected issue date: FY 2013; new start; Affordable Care Act)

### **Medicare Advantage Risk Adjustment Data Submissions**

We will determine whether the diagnoses that MA organizations submitted to CMS for use in CMS's risk-score calculations complied with Federal requirements. We will review the medical record documentation to ensure that the documentation supports the diagnoses submitted to CMS. Payments to MA organizations are adjusted based on the health status of each beneficiary. (Social Security Act, subsections 1853(a)(1)(C) and (a)(3).) MA organizations submit risk adjustment data to CMS in accordance with CMS instructions. (42 CFR § 422.310(b).) (OAS; W-00-09-35078; W-00-10-35078; W-00-11-35078; various reviews; expected issue date: FY 2012; work in progress)

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

We will determine whether CMS properly adjusted payments to MA plans based on the results of its calendar year (CY) 2007 data validation reviews. Risk adjustment data validation is an annual process of verifying diagnosis codes. (42 CFR §§ 422.308(c) and 422.310(e).) The process affects payments to MA plans. CMS contracts with Quality Improvement Organizations or equivalent contractors to verify whether diagnosis codes are supported by medical record documentation. (OAS; W-00-12-35554; various reviews; expected issue date: FY 2012; new start)

### **Risk-Adjusted Payments to Medicare Advantage Organizations that Offer Prescription Drug Plans**

We will review supporting data for beneficiary diagnosis codes submitted by MA organizations that offer prescription drug plans (MA-PD). We will determine the accuracy of the data and the validity of the diagnosis codes. We will also determine the accuracy of the resultant risk scores and risk-adjusted monthly payments to MA-PDs. As an incentive to MA-PDs to accept less healthy and higher-risk beneficiaries, CMS uses a risk-adjusted payment methodology to pay a higher monthly subsidy for beneficiaries diagnosed as less healthy. (42 CFR § 423.329(b).) Sponsor-submitted diagnosis codes are used to determine beneficiaries' final risk scores for calculating monthly payments to MA-PDs. MA-PDs' collection of medical records and diagnoses from appropriate sources (i.e., hospital inpatient facilities, hospital outpatient facilities, and physicians) is critical in determining the appropriate diagnosis codes, risk scores, and monthly payments. Federal regulations require MA organizations that offer MA-PD plans to submit to CMS the risk-adjustment-related data that they obtain from those who provide services to the beneficiaries. (42 CFR §§ 422.310(b) and 423.329(b)(3)(ii).) In 2006, CMS adopted the prescription drug hierarchical condition category (RxHCC) model to calculate the risk scores of all Medicare beneficiaries eligible for Part D. (OAS; W-00-11-35540; various reviews; expected issue date: FY 2012; new start)

### **Duplicate Payments for Drugs by Part C and Part D for Beneficiaries Who Are Institutionalized**

We will determine the extent to which certain drugs for institutionalized beneficiaries that should have been covered under Part C payments to MA plans in 2008 were paid by Part D. We will match information on Part C drugs negotiated between MA plans and CMS against Part D payment data. Matches in the data will represent potential duplicate payments. Under Medicare Part C, CMS

contracts with MA plans to provide managed health care coverage to Medicare enrollees, including all Part A and Part B services and some drugs that the MA plans negotiate as part of their Part C bids. Medicare Part D coverage does not extend to drugs covered under Part A and Part B, including drugs for beneficiaries in Part A skilled nursing facility (SNF) stays. (Social Security Act, § 1860D-2(e)(2)(B).) Drugs used in SNF stays are generally covered under Part A (42 CFR § 409.25). (OAS; W-00-11-35550; various reviews; expected issue date: FY 2012; new start)

### **Duplicate Payments to Cost-Based Health Maintenance Organization Plans Under Capitation Agreements and Fee for Service**

We will identify duplicate Medicare capitation and fee-for-service (FFS) payments to selected cost-based Health Maintenance Organization (HMO) plans. Medicare FFS billings that capitated providers submit for services provided to their Medicare enrollees will result in duplicate payments to the providers. Under capitation agreements, health care providers are paid for services furnished to a cost plan's Medicare enrollees through monthly per capita payments from the cost plan. Federal requirements for costs claimed for Medicare payments to cost-based HMO plans are at 42 CFR pt. 417, subpart O, and CMS's Medicare Managed Care Manual, Pub. 100-16 ch. 17, subchapter B. (OAS; W-00-11-35553; various reviews; expected issue date: FY 2012; new start)

### **Accuracy of Expenditures Claimed on Cost Reports by Health Care Prepayment Plans (New)**

We will review expenditures claimed on cost reports by selected Health Care Prepayment Plans (HCPP). We will determine whether selected HCPPs' expenditures were reasonable and allowable for reimbursement. HCPPs must submit a final cost report to CMS within 120 days after the close of the contract period. (42 CFR § 417.810(b).) CMS reconciles the final cost report to the monthly payments to determine any liability due CMS or the HCPP. HCPPs are entitled to reimbursement only for expenditures that are reasonable and necessary. (42 CFR § 417.802(a).) (OAS; W-00-11-35563; various reviews; expected issue date: FY 2013; work in progress)

### **Quality-Based Bonus Payments to Unrated Plans in 2011 and 2012 (New)**

We will determine the amounts of quality-based bonus payments made to unrated MA plans in 2011 and 2012. We will also determine the extent to which CMS collects data for MA plans that are unrated. Medicare makes adjustment payments to MA plans based on their quality ratings. (Social Security Act, § 1853, amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).) Quality ratings are reflected on a five-star scale. The Affordable Care Act requires that quality-based bonus payments be paid to qualifying new MA plans that have not had MA contracts in the preceding 3 years. In addition, the law requires the Secretary to develop a methodology to determine whether plans with low enrollment qualify for quality bonus payments. (OEI; 00-00-00000; expected issue date: FY 2012; new start; Affordable Care Act)

### **Quality of the Part C Bid Review Process**

We will assess work performed by CMS's Office of the Actuary and its contracted actuary reviewers to ensure that its reviews of Part C bids are in accordance with Medicare policies and procedures and that issues identified during reviews are sufficiently addressed before bid approval. Our audit will include a review of compliance with the desk review methodology, as well as an assessment of the quality of that methodology. CMS's authority to review the aggregate bid amounts submitted by MA plans is at 42 CFR § 422.256. (OAS; W-00-11-35555; various reviews; expected issue date: FY 2012; new start)

**Medicare Advantage Organizations' Oversight of Contractors**

We will review MA organizations' oversight of contractors that provide enrollees benefits, such as prescription drugs and mental health services. We will determine the extent to which MA organizations oversee and monitor their contractors' compliance with regulations and examine the processes that they use to ensure that contractors fulfill their contractual obligations. MA organizations are accountable for the performance of related entities. MA organizations that delegate responsibilities under their contracts with CMS to other entities must include in their contracts with those entities provisions specifying that the entities must comply with all applicable Medicare laws, regulations, and CMS instructions. (42 CFR § 422.504(i)(4)). (OEI; 00-00-00000; expected issue date: FY 2013, new start)

**Medicare Advantage Plans Oversight of Durable Medical Equipment Suppliers**

We will review MA plans' oversight of contractors that provide durable medical equipment (DME) and services to enrollees. We will determine the effectiveness of MA plans' controls over the selection of suppliers, assessment of medical need for DME, and validation of service delivery to prevent fraud, waste, and abuse in payments to DME suppliers servicing MA enrollees. DME is part of the basic Medicare-covered services that MA plans provide, mostly by subcontracting with DME suppliers. Medicare coverage of medically necessary DME that is prescribed by a physician and furnished to enrollees is allowed by the Social Security Act, § 1834(a), and at 42 CFR pt. 414, subpart D. (OAS; W-00-10-35515; W-00-11-35515; various reviews; expected issue date: FY 2012; work in progress)

**Medicare Advantage Organizations' Identification of Potential Fraud and Abuse**

We will review the extent to which potential fraud and abuse incidents were identified and addressed by MA organizations in 2009. We will also determine whether MA organizations conducted inquiries, initiated corrective actions, or referred for further investigation incidents with potential for fraud and abuse. Previous OIG work found that 28 percent of stand-alone Part D sponsors did not identify any potential fraud and abuse incidents in 2007. Federal Regulations require each MA organization to have a compliance plan that includes measures to detect, correct, and prevent fraud, waste, and abuse. (42 CFR § 422.503.) (OEI; 03-10-00310; expected issue date: FY 2012; work in progress)

**Medicare Advantage Organizations' Reporting Requirements**

We will review MA organizations' compliance with CMS's reporting requirements for plan year 2009. We will also review CMS's oversight of MA organizations' reporting requirements and the actions CMS has taken to enforce reporting requirements. CMS requires MA organizations to develop, compile, evaluate, and report certain information to CMS and others. (42 CFR 422.516(a).) The information is necessary for CMS to assess and report on MA organizations' operations, costs, availability and utilization of services. In the past, CMS has been unable to complete such assessments and reports because of lack of data. (OEI; 03-11-00720; expected issue date: FY 2012; work in progress)

**Medicare Advantage Plans' Compensation of Field Marketing Organizations (New)**

We will determine the extent to which MA plans vary in their compensation of field marketing organizations (FMO). We will also determine whether MA plans' compensation of FMOs implicates the antikickback statute. (42 U.S.C § 1320a-7b(b).) MA plan sponsors may hire FMOs to sell or promote Medicare products on the plan sponsor's behalf either directly or through sales agents or a

combination of both. Pertinent Federal regulations do not establish limits on the FMO compensation paid by MA plans. (42 CFR § 422.2274(a)(1)(iv).) Significant variation in FMO compensation could lead FMO-employed sales agents to enroll Medicare beneficiaries in MA plans based on specific financial incentives rather than a plan that best meets a beneficiary's health care needs. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

## Part D (Prescription Drug Program)

The administration of Part D depends 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 continuing and planned reviews of Medicare Part D program administration follow.

## Part D Drug Pricing and Payment-Related Reviews

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

DIR—DIRECT AND INDIRECT REMUNERATIONS  
 HIV—HUMAN IMMUNODEFICIENCY VIRUS  
 PBM—PHARMACY BENEFIT MANAGER  
 PDE—PRESCRIPTION DRUG EVENT

PDP—PRESCRIPTION DRUG PLAN  
 TROOP—TRUE OUT-OF-POCKET [COSTS]  
 UM—UTILIZATION MANAGEMENT [CONTROLS]

### **Increase in Prices for Part D Brand Name Drugs (New)**

We will review annual changes in prices for brand-name prescription drugs used by Medicare Part D beneficiaries and determine whether Part D prices (including rebates) are rising faster than inflation. We will also determine how price increases for brand-name drugs affect Medicare Part D payment amounts. This work is similar to an ongoing study involving Medicaid. However, unlike Medicaid, manufacturer rebates under Part D are not statutorily set, and tend to be much lower. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medicare Part D Claims Duplicated in Part A and Part B**

We will review Medicare Part D claims to determine whether they were duplicated in Part A or Part B. We will also determine the extent to which payments for the sampled Part D claims were correct and supported. 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. (Social Security Act, § 1860D-2(e)(2)(B).) Medicare Part A covers drugs for beneficiaries who are receiving treatments as hospital inpatients. 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. (OAS; W-00-11-35409; various reviews; expected issue date: FY 2012; new start)

### **Characteristics Associated With Part D Billing in 2009**

We will review Part D drugs billed in 2009 to identify characteristics of associated pharmacies, prescribers, and beneficiaries. We will also identify the pharmacies, prescribers, and beneficiaries associated with atypically high billing and determine what, if any, characteristics they have in common. Drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans, and the Department of Health and Human Services (HHS) has the right to inspect and audit the sponsors' records pertaining to the information. (Social Security Act, § 1860(D)-15(f)(1).) (OEI; 02-09-00600; OEI; 02-09-00603; OEI; 02-09-00604; various reviews; expected issue date: FY 2012; work in progress)

### **Drug Costs Paid by Part D Sponsors Under Retail Discount Generic Programs**

We will review drug costs for specific Part D-covered drugs on prescription drug event (PDE) records to determine whether contracted prices between pharmacies and Part D sponsors were accurately reflected. We will also review contracts between sponsors and pharmacies and PDE records to determine the extent to which sponsors and the Federal Government have benefited from retail discount generic programs. Sponsors contract with pharmacies to dispense drugs to eligible Medicare beneficiaries and pay negotiated rates for drugs dispensed to these beneficiaries. A prescription drug plan permits the participation of any pharmacy that meets the terms and conditions under the plan. (Social Security Act, § 1860D-4(b).) (OAS; W-00-12-35510; various reviews; expected issue date: FY 2012; work in progress)

### **Part D Payments for Drugs Dispensed at Retail Pharmacies With Discount Generic Programs (New)**

We will determine whether Part D claims were paid at the discounted prices available at certain retail pharmacies, and whether the Plan Finder Website is accurately reporting these prices to beneficiaries. In 2006, several retail chain pharmacies began offering certain generic drugs at discounted prices (e.g., \$4 for a 30-day supply). Typically, sponsors should also pay these discounted prices if their contracts include a "usual and customary" clause, which means they pay the lowest price that is consistently charged at a pharmacy. These prices should also be reflected in CMS's Plan Finder Web site, which helps beneficiaries choose a prescription drug plan based on estimates of costs and coverage. (OEI; 03-11-00460; expected issue date: FY 2012; 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. We will determine whether payments under Part D are correct, supported, and not duplicated in hospice per diem amounts. We will also determine the extent of any duplication found and identify controls to prevent duplicate drug payments. Medicare Part D drug plans should not pay for drugs that are covered under the Part A hospice benefit. CMS publishes hospice payment rates, which include prescription drugs used for pain relief and symptom control related to the beneficiary's terminal illness. (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 11, § 30.2.) Hospice providers are paid per diem amounts, which include payments for these drugs. 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. (Social Security Act, § 1860D-2(e)(2)(B).) (OAS; W-00-10-35307; W-00-11-35307; various reviews; expected issue date: FY 2012; work in progress)

**Aberrant Part D Claims For Schedule II and Other Drugs**

We will review Medicare Part D claims to identify aberrant claims (those that deviate from the usual patterns) and determine how they relate to pharmacies, physicians, and/or beneficiaries. We will also determine whether Part D sponsors are appropriately processing Medicare Part D claims for Schedule II drugs (drugs with an accepted medical use and a high potential for abuse and dependency). Part D sponsors must submit the information necessary for the Secretary to determine payments to the plans, and HHS has the right to inspect and audit the sponsors' records pertaining to the information. (Social Security Act, § 1860(D)-15(f)(1).) (OAS; W-00-10-35411; W-00-11-35411; various reviews; expected issue date: FY 2012; work in progress)

**Refills of Schedule II Drugs (New)**

We will review the PDE records for Schedule II drugs to determine whether Part D sponsors are in compliance with Federal regulations prohibiting refills of prescriptions for Schedule II drugs. Part D does not allow refills of Schedule II drugs. (21 CFR § 1306.12(a).) Schedule II drugs have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused (21 U.S.C. § 812(b)(2).) Refills of prescriptions for a controlled substances listed in Schedule II are prohibited. (21 CFR § 1306.12(a).) (OAS; W-00-11-35411; various reviews; expected issue date: FY 2012; work in progress)

**Medicare Part D Expenditures for Revatio (New)**

We will review the extent to which CMS's payments to Part D sponsors subsidized the prescribing of Revatio for erectile dysfunction since January 1, 2007, when erectile dysfunction drugs were excluded from the Part D program. We will use PDE data to perform a trend analysis to determine whether the use of Revatio has increased since January 1, 2007 and determine whether Revatio was used for erectile dysfunction treatment. Covered Part D drugs do not include drugs when used for the treatment of sexual or erectile dysfunction unless such drugs were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the the Food and Drug Administration (FDA). Revatio is approved by FDA for the treatment of pulmonary hypertension. (Social Security Act, § 1860D-2(e)(2)(A).) (OAS; W-00-11-35525; various reviews; expected issue date: FY 2012; work in progress)

**Questionable Part D Billing for HIV Drugs (New)**

We will identify questionable billing for human immunodeficiency virus (HIV) drugs under Medicare Part D. We will determine the extent to which Part D paid for HIV drugs for beneficiaries who did not appear to have the appropriate medical indications. We will also identify pharmacies and prescribers associated with a high number of beneficiaries with questionable characteristics. Part D covers drugs that are prescribed and used for medically accepted indications. We will look at the extent to which Medicare paid for drugs for beneficiaries who did not have a diagnosis of HIV, did not receive any other related services from the prescriber, did not receive recommended laboratory services, and/or who are receiving a combination of drugs that are contra-indicated. (OEI; 02-11-00170; expected issue date: FY 2012; work in progress)

**Prescription Drug Event Data Submitted for Incarcerated Individuals (New)**

We will review PDE data to determine the extent to which sponsors submitted data for prescription drugs for incarcerated individuals under the Medicare Part D program and whether CMS accepted such data. Individuals must live in the service area of a Part D plan to be eligible for benefits under the Part D program. (42 CFR § 423.30(a)(ii).) However, a "Service area" does not include facilities in

which individuals are incarcerated. (42 CFR § 423.4.) OAS; W-00-11-35577; various reviews; expected issue date: FY 2012; work in progress

### **Part D Pharmaceutical Manufacturer Rebates**

We will review contracted pharmaceutical manufacturer rebates collected by Part D sponsors and pharmacy benefit managers (PBM). We will identify the rebate amounts negotiated between the sponsors/PBMs and pharmaceutical manufacturers, compare them with the actual rebates paid, and analyze any discrepancies. Regulations calculate Part D reinsurance and risk-corridor payments on the basis of amounts actually paid by the Part D sponsors, net of direct or indirect remunerations (DIR). (42 CFR pt. 423, subpart G.) DIR includes all rebates, subsidies, and other price concessions from sources (including but not limited to manufacturers and pharmacies) that serve to decrease the costs incurred by Part D sponsors for Part D drugs. The term “risk corridor” relates to triggers that are set to protect prescription drug plans from unexpected losses and that allow the Government to share in unexpected gains. In its guidance on reporting requirements, CMS requires that Part D sponsors submit DIR reports for use in the Part D payment reconciliation process. (OAS; W-00-11-35508; various reviews; expected issue date: FY 2012; work in progress)

### **Drug Pricing and Payments: Part D Payment Reconciliation Reopening (New)**

We will review CMS’s processes for reopening final payment determinations. We will review the data received and CMS’s policies, procedures, and instructions. CMS may reopen and revise an initial or reconsidered final payment determination, within time limitations that apply depending on the reason for reopening. (42 CFR § 423.346(a).) CMS reopened final payment determinations for 2006 for all Part D sponsors. In December 2010, CMS announced that it will reopen the 2006 and 2007 Part D payment reconciliations. This will be the second time that 2006 was reopened. CMS allowed sponsors to request reopening and to submit additional PDE data and DIR data. (OAS; W-00-12-35621; various reviews; expected issue date: FY 2012; new start)

### **Off-Formulary Drugs in Part D**

We will review PDE data, Part D payment data, and CMS-approved Part D formularies to determine the extent to which selected Part D sponsors submitted data for drugs that were not included on their approved Part D formularies and whether costs submitted by sponsors were for drugs that were not included in their approved formularies. Each Medicare prescription drug plan has a list of drugs it covers. This list is called a formulary. A “covered Part D drug” is one that is included in a plan’s formulary or treated as being included in the formulary as a result of a coverage determination or appeal. (42 CFR § 423.100.) (OAS; W-00-11-35560; various reviews; expected issue date: FY 2012; new start)

### **Part D Formulary Coverage Determinations and Beneficiary Appeals Process**

We will review the coverage determination and appeals processes Part D sponsors established pursuant to Federal regulations, determine the number of beneficiaries requesting and appealing coverage determinations, and determine whether these processes comply with Federal regulations and CMS’s guidelines. Enrollees are permitted to appeal, among other things, a determination not to cover a drug because it is not included in the formulary. (42 CFR § 423.566(b).) Each Medicare prescription drug plan has a list of drugs it covers. This list is called a formulary. Each Part D sponsor and each Part D plan that it offers must establish and maintain procedures for standard and expedited coverage determinations and appeals. (42 CFR pt. 423 subpart M.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)



### **Utilization Management Controls in Medicare Part D (New)**

We will determine the extent to which Part D plan sponsors are applying utilization management (UM) controls for drugs on their formularies that are not approved by CMS. This review will also assess CMS oversight in monitoring, detecting, and preventing non-CMS-approved UM controls used by Medicare Part D sponsors. Each Medicare prescription drug plan has a list of drugs it covers. This list is called a formulary. UM controls are commonly applied to formularies as a way to promote safe and cost-effective use of drugs. Some of the more commonly applied UM controls include prior authorization, step therapy, and quantity limits. Sponsors must inform enrollees of UM controls for formulary drugs. (42 CFR §423.128.) Further, sponsors must receive CMS approval for any UM control changes. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medicare Part D Risk Sharing and Risk Corridors**

We will analyze risk-sharing payments between the Government and Part D sponsors for plan years 2006 to 2010 and the financial impact of risk corridors on the Part D program. We will determine whether there is a potential for cost savings if the existing risk corridor thresholds are retained. Previous OIG reports found that in 2007 and 2008, many Part D sponsors had profits large enough to trigger risk sharing. The Federal Government shares with sponsors a portion of any unexpected Part D profits and losses. Risk corridors determine the amount of unexpected profits or losses that the Federal Government and sponsors share. CMS has the authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. (Social Security Act § 1860D-15.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Sponsors' and Plans' Implementation of Supporting Systems at Small- and Medium-Size Plans and Plans New to Medicare**

We will review the implementation of systems that support Part D prescription drug benefit plans and the expansion of beneficiary choices at MA plans, 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 the general and application controls that are critical to support these systems' 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, true out-of-pocket (TrOOP) costs, and PDE operations. This is a followup on issues identified in prior reviews of larger plans. (OAS; W-00-12-41013; various reviews; expected issue date: FY 2012; new start)

### **Accuracy of Sponsors' Tracking of True Out-of-Pocket Costs**

We will review the accuracy of Part D sponsors' tracking of beneficiaries' TrOOP costs. We will determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify toward catastrophic coverage. For 2007, for example, once an enrollee had reached \$3,850 in annual TrOOP costs (or \$5,451 in total drug spending), the enrollee had met the annual out-of-pocket threshold and the enrollee's cost sharing was capped—referred to as the catastrophic coverage phase). (Social Security Act, § 1860D-2(b)(4).) (OAS; W-00-11-35234; various reviews; expected issue date: FY 2012; new start)

### **Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts (New)**

We will review data submitted by Part D sponsors used in calculating the coverage gap discount. We will review the accuracy of the sponsor-submitted data to ensure that beneficiary payments are correct and amounts paid to sponsors are supported. Federal law requires the Secretary to establish

a Medicare coverage gap discount program. (Social Security Act, § 1860D-14A, as amended by the Affordable Care Act.) This program provides relief to beneficiaries who are responsible for paying all drug costs during their coverage gaps. Sponsors track beneficiary payment information and the drug cost data necessary to calculate eligibility for the program. (OAS; W-00-12-41501; various reviews; expected issue date: FY 2012; new start; Affordable Care Act)

### **Quality of Sponsor Data Used in Calculating Coverage-Gap Rebates (New)**

We will review data submitted by Part D sponsors used in calculating coverage-gap rebates to ensure that beneficiary payments were correct. Applicable Part D enrollees who reached the Part D coverage gap in 2010 were eligible for a one-time \$250 payment. (Social Security Act, § 1860D-14A(g)(1), subparagraphs (A) through (D) and § 1860D-42(c), as amended by the Affordable Care Act.) The basis for the payment was data submitted by Part D sponsors. Sponsors tracked beneficiary payment information and the drug cost data necessary to calculate eligibility for the rebate payment. Sponsor-submitted data were critical to ensuring accurate payments under the program. (OAS; W-00-12-41500; various reviews; expected issue date: FY 2012; new start; Affordable Care Act)

## **Part D Administration and Program Integrity**

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

MEDIC—MEDICARE PRESCRIPTION DRUG INTEGRITY CONTRACTOR  
P&T—PHARMACY AND THERAPEUTICS (COMMITTEE)

PBM—PHARMACY BENEFIT MANAGER

### **Safety and Effectiveness of Part D Drugs**

We will review whether the drugs used in the Part D program were previously found to be safe and effective by FDA and whether Part D beneficiaries were dispensed only drugs that FDA had deemed safe and effective. To ensure that drugs are safe and effective, FDA requires that drugs used by the public be approved and registered. (21 U.S.C. § 355). As part of a safety initiative, CMS instituted a policy effective January 1, 2010, to ensure that Part D beneficiaries receive only drugs that are properly registered with FDA. (OAS; W-00-12-35561; various reviews; expected issue date: FY 2012; new start)

### **Sponsors' Documentation of Administrative Costs Included in Bid Proposals**

We will review the appropriateness of Part D sponsors' documentation supporting administrative costs included in their annual bid proposals to CMS. Part D sponsors submit bids for the costs of providing prescription drug coverage, including administrative costs. (Social Security Act, § 1860D-11(b) and 42 CFR § 423.265(c)(1).) Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. (OAS; W-00-11-35506; various reviews; expected issue date: FY 2012; new start)

### **Sponsors' Documentation of Investment Income Included in Bid Proposals**

We will determine the appropriateness of Part D sponsors' documentation supporting investment income included in their annual bid proposals to CMS. Federal regulations require Part D sponsors to submit bids for the costs of providing prescription drug coverage, including returns on investment and profits. (42 CFR § 423.265(c)(1).) Sponsors' bids are the basis for calculating Medicare's subsidy

payments to Part D plans and beneficiary premiums. (OAS; W-00-11-35507; various reviews; expected issue date: FY 2012; new start)

### **Medicare's Audits of Stand-Alone Part D Prescription Drug Plans**

We will review the extent to which CMS completed seven types of audits of stand-alone prescription drug plans (PDP) from January 2006 through December 2009 and the types and numbers of problems identified through the audits. We will also determine what actions CMS took to follow up with PDP sponsors about the problems identified. The seven audit types are auto-enrollment readiness, benefit integrity, bid, compliance plan, long-term-care pharmacy contract, pharmacy access, and program. CMS conducts these audits as part of its oversight of the Part D program. The Social Security Act, § 1860D-12(b)(3)(C), governs audit authority for Part D. (OEI; 03-09-00330; expected issue date: FY 2012; work in progress)

### **Medicare's Audits of Part D Sponsors' Financial Records**

We will review CMS's audits of Part D sponsors' financial records to determine whether they were conducted in accordance with Federal regulations. We will also examine CMS's audit guide, the timeliness of its audits, and actions taken to address audit findings. Federal law and regulations require CMS annually to audit the financial records of at least one-third of Part D sponsors that offer plans, including but not limited to data relating to Medicare utilization and costs such as allowable reinsurance and risk-corridor costs, low-income subsidies, and other costs. (Social Security Act, § 1860D-12(b)(3)(c), and 42 CFR § 423.504(d)(1).) This review is part of a series of OIG reviews examining CMS performance of required Part D program, bid, financial, and compliance audits. (OAS; W-00-10-35511; various reviews; expected issue date: FY 2012; work in progress)

### **Medicare Prescription Drug Integrity Contractors' Activities to Detect and Deter Fraud and Abuse in Part D (New)**

We will evaluate the operations of the Medicare Prescription Drug Integrity Contractors (MEDIC) to provide an update on previously identified issues, a functional realignment, and MEDICs' fulfillment of additional responsibilities for the Medicare Part C and D programs. In 2006, CMS awarded contracts to three regional MEDICs to perform functions that fight fraud and abuse for the Part D program. This is a followup to OIG's review, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse* (OEI-03-08-00420). (OEI; 03-11-00310; expected issue date: FY 2012; work in progress)

### **Sponsors' Internal Controls for Fraud, Waste, and Abuse**

We will review the reliability of Medicare Part D sponsors' internal controls to guard against fraud, waste, and abuse. Federal law requires Part D sponsors to have such programs. (Social Security Act, § 1864D-4(c).) Federal regulations require sponsors to have in place compliance plans that include comprehensive methods to detect, correct, and prevent fraud, waste, and abuse. (42 CFR § 423.504(b)(4)(vi)(H).) In addition, CMS issued guidance that provides interpretive rules and guidelines for Part D sponsors for implementing the requirements. (CMS's *Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9) (OAS; W-00-12-35512; various reviews; expected issue date: FY 2012; new start)

### **Sponsors' Audits of Pharmacies**

We will review the process that Part D sponsors and their PBMs use in auditing pharmacies. We will determine whether recoveries by Part D sponsors or their PBMs are properly accounted

for and the extent to which pharmacy audits focus on uncovering fraud, waste, and abuse versus program noncompliance. Sponsor audits validate payments by the sponsors to pharmacies; 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. CMS requires Part D sponsors to be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Sponsor erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit. (Medicare Part D Reporting Requirements for Contract Year 2008, section XI, “Overpayments.”) (OAS; W-00-12-35235; various reviews; expected issue date: FY 2012; new start; and OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Sponsors’ Pharmacy and Therapeutics Committees: Potential Conflicts of Interest**

We will review Part D Pharmacy and Therapeutics committees’ disclosed potential conflicts of interest and describe the nature of such conflicts. Sponsors using formularies must have Pharmacy and Therapeutics committees that select the drugs on sponsors’ formularies and determine cost sharing, prior authorization, quantity limits, generic substitution, and other issues affecting drug access. (42 CFR § 423.120(b)(1).) Each committee must have at least one physician and one pharmacist who are free of conflicts of interest. (OEI; 05-10-00450; various reviews; expected issue date: FY 2012; work in progress)

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*The [Work Plan](#) is one of OIG’s three core publications. The [Semiannual Report to Congress](#) summarizes OIG’s most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. The annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.*

Part III:  
Medicaid Reviews

## Part III: Medicaid Reviews

The Federal and State Governments jointly fund Medicaid, a program that provides medical assistance to certain low-income individuals. The Federal share of a State's expenditures is called the Federal medical assistance percentage (FMAP). States have considerable flexibility in structuring their Medicaid programs within broad Federal guidelines governing eligibility, provider payment levels, and benefits. As a result, Medicaid programs vary widely from State to State.

Our continuing and new reviews of Medicaid in fiscal year (FY) 2012 address prescription drugs, long-term and community care, other services, program integrity and accountability, administration, information systems, and managed care.

### Medicaid Prescription Drug Pricing, Reimbursement, and Rebates

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

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|--|--|
| AMP—AVERAGE MANUFACTURER PRICE               | FUL—FEDERAL UPPER LIMIT                |
| AWP—AVERAGE WHOLESALE PRICE                  | MCO—MANAGED CARE ORGANIZATION          |
| CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES | STATE MAC—STATE MAXIMUM ALLOWABLE COST |
| DRA—DEFICIT REDUCTION ACT OF 2005            | URA—UNIT REBATE AMOUNT                 |
| FFP—FEDERAL FINANCIAL PARTICIPATION          | WAC—WHOLESALE ACQUISITION COST         |
| FMAP—FEDERAL MEDICAL ASSISTANCE PERCENTAGE   |  |

Objectives and context for continuing and new *Work Plan* reviews of Medicaid follow.

#### Calculation of Average Manufacturer Prices

We will review selected drug manufacturers to evaluate methodologies they use to calculate the average manufacturer price (AMP) and the best price for the Medicaid drug rebate program and for drug reimbursement. We will also determine whether the methodologies are consistent with statutes, regulations, and manufacturers' rebate agreements and the Centers for Medicare & Medicaid Services (CMS) *Drug Manufacturer Release(s)*. Several changes to the Medicaid drug rebate statute and to Medicaid reimbursement for multiple-source drugs involve revisions in the calculation of the AMP and the best price. The changes will affect amounts that pharmaceutical manufacturers report under the Medicaid drug rebate program and will affect the Federal upper limit (FUL) for drug reimbursement. (Deficit Reduction Act of 2005 (DRA), § 6001.) CMS uses the AMP and the best price to determine unit rebate amounts (URA). Manufacturers must pay rebates to States based on the URAs. (OAS; W-00-11-31202; various reviews; expected issue date: FY 2012; new start)

#### Recalculation of Base-Date Average Manufacturer Prices

We will review changes to base-date AMPs and assess the impact of such changes on Medicaid rebates. We will examine manufacturers' rationales and supporting data for changes to base-date

AMPs. Manufacturers pay additional rebates for single-source drugs based on the difference between AMPs and base-date AMPs adjusted for inflation. (Social Security Act, § 1927(c).) To ensure that such rebates will not increase because of changes in AMPs, Federal regulations allow manufacturers to revise the base-date AMPs against which these inflationary measures are indexed. (42 CFR § 447.510(c).) Additional rebates paid by manufacturers reflect an integral and statutorily required aspect of the Medicaid drug rebate program. (DRA, § 6001.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Federal Upper Payment Limit Drugs**

We will review prescription drug claims to determine whether pharmacies have altered prescriptions to maximize reimbursements by avoiding certain dosage forms for drugs that have FULs on reimbursements. We will determine whether there has been manipulation of FULs. As a result of whistleblowers' actions, several pharmacies have admitted changing dosage forms for some commonly prescribed Medicaid drugs, thereby inflating reimbursements by avoiding FULs established on other dosage forms. The FULs for all multiple-source drugs were established by the Social Security Act, § 1927(e)(4). (OAS; W-00-12-31333; various reviews; expected issue date: FY 2012; new start)

### **State Maximum Allowable Cost Programs**

We will review State Maximum Allowable Cost (State MAC) programs to determine how State MAC lists are developed, how State MAC prices are set, and how State MAC prices compare to the FUL amounts. This review will compare State MAC programs to determine which ones are most successful in reducing Medicaid expenditures. To take advantage of lower market prices for certain generic products, States use the FUL list and/or State MAC programs in determining reimbursement amounts. State MAC programs are designed to ensure that the Medicaid program pays appropriate prices for generic drugs. In 2004, a CMS-contracted study looked at State MAC programs in five States and found considerable variation between these programs and the FUL program. The study concluded that expansion of existing State MAC programs and implementation of new ones could contribute to cost containment efforts nationwide. (OEI; 03-11-00640; expected issue date: FY 2012; work in progress)

### **Appropriateness of Federal Upper Limit Amounts (New)**

We will compare FUL amounts under the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) methodology to an estimate of pharmacy acquisition costs for selected drugs. The Office of Inspector General (OIG) has a long history of examining FULs for generic drugs paid under Medicaid. Numerous reports found that a previous method for calculating FULs (150 percent of the lowest average wholesale price (AWP) or wholesale acquisition cost (WAC) caused Medicaid to overpay substantially. Our previous FUL reports consistently recommended that CMS work with Congress to ensure that FULs more accurately represent pharmacy acquisition costs. A revised method that set FULs at 250 percent of the lowest AMP was enacted by the DRA; however, it was never implemented because of an injunction imposed by the Federal District Court of the District of Columbia. A recent law changed the FUL calculation to no less than 175 percent of the average AMP. (Affordable Care Act, § 2503.) CMS implemented this latest change to the calculation in 75 Fed. Reg. 69591 (November 15, 2010). (OEI; 03-11-00650; expected issue date: FY 2012; work in progress; Affordable Care Act)

### **Update of Manufacturer Compliance With AMP Reporting Requirements (New)**

We will review manufacturer compliance with AMP reporting requirements and determine what percentage of manufacturers complied with AMP reporting requirements in 2011. We will assess whether stepped-up enforcement actions by CMS and OIG are reflected in increased compliance by manufacturers. A previous OIG review found that in 2008 more than half of the drug manufacturers that were required to submit quarterly AMPs to CMS failed to comply with reporting requirements in at least one quarter. Manufacturers were even less likely to comply with monthly AMP reporting requirements, with more than three-fourths submitting late, incomplete, or no AMPs in at least 1 month of 2008. After the release of this report, CMS and OIG worked to increase manufacturer compliance. Price-reporting obligations for certain drug manufacturers, including the obligation to report AMP data to CMS quarterly and monthly, are set forth in the Social Security Act, § 1927(b)(3), and 42 CFR §§ 447.510(a) and (d). (OEI; 00-00-00000; expected issue date: FY 2012; new start)

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

We will review the accuracy of States' submissions of Medicaid drug claims to CMS for reimbursement. We will determine whether the tape that CMS provides to States includes all covered drugs and indicates drugs' termination dates, if applicable. We will also determine whether reimbursements are correct and are supported for the drugs claimed. A drug manufacturer must have a rebate agreement with CMS to have its outpatient drugs covered under Medicaid. (Social Security Act, § 1927(a)(1).) 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 instructs States to use the tape to verify coverage of the drugs for which they claim reimbursement. (OAS; W-00-10-31203; W-00-11-31203; various reviews; expected issue date: FY 2012; work in progress)

### **Compound Drug Claims**

We will review a State agency's Medicaid claims for compound drugs to determine whether the drugs' components complied with Federal requirements for reimbursement and collection of rebates. 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. Compound drugs are custom blended by pharmacists from bulk ingredients based on doctors' prescriptions. For payments to be available under Medicaid or Part B of Medicare, Federal law requires manufacturers to enter into and have in effect rebate agreements with the Secretary of Health & Human Services (HHS) (except that the Secretary may authorize a State to enter directly into agreements with a manufacturer) and meet certain other requirements. (Social Security Act, § 1927.) States may then claim Federal financial participation (FFP) and report drug utilization to the manufacturers for rebates. CMS requires States to use a drug tape that lists all drugs covered by rebate agreements to determine whether the drugs they purchase are eligible for Medicaid coverage. (CMS's *Medicaid Drug Rebate Program State Release No. 130*.) CMS outlined States' responsibility for preventing claims for terminated drugs in its *Medicaid Drug Rebate Program State Release No. 19*. (OAS; W-00-12-31317; various reviews; expected issue date: FY 2012; work in progress)

### **Medicaid Claims for Drugs Purchased Under Retail Discount Generic Programs**

We will review Medicaid claims for generic drugs to determine the extent to which large chain pharmacies are billing Medicaid the usual and customary charges for drugs provided under their retail discount generic programs. We will also examine CMS's policies and procedures for



ensuring that Medicaid is billed properly under retail discount generic programs. The discount programs typically offer selected generic drugs to anyone with a prescription for \$4 for a 30-day supply or \$10 for a 90-day supply. Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for covered generic outpatient drugs without established upper limits not exceed (in the aggregate) the lower of the estimated acquisition cost for drugs, plus a reasonable dispensing fee, or the provider's usual and customary charge to the public for the drugs. (42 CFR § 447.512.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Impact of the Deficit Reduction Act of 2005 on Rebates for Authorized Generic Drugs**

We will review drug-pricing and rebate data that drug manufacturers report to State Medicaid agencies to determine the extent to which manufacturers are reporting pricing data and paying rebates for authorized generic drugs. We will also determine to what extent Medicaid rebates have changed since the implementation of certain provisions and whether the number of new authorized generics changed after implementation. CMS stated in its 2007 final rule on Medicaid prescription drugs that best-price calculations must now include the prices available to secondary manufacturers of authorized generic drugs. The change in definition has the potential to increase the amount of rebates due from single-source drugs' primary manufacturers. Federal regulations define "authorized generics" as versions of brand-name drugs produced and/or marketed with the consent of the original brand manufacturers and marketed under the brand manufacturers' original drug applications. (42 CFR § 447.506.) Rebates to States from manufacturers are based in part on the difference between the AMP of a drug and the best price of the drug. (Social Security Act, § 1927.) The definition of "best price" was clarified to include the lowest price available to any entity for any such drug sold under a new drug application. (DRA, § 6001.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Zero-Dollar Unit Rebate Amounts**

We will determine whether States are effectively collecting drug rebates from manufacturers for drugs with zero-dollar URAs. We will determine the financial impact of zero-dollar URAs and examine possible causes for States not receiving required rebates from manufacturers. Previous OIG work found that States may not be collecting all possible drug rebates from manufacturers when CMS is unable to calculate URAs. URAs are based on pricing data reported by drug manufacturers. At the end of every quarter, CMS calculates URAs for drugs included in the Medicaid drug rebate program and provides the amounts to State Medicaid agencies. If and when manufacturers have not reported the necessary data for the calculations, the URAs for such products are listed as \$0, i.e., zero-dollar URAs. Even so, Medicaid requires States to work with manufacturers to determine the appropriate rebates for the drugs. (OEI; 03-11-00470; expected issue date: FY 2012; work in progress)

### **States' Efforts and Experiences With Resolving Rebate Disputes**

We will review the causes of and resolutions to Medicaid rebate disputes and the methods States use to resolve such disputes. In 2008, Medicaid spent approximately \$24 billion on prescription drugs and received approximately \$8 billion in rebates. Previous OIG reports have found large amounts in uncollected rebates. Federal law requires drug manufacturers to enter into drug rebate agreements as a prerequisite to coverage of their drugs under Medicaid State plans. (Social Security Act, § 1927(a).) (OEI; 05-11-00580; expected issue date: FY 2012; work in progress)

### States' Collection of Rebates for Drugs Paid by Managed Care Organizations (New)

We will determine whether Medicaid managed care organizations (MCO) are providing State Medicaid agencies with the utilization data needed to collect rebates for drugs used by Medicaid MCOs enrollees. This review will determine whether States have procedures to verify the accuracy of the utilization data provided by Medicaid MCOs, whether and how States are invoicing manufacturers for these rebates, whether States are collecting these rebates from manufacturers, and what procedures States have to track rebate collection for drugs dispensed to Medicaid MCO enrollees. Medicaid rebate requirements were expanded to include drugs dispensed to MCO enrollees. Medicaid MCOs are required to report enrollees' drug utilization data to the State for the purpose of collecting rebates from manufacturers. (Affordable Care Act, § 2501.) CMS has provided guidance through State Medicaid Director Letters to States on implementation of this provision. Although the Congressional Budget Office has estimated this requirement would reduce expenditures by \$3.7 billion over a 5-year period, States and manufacturers have expressed concerns about how this requirement will be implemented. (OEI; 03-11-00480; expected issue date: FY 2012; work in progress)

### Federal Share of Rebates (New)

We will review States' reporting of the Federal share of Medicaid rebate collections. We will determine whether States are correctly identifying and reporting the increases in rebate collections. Three new provisions in law should result in increased rebate payments by drug manufacturers to the States. The provisions will increase the minimum rebate percentages, increase the additional rebate on new formulations of existing drugs, and allow for rebates on drugs dispensed through Medicaid MCOs. (Social Security Act, §§ 1927(b) and (c), as amended by the Affordable Care Act, § 2501.) Any increase in rebate collections that results from these new provisions is not shared with the States but is considered 100 percent Federal. (Social Security Act, § 1927(b)(1)(C).) (OAS; W-00-12-31450; various reviews; expected issue date: FY 2012; new start; Affordable Care Act)

### Rebates on New Formulations (New)

We will review drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs. We will also determine whether manufacturers have correctly identified all their drugs that are subject to a new provision in law. A recent change increases the additional rebate for drugs that are new formulations of existing drugs if certain conditions are met. (Social Security Act, § 1927(c)(2)(C), as amended by the Affordable Care Act, § 2501.) Manufacturers pay the additional rebate that is based on the existing drug if it is higher than the additional rebate that is based on the new formulation. (OAS; W-00-12-31451; various reviews; expected issue date: FY 2012; new start; Affordable Care Act)

## Home, Community, and Personal Care Services

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

ALF—ASSISTED LIVING FACILITIES  
 CDT—CONTINUING DAY TREATMENT  
 FFP—FEDERAL FINANCIAL PARTICIPATION

HCBS—HOME- AND COMMUNITY-BASED SERVICES  
 HHA—HOME HEALTH AGENCY  
 PCS—PERSONAL CARE SERVICES

**Home Health Services: Screenings of Health Care Workers**

We will review health-screening records of Medicaid home health care workers to determine whether the workers were screened in accordance with Federal and State requirements. Examples of screenings can include vaccinations for hepatitis and influenza. Home health agencies provide health care services to Medicaid beneficiaries while visiting beneficiaries' homes. Home health care agencies must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations and with accepted standards that apply to personnel providing services within such an agency. (Social Security Act, §1891(a)(5).) The Federal requirements for home health services are found at 42 CFR §§ 440.70, 441.15, and 441.16 and at 42 CFR pt 484. Other applicable requirements are found in State and local regulations. (OAS; W-00-11-31387; various reviews; expected issue date: FY 2012; new start)

**Home Health Services: Agency Claims**

We will review home health agency (HHA) claims to determine whether providers have met applicable criteria to provide services and whether beneficiaries have met eligibility criteria. 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. The standards and conditions for HHA's participation in Medicaid are at 42 CFR § 440.70 and 42 CFR pt. 484. (OAS; W-00-10-31304; W-00-11-31304; various reviews; expected issue date: FY 2012; work in progress)

**Home Health Services: Homebound Requirements (New)**

We will review CMS policies and practices for reviewing the sections of Medicaid State plans related to eligibility for home health services and describe how CMS intends to enforce compliance with appropriate eligibility requirements for home health services. We will also identify the number of States that violate Federal regulations by inappropriately restricting eligibility for home health services to homebound recipients. States must ensure that the services available to any individual in a categorically or medically needy group are comparable to the services available to the entire group. (42 CFR § 440.240(b).) States may not arbitrarily deny or reduce the amount, duration, or scope of a required service because of a beneficiary's diagnosis, type of illness, or condition. (42 CFR § 440.230(c).) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

**Home- and Community-Based Services: Federal and State Oversight of Quality of Care**

We will review CMS and State oversight of home- and community-based services (HCBS) waiver programs to determine the extent to which CMS oversees States' efforts to ensure the quality of care provided under such waiver programs. We will also determine the extent to which States monitor the quality of care given to participants in HCBS waiver programs for the aged and disabled. Medicaid HCBS waiver programs allow States to provide alternative services for those who otherwise would require care in nursing homes. States must provide assurances that necessary safeguards have been taken to protect the health and welfare of recipients. (42 CFR § 441.302.) However, a 2003 Government Accountability Office (GAO) review found that CMS and States did not provide adequate oversight of HCBS waivers. (OEI; 02-08-00170; expected issue date: FY 2012; work in progress)

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

We will determine the extent to which assisted-living facilities (ALF) provide HCBS to their Medicaid-eligible residents. We will also determine how States and CMS ensure that ALFs are meeting provider standards, plans of care are established and followed by ALFs, and ALFs meet other Federal requirements for HCBS services. Federal regulations require States to provide CMS with assurances that necessary safeguards have been taken to protect the health and welfare of HCBS recipients. (42 CFR § 441.302.) ALFs may receive Medicaid funding through the HCBS waiver program pursuant to the Social Security Act, § 1915(c). (OEI; 09-08-00360; expected issue date: FY 2012; work in progress)

### **Home- and Community-Based Services: Vulnerabilities in Providing Services (New)**

We will determine the extent to which HCBS waiver participants have plans of care, receive the services in their plans, and receive services from qualified providers. We will also identify recipient concerns about the quality of care they receive. Medicaid HCBS allow States to provide care in the home or community for individuals who would otherwise require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded (Social Security Act, § 1915(c)(1).) States offering HCBS waiver programs must provide adequate planning for services and provide those services through qualified providers, as well as ensure the health and welfare of participants. (Social Security Act, §§ 1915 (c)(1) and 1902(a)(23).) (OEI; 02-11-00700; expected issue date: FY 2013; work in progress)

### **Home- and Community-Based Services: Waiver Program Administrative Costs**

We will determine the reasonableness of Medicaid HCBS waiver program administrative costs. We will also determine whether States' contractual arrangements with nonprofit entities for administration of HCBS waiver programs are economical. The HCBS waiver program permits States to furnish arrays of services that help Medicaid beneficiaries to live in the community and avoid institutionalization. (Social Security Act, § 1915(c).) Some States have contracted with nonprofit groups to administer waiver programs. Because CMS's methodology for reviewing waiver applications does not examine administrative costs, it may be possible that States have claimed the Federal share of contracted administrative costs in amounts exceeding Medicaid's actual average administrative costs. The Federal share of Medicaid matches most administrative expenditures at the 50-percent rate if the expenditures are for the "proper and efficient" administration of Medicaid. (OAS; W-00-11-31332; various reviews; expected issue date: FY 2012; work in progress)

### **Home- and Community-Based Services: Adult Day Care Services for Elderly Individuals Who Have Chronic Functional Disabilities**

We will determine whether Medicaid payments to providers for adult day care services complied with Federal and State regulations. Medicaid allows payments for elderly individuals with chronic functional disabilities, through HCBS waiver programs. (Social Security Act, § 1929(a)(7).) (OAS; W-00-11-31386; various reviews; expected issue date: FY 2012; new start)

### **Community Residence Rehabilitation Services**

We will review Medicaid payments for beneficiaries who reside in community residences for people who have mental illnesses to determine whether States improperly claimed FFP. Previous OIG work in one State found improperly claimed Medicaid reimbursement for individuals who were no longer residing in a community residence. To be allowable, costs must be authorized, or not

prohibited, under State or local laws or regulations. (Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Attachment A, § C.1.c.) (OAS; W-00-09-31087; W-00-10-31087; W-00-11-31087; various reviews; expected issue date: FY 2012; work in progress)

### **Continuing Day Treatment Providers**

We will review Medicaid payments to continuing day treatment (CDT) providers in one State to determine whether Medicaid payments to CDT providers in that State are adequately supported. CDT providers render an array of services to those who have mental illnesses on a relatively long-term basis. A CDT provider bills Medicaid on the basis of the number of service hours rendered to a beneficiary. 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. To be allowable, costs must be authorized, or not prohibited, under State or local laws or regulations. (OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Att. A, § C.1.c.) (OAS; W-00-09-31128; W-00-11-31128; various reviews; expected issue date: FY 2012; work in progress)

### **Medicaid School-Based Services**

We will review Medicaid payments for school-based services in selected States to determine whether the costs claimed for such services are reasonable and properly allocated. Medicaid may pay for medical services provided to students with special needs pursuant to individualized education plans. (Social Security Act, § 1903(c).) Direct medical services may include physical therapy; occupational therapy; speech therapy; and nursing, personal care, psychological, counseling, and social work services. Some States use random moment time studies to develop school-based health service payment rates. Costs claimed must be reasonable and allocated according to the benefit received. (OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*.) (OAS; W-00-11-31391; various reviews; expected issue date: FY 2012; work in progress)

### **Personal Care Services**

We will review Medicaid payments for personal care services (PCS) to determine whether States have appropriately claimed the FFP. Medicaid covers PCS only for those who are not inpatients or residents of hospitals, nursing facilities, institutions for mental diseases, or intermediate care facilities for those with mental retardation. (Social Security Act, § 1905(a)(24).) PCS must be authorized by a physician or (at the option of the State) otherwise authorized in accordance with a plan of treatment, must be provided by someone who is qualified to render such services and who is not a member of the individual's family, and must be furnished in a home or other location. Beginning January 1, 2007, States are allowed to pay individuals for self-directed personal assistance services for the elderly and disabled, including PCS that could be provided by a family member. (DRA, § 6087.) (OAS; W-00-09-31035; W-00-10-31035; W-00-11-31035; various reviews; expected issue date: FY 2012; work in progress)

## Other Medicaid Services and Payments

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

DME—DURABLE MEDICAL EQUIPMENT

OMB—OFFICE OF MANAGEMENT AND BUDGET

HCBS—HOME- AND COMMUNITY-BASED SERVICES

UPL—UPPER PAYMENT LIMITS

NPI—NATIONAL PROVIDER IDENTIFIERS

### Hospice Services: Compliance With Reimbursement Requirements

We will determine whether Medicaid payments for hospice services complied with Federal reimbursement requirements. Medicaid may cover hospice services for individuals with terminal illnesses. (Social Security Act, § 1905(o)(1)(A).) Hospice care provides relief of pain and other symptoms and supportive services to terminally ill persons and assistance to their families in adjusting to the patients' illness and death. An individual, having been certified as terminally ill, must elect hospice coverage and waive all rights to certain otherwise covered Medicaid services. (CMS's *State Medicaid Manual*, Pub. 45, § 4305.) In FY 2010, Medicaid payments for hospice services totaled more than \$816 million. (OAS; W-00-11-31385; various reviews; expected issue date: FY 2012; new start. OEI; 00-00-00000; expected issue date: FY 2013; 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. Previous OIG work involving Medicare inpatient and outpatient claims found that many excessive payments to the hospitals were attributable to billing errors on the submitted claims, such as inaccuracies in diagnosis codes, admission codes, discharge codes, procedure codes, charges, Healthcare Common Procedure Coding System codes, and number of units billed. To be allowable, costs must be necessary and reasonable for the proper and efficient performance and administration of Federal awards. (Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, Att. A, § C.1.a.) Costs must be authorized, or not prohibited, under State or local laws or regulations. (§ C.1.c.) CMS adjusts quarterly payments to States to account for overpayments and underpayments by States to providers. (Social Security Act, § 1903(d)(2)(A), and 42 CFR pt. 433, subpart E.) (OAS; W-00-11-31127; various reviews; expected issue date: FY 2012; work in progress)

### Payments for Physical, Occupational, and Speech Therapy Services

We will determine the extent to which payments for Medicaid physical, occupational, and speech therapy services comply with State standards and limits on coverage. Previous OIG studies found that some therapy services provided under Medicare were billed incorrectly. Through a review of selected States, we will determine whether Medicaid has similar program integrity issues. States may provide physical, occupational, and speech therapy services to Medicaid beneficiaries pursuant to the Social Security Act, § 1905(a), and regulations at 42 CFR § 440.110. (OEI; 07-10-00370; expected issue date: FY 2012; work in progress)

### Medicaid Medical Equipment

We will determine whether Medicaid payments for medical supplies and equipment were properly authorized by physicians, the products were received by the beneficiaries, and the amounts paid were within Medicaid payment guidelines. Rules and guidance about necessary medical supplies and

equipment for home health services; physical therapy services; occupational therapy services; services for individuals with speech, hearing, and language disorders; and HCBS are in Federal regulations at 42 CFR pt. 440 and various provisions of CMS's *State Medicaid Manual*. (OAS; W-00-11-31390; various reviews; expected issue date: FY 2012; new start)

### **Medicaid 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 Medicaid. Previous OIG work found improper claims for enhanced funds for family planning services. States may claim Medicaid reimbursement for family planning services at the enhanced Federal matching rate of 90 percent. (Social Security Act, § 1903(a)(5).) (OAS; W-00-10-31078; W-00-11-31078; various reviews; expected issue date: FY 2012; work in progress)

### **Payments for Transportation Services**

We will review payments to providers for transportation services to determine the appropriateness of State Medicaid agencies' payments for such services. Federal regulations require States to ensure necessary transportation for Medicaid beneficiaries to and from providers. (42 CFR § 431.53.) Each State may have different Medicaid coverage criteria, reimbursement rates, rules governing covered services, and beneficiary eligibility for services. (OAS; W-00-09-31121; W-00-10-31121; W-00-11-31121; various reviews; expected issue date: FY 2012; work in progress)

### **State-Operated Facilities: Reasonableness of Payment Rates (New)**

We will determine whether Medicaid payment rates to State-operated facilities are reasonable and in accordance with Federal and State requirements. We will determine in selected States the extent to which payments to providers have exceeded the requirements. Payments for services must be consistent with efficiency, economy, and quality of care. (Social Security Act, §1902(a)(30)(A).) Federal regulations state that a cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. (2 CFR § 225, Appendix A, § C. 2.) (OAS; W-00-11-31398; various reviews; expected issue date: FY 2012; work in progress)

### **Payments for Health-Care-Acquired Conditions (New)**

We will determine whether selected State agencies made Medicaid payments for health-care-acquired conditions and provider-preventable conditions and quantify the amount of Medicaid payments for such conditions. As of July 1, 2011, Federal payments to States under the Social Security Act, § 1903, are prohibited for any amounts expended for providing medical assistance for health care-acquired conditions. (Affordable Care Act, § 2702.) Federal regulations prohibiting Medicaid payments by States for services related to health care-acquired conditions and provider-preventable conditions are at 42 CFR § 447.26. (OAS; W-00-12-31452; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)

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

We will review Medicaid supplemental payments by States to private hospitals to determine whether errors exist involving such payments. Federal funds are not available for Medicaid payments that exceed applicable upper payment limits (UPL). Prior OIG work involving supplemental payments to public facilities found errors. Federal regulations 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. (42 CFR § 447.272.) 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. Medicaid agencies pay for inpatient hospital and long-term-care services using rates determined in accordance with methods and standards specified in their approved State plans. (42 CFR § 447.253(i).) (OAS; W-00-10-31126; W-00-11-31126; various reviews; expected issue date: FY 2012; work in progress)

### **Supplemental Payments to Public Providers (New)**

We will review Medicaid supplemental payments by States to public providers (State and Non-State government operated facilities) and determine whether they comply with Federal UPL requirements. Federal funds are not available for Medicaid payments that exceed the UPL. This is a followup to previous OIG work involving supplemental payments to public facilities that resulted in program revisions that saved billions in Medicaid funding. Our work will focus on the amount of Medicaid funding claimed by selected States as part of UPL programs, as well as the use of the funds. States are permitted to make payments to providers under their approved plans to hospitals up to the applicable aggregate UPL based on reasonable estimations of what Medicare would have paid for equivalent services. Federal regulations define the UPL for inpatient and outpatient hospital services at 42 CFR § 447.272 and 42 CFR § 447.321. A State agency's proposed payment rate is not to exceed the UPL. (42 CFR § 447.253(b)(2).) (OAS; W-00-12-31453; various reviews; expected issue date: FY 2013; new start)

### **Medicaid Nursing Facility Incentive Payments**

We will review Medicaid incentive payments by States to nursing facilities based on the facilities' quality-of-care performance measures. We will determine whether States have sufficient controls to assess nursing facilities' quality-of-care performance measures and determine whether incentive payments were in accordance with program requirements. States are authorized to establish programs to reward nursing facilities (through public recognition, incentive payments, or both) that provide the highest quality care to their Medicaid-eligible residents. (Social Security Act, § 1919(h)(2)(F).) (OAS; W-00-10-31331; W-00-11-31331; various reviews; expected issue date: FY 2012; work in progress)

### **Emergency Payments by State Medicaid Agencies (New)**

We will determine whether emergency payments to providers made by State Medicaid agencies were adequately supported. We will review the emergency payments and assess States' overpayment reconciliation and recoupment processes to determine whether charges to Medicaid were based on actual expenditures. Emergency payments often occur during transitions between fiscal agents or when systems are upgraded. These payments have a substantial additional risk of inaccuracy because they may bypass the usual payment edits and claim-support requirements. One State Medicaid agency recently made \$792 million in emergency payments to providers, for which the State auditor identified numerous deficiencies, including that such payments were not supported by valid claims but based on estimates. Federal regulations require States to account for Medicaid funds based on expenditures, not estimates. (42 CFR § 430.30 .) (OAS; W-00-12-31454; various reviews; expected issue date: FY 2012; new start)



## Medicaid Integrity and Accountability

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CHIP—CHILDREN’S HEALTH INSURANCE PROGRAM

CPE—CERTIFIED PUBLIC EXPENDITURES

DRA—DEFICIT REDUCTION ACT OF 2005

FFP—FEDERAL FINANCIAL PARTICIPATION

FFS—FEE FOR SERVICE

FORM CMS-64—QUARTERLY MEDICAID STATEMENT OF EXPENDITURES

MEDI-MEDI—MEDICARE AND MEDICAID DATA MATCHING PROJECT

MIC—MEDICAID INTEGRITY CONTRACTOR

MIP—MEDICAID INTEGRITY PROGRAM

OMB—OFFICE OF MANAGEMENT AND BUDGET

PERM—PAYMENT ERROR RATE MEASUREMENT (PROCESS)

### Early Results From Medicaid Integrity Contractors

We will review the progress of CMS’s Medicaid Integrity Contractors (MIC) in completing program integrity tasks outlined in their contracts. We will also examine the results of the MICs’ work. An integral part of the Medicaid Integrity Program (MIP) is the program integrity work that will be performed by MICs. MICs are tasked with preventing and detecting Medicaid fraud, waste, and abuse through the review of the actions of individuals or entities furnishing items or services under Medicaid. CMS began awarding contracts in April 2008 and subsequently awarded contracts covering CMS’s 10 regions. The MIP was established by the Social Security Act, § 1936, as amended by the DRA, § 6034. (OEI; 05-10-00200; 05-10-00210; expected issue date: FY 2012; work in progress)

### Medicare and Medicaid Data Matching Project

We will review CMS’s oversight and monitoring of the Medicare and Medicaid Data Matching Project (Medi-Medi) contractors to determine whether they are meeting contractual requirements outlined in the Medi-Medi task orders. We will also determine the extent to which Medi-Medi contractors identified potential fraud, waste, and abuse through the Medi-Medi project. This review matches 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. CMS began the Medi-Medi project in 2001 in partnership with California to improve coordination of Medicare and Medicaid program integrity efforts pursuant to the Social Security Act, § 1893. As of 2007, there were 10 active Medi-Medi task orders in California, Texas, Washington, Pennsylvania, North Carolina, New Jersey, New York, Florida, Ohio, and Illinois. Federal regulations provide policies and establish responsibilities for agencies to record and maintain contractor performance information. (48 CFR §§ 42.1500 to 42.1503.) (OEI; 09-08-00370; expected issue date: FY 2012; work in progress)

### Addressing Vulnerabilities Identified During Medicaid State Program Integrity Reviews (New)

We will review corrective actions that State Medicaid agencies have implemented to address the findings and recommendations from State Medicaid program integrity reviews conducted by CMS. We will determine why States have not implemented all corrective actions, examine the followup CMS performed to ensure that corrective actions were taken by States, and examine the evidence CMS reviews to ensure that corrective actions were implemented. As part of the MIP, CMS conducts a triennial review of each State’s program integrity functions to assess their effectiveness and compliance with Federal requirements. CMS issues to the State a final report of findings and recommendations and requires the State to provide a corrective action plan within 30 days of the report issuance. The MIP was established by DRA, § 6034. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Claims With Inactive or Invalid Physician Identifier Numbers**

We will review Medicaid claims to determine the extent to which State agencies have controls in place to identify claims associated with inactive or invalid national provider identifiers (NPI), including claims for services alleged to have been provided after the dates of the referring physicians' deaths. In a prior OIG review, we found instances in which Medicare had paid durable medical equipment (DME) claims with inactive or invalid NPIs for the referring physicians. In 2009, the Senate Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, reported that a substantial volume of Medicare-paid DME claims contained NPIs of deceased physicians. Given the vulnerabilities identified in the Medicare program, we will review State Medicaid programs to determine whether States have controls in place to identify claims with inactive or invalid NPIs. (OAS; W-00-11-31338; various reviews; expected issue date: FY 2012; new start)

### **Beneficiaries With Multiple Medicaid Identification Numbers**

We will review duplicate payments on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and the procedures for preventing such payments. We will determine whether States made duplicate Medicaid payments on behalf of these beneficiaries. A preliminary data match has identified a significant number of individuals who were assigned more than one Medicaid identification number and for whom multiple Medicaid payments were made for the same period. The IPIA states that a duplicate payment is an improper payment. (OAS; W-00-11-31374; various reviews; expected issue date: FY 2012; work in progress)

### **State Medicaid Fraud Control Units Performance Standards**

We will review the overall management, operations, and performance of a State Medicaid Fraud Control Unit (MFCU). The Secretary has delegated to OIG the responsibility for administering the MFCU grants and providing oversight and guidance to the MFCUs. Part of that oversight responsibility, as required by 42 CFR § 1007.15(d), includes certifying and then annually recertifying every State MFCU. Section 1902(a)(61) of the Social Security Act required the Secretary to establish performance standards that could be used in evaluating a MFCU's performance for recertification purposes; the twelve standards were published at 59 Federal Register 49080. Periodically, OIG conducts an in depth, on-site review of each State MFCU as part of the recertification process. We will determine the extent to which a State MFCU operates in accordance with the twelve published performance standards and identify areas for improvement in the MFCU's management and operations. (OEI, 02-11-00440, expected issue date: FY 12; work in progress; multiple reviews; new start)

### **State Agencies' Terminations of Providers Terminated Under Medicare or by Other States (New)**

We will review States' compliance with a new requirement that State Medicaid agencies terminate providers that have been terminated under Medicare or by another State. We will determine whether such providers are terminated by all States, assess the status of the supporting information-sharing system, determine how CMS is ensuring that States share complete and accurate information, and identify obstacles States face in complying with the termination requirement. This new requirement became effective January 1, 2011. (Social Security Act, § 1902(a)(39), as amended by the Affordable Care Act, § 6501.) We will compare lists of providers terminated from Medicare and each State Medicaid program and examine the information-sharing system being implemented

to comply with the requirement. (Affordable Care Act, § 6401(b)(2).) (OEI; 00-00-00000; expected issue date: FY 2012; new start; Affordable Care Act)

### **Federally Excluded Providers and Suppliers**

We will review Medicaid payments to providers and suppliers to determine the extent to which payments were for services provided during periods of exclusion from Medicaid. Excluded providers and suppliers are not permitted to receive payments for services provided during periods of exclusion. (Social Security Act, §§ 1128, 1128A, and 1156, and 42 CFR § 1001.1901.) (OAS; W-00-10-31337; W-00-11-31337; various reviews; expected issue date: FY 2012; work in progress)

### **States' Contingency Fee Payment Arrangements**

We will determine the extent to which State Medicaid agencies have contracted with consultants through contingency fee payment arrangements and determine how the impact the arrangements have affected the submission of questionable or improper claims to the Federal Government. Previous OIG work in one State found that improper claims had been submitted by the State as a result of a contingency fee payment arrangement. 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. The claiming of the costs of such contingency fee arrangements from the Federal Government are precluded by OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*. (OAS; W-00-07-31045; W-00-08-31045; W-00-11-31045; various reviews; expected issue date: FY 2012; work in progress)

### **Federal Funds Generated Through Medicaid Provider Taxes (New)**

We will review State health care-related taxes imposed on various Medicaid providers to determine whether the taxes comply with applicable Federal requirements. Our work will focus on the mechanism States use to raise revenue through provider taxes and determine the amount of Federal funding generated. Previous OIG work has raised concerns about States' use of health-care-related taxes. Many States finance a portion of their Medicaid spending by imposing taxes on health care providers. Health-care-related taxes are defined by Federal regulations that set forth the standard for permissible health-care-related taxes. (42 CFR §§ 433.55 and 433.68.) (OAS; W-00-12-31455; various reviews; expected issue date: FY 2013; new start)

### **Impact of Certified Public Expenditures**

We will determine whether States are complying with Federal regulations for claiming certified public expenditures (CPE). CPEs are normally generated by local governments as part of their contribution to the coverage of Medicaid services. States may claim CPEs to provide the State's share in claiming Federal reimbursement as long as the CPEs comply with Federal regulations and the CPEs are being used for the required purposes. (42 CFR § 433.51 and 45 CFR § 95.13.) (OAS; W-00-12-31110; various reviews; expected issue date: FY 2012; new start)

### **Overpayments: Medicaid Credit Balances**

We will review patient accounts of providers to determine whether there are Medicaid overpayments in the accounts with credit balances. Previous OIG work found Medicaid overpayments in patients' accounts with credit balances. Medicaid is the payer of last resort and providers are to identify and refund overpayments received. (Social Security Act, § 1902(a)(25); 42 CFR pt. 433, subpart D; various State laws; and CMS's *State Medicaid Manual*, Pub. No. 45, pt. 3,

§ 3900.1.) (OAS; W-00-10-31311; W-00-11-31311; various reviews; expected issue date: FY 2012; work in progress)

### **States' Efforts To Improve Third-Party Liability Payment Collections in Medicaid**

We will review States' procedures for identifying and collecting third-party payments for services provided to Medicaid beneficiaries to determine the extent to which States' efforts have improved since our last review. We will also examine changes to State laws and Medicaid procedures and determine whether such changes have improved States' identification of third-party liabilities. Many Medicaid beneficiaries may have additional health insurance through third-party sources, such as employer-sponsored health insurance. OIG work in 2006 described problems that State Medicaid agencies had in identifying and collecting third-party payments. States are to take all reasonable measures to ascertain the legal liabilities of third parties with respect to health care items and services. (Social Security Act, § 1902(a)(25).) The DRA, § 6035, clarified the provision for entities defined as third-party payers. (OEI; 05-11-00130; expected issue date: FY 2012; work in progress)

### **Proper Allocation of Medicaid Administrative Costs**

We will review administrative costs claimed by several States to determine whether they were properly allocated and claimed or directly charged to Medicaid. Prior reviews in one State noted problems with the State's administrative costs. The Federal share of Medicaid administrative costs is typically 50 percent, with enhanced rates for specific types of costs. Federal cost sharing for the proper and efficient administration of Medicaid State plans is provided by the Social Security Act, § 1903(a)(7). Administrative costs are claimed in accordance with OMB Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, and State requirements. (OAS; W-00-10-31123; W-00-11-31123; various reviews; expected issue date: FY 2012; work in progress)

### **Form CMS-64: Oversight of State Data Reporting**

We will examine CMS's oversight of State quarterly expenditure reporting on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64). We will also identify opportunities to improve the accuracy of such reporting. Previous OIG and GAO studies have shown significant inaccuracies in the reporting of State expenditures, thus affecting the Federal reimbursement match. The Form CMS-64 is a detailed accounting of expenditures that the Federal Government uses to reimburse States under Title XIX of the Social Security Act. Federal regulations require each State to submit the Form CMS-64 as a report of actual quarterly expenditures. (42 CFR § 430.30(c).) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Form CMS-64: Pharmacy Prescription Drug Claims**

We will review Medicaid pharmacy prescription drug claims for selected State Medicaid agencies to determine whether States accurately reported Medicaid expenditures for prescription drugs and whether the claims related to the expenditures were adequately supported by pharmacy records. CMS requires States to report actual expenditures on Form CMS-64 and maintain supporting documentation. (CMS's *State Medicaid Manual*, Pub. 45, pt. 2, §§ 2497 and 2500.) (OAS; W-00-09-31318; W-00-11-31318; various reviews; expected issue date: FY 2012; work in progress)

### **Form CMS-64: Medicaid Monetary Drawdowns (New)**

We will review the Medicaid monetary drawdowns that States received from the Federal Reserve System to determine whether they were supported by actual expenditures reported by the States on the Form CMS-64. States draw monetary advances against a continuing letter of credit certified to

the Secretary of the Treasury in favor of the State payee throughout a quarter. (42 CFR § 430.30(d)(4).) After the end of each quarter, States must submit the Form CMS-64, which shows the disposition of Medicaid funds used to pay for actual medical and administrative expenditures for the reporting period. (42 CFR § 430.30(c).) The amounts reported on the Form CMS-64 should reconcile the monetary advances for a quarter. (OAS; W-00-12-31456; various reviews; expected issue date: FY 2012; new start)

#### **Form CMS-64: Medicaid Overpayment Reporting and Collections (New)**

We will determine whether States are reporting overpayments identified by Federal audits on the Form CMS-64, as Federal regulations require. For cases in which CMS concurred with our prior recommendations, we will determine whether the overpayments have been recouped. Prior OIG reviews identified Medicaid overpayments in various States, and we recommended collection of those overpayments. If a Federal review indicates that a State has failed to identify an overpayment, CMS is to consider the overpayment as discovered on the date that the Federal official first notifies the State in writing of the overpayment and specifies a dollar amount subject to recovery. (42 CFR § 433.316(e).) Federal regulations require States' use of the Form CMS-64. (42 CFR part 433, subpart F). (OAS; W-00-11-31399; various reviews; expected issue date: FY 2012; work in progress)

#### **Form CMS-64: Accuracy of Medicaid Collections and Federal Share (New)**

We will determine whether States accurately captured Medicaid collections on their Form CMS-64, as well as returned the correct Federal share related to those collections. Previous OIG work revealed multiple errors in compiling collections amounts on the Form CMS-64, particularly errors related to the calculation of the Federal share returned. The States should report collections on lines 9a-9e of the Form CMS-64. These collections decrease the total expenditures reported for the period. (42 CFR §§ 433.154 and 433.320.) Instructions for line 9 indicate that States should compute the Federal share of collections at the rate at which CMS matched the original expenditure. (CMS's *State Medicaid Manual*, § 2500.1(B).) (OAS; W-00-12-31457; various reviews; expected issue date: FY 2012; new start)

#### **Payment Error Rate Measurement: Fiscal Year 2008 Error Rate**

We will evaluate certain aspects of CMS's Medicaid Payment Error Rate Measurement (PERM) process for determining the FY 2008 Medicaid fee for service (FFS) payment error rate. We will also determine whether the independent medical review organization met its contractual obligations to CMS and will analyze the organization's review. We will also evaluate the methodology and medical review determinations underlying the error rate testing conducted by the PERM contractor. Federal agencies are to annually develop a statistically valid estimate of improper payments under programs with a significant risk of erroneous payments. (Improper Payments Information Act of 2002 (IPIA) and the OMB implementation of IPIA in Memorandum M-06-23.) CMS contracted with an independent medical review organization to perform a random independent review of its PERM contractor's payment determinations for 250 Medicaid FFS claims. (OAS; W-00-10-40045; W-00-11-40045; expected issue date: FY 2012; work in progress)

#### **Payment Error Rate Measurement Program: Error Rate Accuracy and Health Information Security**

We will review CMS's implementation of the PERM process to determine whether it has produced valid and reliable error rate estimates for Medicaid and Children's Health Insurance Program (CHIP) FFS, managed care, and eligibility. We will also review the physical and data security of health

information transmitted by various States for use in the PERM. We will also verify CMS's actions to implement recommendations from a March 2010 OIG review. Annually, Federal agencies must develop statistically valid estimates of improper payments under programs with a significant risk of erroneous payments, including Medicaid and CHIP. (Improper Payments Elimination and Recovery Act (IPERA) and OMB's implementation of IPERA.) CMS developed the PERM process to comply with the IPERA. The process includes conducting FFS, managed care, and eligibility reviews. (42 CFR, pt. 431, subpart Q.) OMB's instructions on protecting sensitive information and reporting incidents involving potential and confirmed breaches of personally identifiable information are provided by OMB Memorandums M-06-16 and M-07-16. OIG has oversight and monitoring responsibilities related to CMS's error rate process pursuant to the Chief Financial Officers Act of 1990. (OAS; W-00-11-40046; various reviews; expected issue date: FY 2012; new start)

### **Payment Error Rate Measurement Program: Eligibility Determinations in One State**

We will review compliance in one State with PERM requirements for reviewing eligibility in its Medicaid and CHIP programs. As part of the PERM program, CMS requires States to have an independent review performed of Medicaid and CHIP eligibility determinations to assess whether they are in compliance with the States' eligibility requirements and have properly documented their eligibility determinations. The PERM process includes conducting required FFS, managed care, and eligibility reviews. (42 CFR pt. 431, subpart Q.) CMS developed the PERM program to comply with IPERA and OMB's implementation of IPERA. (OAS; W-00-12-40038; expected issue date: FY 2012; new start)

## Program Administration, Information Systems, and Data Integrity

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CHIP—CHILDREN'S HEALTH INSURANCE PROGRAM

CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES

FFP—FEDERAL FINANCIAL PARTICIPATION

MDS—MINIMUM DATA SET

MMIS—MEDICAID MANAGEMENT INFORMATION SYSTEM

NCCI—NATIONAL CORRECT CODING INITIATIVE

OMB—OFFICE OF MANAGEMENT AND BUDGET

PARIS—PUBLIC ASSISTANCE REPORTING INFORMATION SYSTEM

VFC—VACCINES FOR CHILDREN (PROGRAM)

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

We will review States' Medicaid buy-in programs for Medicare Part B to 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. States may enroll dual-eligible beneficiaries in the Medicare Part B program. States that operate buy-in programs pay the Medicare Part B premium for each dual-eligible individual that they enroll in Medicare Part B. (Social Security Act, § 1843, and 42 CFR §§ 407.40 through 407.42.) (OAS; W-00-10-31220; W-00-11-31220; various reviews; expected issue date: FY 2012; work in progress)

### **Provider Enrollment: Collection and Verification of Provider Ownership Information by State Medicaid Agencies**

We will review State practices for collection and verification of Medicaid provider ownership information, assess the accuracy of the information on file, and assess the effectiveness of the

practices. Payments to providers that have not disclosed the required information are not eligible for FFP. State Medicaid agencies cannot approve a provider participation agreement or contract with any entity that has not disclosed the required information. Federal regulations require Medicaid providers to disclose the name and address of each person with an ownership or control interest in the provider. (42 CFR § 455.104.) (OEI; 04-11-00590; expected issue date: FY 2012; work in progress)

### **Beneficiary Eligibility: State Agencies' Redeterminations of Medicaid Eligibility (New)**

We will review State agencies' procedures for redetermining the eligibility status of Medicaid beneficiaries and determine the amount of unallowable payments associated with beneficiaries who did not receive the required Medicaid eligibility redeterminations. 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 require that State agencies redetermine the eligibility of Medicaid beneficiaries, with respect to circumstances that may change, at least every 12 months. (42 CFR § 435.916.) (OAS; W-00-11-31140; various reviews; expected issue date: FY 2012; work in progress)

### **State Medicaid Plans' Vaccines for Children Program: Storage and Management of Vaccines**

We will determine the extent to which providers in the Vaccines for Children program (which is a required part of each State's Medicaid plan) are properly storing and managing vaccines. We will also determine the extent to which they perform additional vaccine storage and management activities recommended by the Centers for Disease Control and Prevention (CDC). Vaccines for Children is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. The program was created as a new entitlement to be a required part of each state's Medicaid plan. (Omnibus Budget Reconciliation Act of 1993.) Funding for the program is approved by OMB and allocated through CMS to CDC. (OEI; 04-10-00430; expected issue date: FY 2012; work in progress)

### **Children's Health Insurance Program: Dually Enrolled Beneficiaries in a State**

We will assess the appropriateness of a State's claims for FFP under the State's CHIP program for individuals who were enrolled in the State's Medicaid program. A previous OIG review of CHIP eligibility in one State for the first 6 months of 2005 indicated that the State had made some CHIP payments on behalf of individuals who were also enrolled in Medicaid. 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. (Social Security Act, § 2105(c)(6)(B).) (OAS; W-00-10-31314; W-00-11-31314; various reviews; expected issue date: FY 2012; work in progress)

### **Children's Health Insurance Program: State Compliance With Eligibility and Enrollment Notification and Review Requirements**

We will review State compliance with the CHIP eligibility and enrollment notification and review requirements. We will also determine whether beneficiaries remain enrolled during reviews of suspension or termination in enrollment. Federal regulations contain requirements relating to applicant and enrollee protections. (42 CFR pt. 457, subpart K.) Requirements include, among other things, that eligibility determinations be timely and be in writing and that the State ensure that an applicant or enrollee has an opportunity for an impartial review of eligibility denials and that the

results of such reviews be timely and be in writing. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

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

We will determine whether States are complying with CHIP's 10-percent cap on administrative costs. Administrative expenditures include those related to administration, outreach, and other child health assistance and initiatives. There is a limit on administrative funds that are eligible for Federal matching equal to 10 percent of the amounts expended to provide child health assistance. (Social Security Act, § 2105(c)(2)(A).) (OAS; W-00-10-31226; W-00-11-31226; various reviews; expected issue date: FY 2012; work in progress)

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

We will review Medicaid Management Information System (MMIS) costs in selected States to determine whether costs allocated to Medicaid are allowable. FFP in State expenditures is provided for the design, development, or installation of mechanized claims-processing and information retrieval systems and for the operation of certain systems. Social Security Act, § 1903(a)(3), as implemented by regulations at 42 CFR pt. 433, subpart C. (OAS; W-00-10-31312; W-00-11-31312; various reviews; expected issue date: FY 2012; work in progress)

### **States' Use of the Public Assistance Reporting Information System To Reduce Medicaid Benefits Received From More Than One State**

We will review eligibility data from the Public Assistance Reporting Information System (PARIS) to determine the extent to which States use PARIS to identify Medicaid recipients who are simultaneously receiving Medicaid benefits in more than one State. We will also determine the extent to which States investigate instances in which recipients are receiving Medicaid benefits in more than one State simultaneously and recover Medicaid payments for recipients determined to be ineligible. PARIS is a computer matching and information exchange system operated by the Administration for Children and Families. Using States' eligibility data, PARIS identifies those who concurrently receive benefits from Medicaid and other means-tested programs, such as food stamps, in more than one State. Federal law requires States' Medicaid eligibility determination systems to provide data matching through PARIS. (Social Security Act, § 1903, as amended by the Qualifying Individual Program Supplemental Funding Act of 2008 (QI).) (OEI; 09-11-00780; expected issue date: FY 2012; work in progress)

### **Medicaid National Correct Coding Initiative Effectiveness (New)**

We will review selected States' implementation of National Correct Coding Initiative (NCCI) edits for Medicaid claims. Federal law requires States to incorporate compatible methodologies of the NCCI for Medicaid claims filed on or after October 1, 2010. (Social Security Act, § 1903(r), as amended by the Affordable Care Act, § 6507.) States were permitted to deactivate some or all NCCI edits because of conflicts with State laws, regulations, administrative rules, payment policies, and/or the States' levels of operational readiness. (State Medicaid Director Letter #10-017.) As of April 1, 2011, lack of operational readiness was no longer a permissible basis for deactivation of the edits. (State Medicaid Director Letter #11-003.) After April 1, 2011, the only basis for deactivation is conflicts with State laws, regulations, administrative rules and/or payment policies. (OAS; W-00-12-31459; various reviews; expected issue date: FY 2013; new start; OEI; 00-00-00000; expected issue date: FY 2012; new start; Affordable Care Act)



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

We will review CMS's oversight activities related to data security requirements of State MMIS, which process and pay claims for Medicaid benefits. We will determine whether business associate agreements have been properly executed to protect beneficiary information, including safeguards implemented pursuant to Federal standards. 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 established minimum requirements for contracts with business associates to protect the security of electronic-protected health information. (Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rules at 45 CFR pt. 164, subpart C.) (OAS; W-00-11-41015; various reviews; expected issue date: FY 2012; work in progress)

### **CMS Oversight and Accuracy 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. We will also review CMS's processes for ensuring that nursing homes submit accurate and complete MDS data. MDS data include the residents' physical and cognitive functioning, health status and diagnoses, preferences, and life care wishes. Nursing homes must conduct accurate comprehensive assessments for residents using an instrument that includes the MDS. (Social Security Act, §§ 1819(b)(3)(A)(iii) and 1819(e)(5), and corresponding sections of Title XIX of the Social Security Act.) Federal regulations specify the requirements of the assessment instrument. (42 CFR § 483.20.) CMS implemented a skilled nursing facility prospective payment system based on MDS data in July 1998 and began posting MDS-based quality performance information on its Nursing Home Compare Web site in 2002. About half of the States base their Medicaid payment systems on MDS data. (OEI; 00-00-00000; expected issue date: FY 2012; 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 to determine whether they contain any vulnerabilities that could affect the confidentiality, integrity, and availability of the Medicaid claims' protected health information. Electronic claims transactions may contain protected health information as defined under regulations that also define "health plan" to include Medicaid. (45 CFR § 160.103.) Medicaid programs must comply with the security standards set forth at 45 CFR pt. 164, subpart C, which is known as the HIPAA Security Rule. We will use an application security assessment tool in conducting this review. (OAS; W-00-12-41016; various reviews; expected issue date: FY 2012; new start)

### **Medicaid Security Controls at the Mainframe Data Centers That Process States' Claims Data**

We will review security controls at States' mainframe data centers that process Medicaid claims data. We will focus on security controls, such as access controls over the mainframe operating system and security software. We will also review some limited general controls, such as disaster recovery plans and physical security. OMB requires that agencies implement and maintain programs to ensure that adequate security is provided for all agency information that is collected, processed, transmitted, stored, or disseminated in general support systems and major applications. OMB also established a minimum set of controls to be included in Federal automated information security programs. (OMB Circular A-130, *Management of Federal Information Resources*, Appendix III.) (OAS; W-00-10-40019; W-00-11-40019; expected issue date: FY 2012; work in progress, new start)

## Medicaid Managed Care

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

MCE—MANAGED CARE ENTITIES

MCO—MANAGED CARE ORGANIZATIONS

MSIS—MEDICAID STATISTICAL INFORMATION SYSTEM

OMB—OFFICE OF MANAGEMENT AND BUDGET

### **Completeness and Accuracy of Managed Care Encounter Data (New)**

We will review the extent to which Medicaid managed care encounter data included in Medicaid Statistical Information System (MSIS) submissions to CMS accurately represent all services provided to beneficiaries. We will also determine the extent to which CMS acted to enforce Federal requirements that Medicaid managed care encounter data be included in MSIS. A prior OIG review of 2007 data found that although all 40 States with Medicaid managed care were collecting encounter data and most of those States used the data, only 25 States included it in their MSIS submissions to CMS. Of the 25 States that included encounter data in their MSIS submissions, the MSIS files containing encounter data varied by service (e.g., inpatient, pharmacy, long-term care) and eligibility, as did the data elements reported in each file. Federal law requires States and managed care entities to submit data elements deemed necessary by the Secretary for use in program integrity, program oversight, and administration. (Affordable Care Act, § 6504.) Federal Medicaid matching funds for the operation of an MSIS are authorized pursuant to the Social Security Act, § 1903(a)(3)(B).) Such matching funds can be withheld from States that fail to submit required Medicaid data, including encounter data. (Social Security Act, §§ 1903(m)(2)(A) and 1903(r)(1).) (OEI; 00-00-00000; expected issue date: FY 2012; new start; Affordable Care Act)

### **Managed Care Entities' Marketing Practices**

We will review State Medicaid agencies' oversight policies, procedures, and activities to determine the extent to which States monitor Medicaid managed care entities' (MCE) marketing practices and compliance with Federal and State contractual marketing requirements. We will also determine the extent to which CMS ensures States' compliance with Federal requirements involving Medicaid MCE marketing practices. No marketing materials may be distributed by Medicaid MCEs without first obtaining States' approval. (Social Security Act, § 1932(d)(2).) States are permitted to impose additional requirements in contracts with MCEs about marketing activities. (42 CFR § 438.104.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **State Oversight of Provider Credentialing by Managed Care Entities**

We will determine how States ensure that Medicaid MCEs (specifically MCOs), prepaid inpatient health plans, and prepaid ambulatory health plans comply with credentialing and recredentialing requirements. We will also determine how CMS ensures that States comply with provider credentialing requirements. Each entity must document its process for credentialing and recredentialing providers and not discriminate against providers that serve high-risk populations or specialize in high-cost treatment. Federal regulations require States to ensure that entities serving the Medicaid population implement written policies and procedures for selection and retention of providers. (42 CFR 438.214.) (OEI; 09-10-00270; expected issue date: FY 2012; work in progress)

### **Excluded Individuals Employed by in Managed Care Networks**

We will determine the extent to which OIG-excluded individuals were employed by entities that provide services through MCE provider networks in 2009. We will also determine the extent to

which safeguards are in place to prevent excluded individuals and entities from participating in Medicaid managed care provider networks. HHS and OIG have authority to exclude individuals and entities from all Federal health care programs pursuant to the Social Security Act, §§ 1128, 1156, and 1892. Medicaid and any other Federal health care programs are precluded from paying for any items or services furnished, ordered, or prescribed by an excluded individual or entity, except under specific limited circumstances. (Social Security Act, § 1862(e)(1), and 42 CFR § 1001.1901(b).) The payment prohibition applies to the excluded individual or entity, anyone who employs or contracts with the excluded individual or entity, and any hospital or other provider through which the excluded individual or entity provides services. Recent State Medicaid program integrity reviews by CMS's Medicaid Integrity Group have identified provider enrollment, including the employment of excluded providers, as one of the most common vulnerabilities. (OEI; 07-09-00632; expected issue date: FY 2012; work in progress)

### **Managed Care Fraud and Abuse Safeguards**

We will review Medicaid MCO fraud and abuse safeguards and State Medicaid agencies' oversight plans and procedures and determine the extent to which States monitor such safeguards for compliance with Federal requirements. We will also review CMS's plans and procedures for overseeing States' compliance with these requirements. Federal regulations require Medicaid MCOs to have administrative and management arrangements or procedures, including mandatory compliance plans, that are designed to guard against fraud and abuse. (42 CFR § 438.608.) (OEI; 01-09-00550; expected issue date: FY 2012; work in progress)

### **Managed Care Organizations' Use of Prepayment Review To Detect and Deter Fraud and Abuse**

We will determine the extent to which Medicaid MCOs use prepayment reviews to detect and deter fraud and abuse. We will also examine the results of MCO prepayment reviews, the challenges addressed in developing and implementing the prepayment programs, and lessons MCOs learned about them. Federal regulations require Medicaid MCOs to have administrative and management arrangements or procedures that are designed to guard against fraud and abuse and that include mandatory compliance plans and provisions for internal monitoring and auditing. (42 CFR § 438.608.) Prepayment reviews can serve as effective fraud and abuse safeguards because they occur during the claims-processing phase prior to claim payment. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Medicaid Managed Care Plans' Medical Loss Ratio**

We will review managed care plans with contact provisions that require a minimum percentage of total costs to be expended for medical expenditures (medical loss ratio) to determine whether a refund was made to the State agency when the minimum medical loss ratio threshold was not met. Prior OIG work found that, although the minimum medical loss ratios were not met, the managed care plans did not make the required refund to the State agency. State Agencies must properly report expenditures and to apply any applicable credits. (OMB Circular A-87.) (OAS; W-00-11-31372; various reviews; expected issue date: FY 2012; work in progress)

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Part IV:

Legal and Investigative  
Activities Related to Medicare and Medicaid

## Part IV: Legal and Investigative Activities Related to Medicare and Medicaid

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN PART IV:

CIA—CORPORATE INTEGRITY AGREEMENT

CMP—CIVIL MONETARY PENALTY

CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES

CPG—COMPLIANCE PROGRAM GUIDANCE

DME—DURABLE MEDICAL EQUIPMENT

DOJ—DEPARTMENT OF JUSTICE

MFCU—[STATE] MEDICAID FRAUD CONTROL UNIT

## Legal Activities

The Office of Inspector General's (OIG) resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalties (CMP) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIA) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the antikickback statute, and provides compliance program guidance (CPG). OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements and provides them a self-disclosure protocol and guidance.

### Exclusions From Program Participation

OIG may exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs for many reasons, some of which include program-related convictions, patient abuse or neglect convictions, licensing board disciplinary actions, or other actions that pose a risk to beneficiaries or programs. (Social Security Act, § 1128, § 1156, and other statutes.) Exclusions are generally based on referrals from Federal and State agencies. We work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. In fiscal year (FY) 2010, OIG excluded 3,340 individuals and entities from participation in Federal health care programs. The total for FY 2011 will be published in OIG's Fall FY 2011 *Semiannual Report to Congress*. Searchable exclusion lists are available on OIG's Web site at: <http://exclusions.oig.hhs.gov/>.

### Civil Monetary Penalties

OIG pursues CMP cases, when supported by appropriate evidence, 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); violations of the Emergency Medical Treatment and Labor Act of 1986; items and services furnished to patients of a quality that fails to meet professionally recognized standards of health care; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

### False Claims Act Cases and Corporate Integrity Agreements

When adequate evidence of violations exists, OIG staff members work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal false claims cases against individuals

and entities that defraud the Government. Authorities relevant to this work come from the False Claims Amendments Act of 1986 and the Fraud Enforcement and Recovery Act of 2009. We assist DOJ prosecutors in litigation and settlement negotiations arising from these cases. We also consider whether to invoke our exclusion authority based on the defendants' conduct. When appropriate and necessary, we require defendants to implement CIAs aimed at ensuring compliance with Federal health care program requirements.

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

OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Subsequently, OIG assesses providers' compliance with the terms of the integrity agreements. For example, we conduct site visits to entities that are subject to integrity agreements to verify compliance, to confirm information submitted to us by the entities, and to assess the providers' compliance programs. We review a variety of information submitted by providers to determine whether their compliance mechanisms are appropriate and identify problems and establish a basis for corrective action. When warranted, we impose sanctions, in the form of stipulated penalties or exclusions, on providers that breach integrity agreement obligations. Active CIAs, Certification of Compliance Agreements, and settlement agreements with integrity provisions are listed on OIG's Web site at: [http://www.oig.hhs.gov/fraud/cia/cia\\_list.asp](http://www.oig.hhs.gov/fraud/cia/cia_list.asp).

### **Review of Entities That Do Not Enter Into Corporate Integrity Agreements (New)**

We will review entities, including providers and/or suppliers that settled fraud cases with the Government but declined to enter into CIAs with OIG. CIAs promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). OIG reviews may be similar to or more extensive than those that would be performed by Independent Review Organizations under CIAs to assess the entity's compliance with Federal health care program standards. (OAS; W-00-12-30070; various reviews; expected issue date: FY 2012; new start)

### **Advisory Opinions and Other Industry Guidance**

To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the antikickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful advice on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and CPG for specific areas. Examples are available on OIG's Web site at:

- Advisory Opinions: <http://www.oig.hhs.gov/fraud/advisoryopinions.asp>
- Fraud Alerts: <http://www.oig.hhs.gov/fraud/fraudalerts.asp>
- Compliance Guidance: <http://www.oig.hhs.gov/fraud/complianceguidance.asp>
- Open Letters: <http://www.oig.hhs.gov/fraud/openletters.asp>

### **Provider Compliance Training**

In spring 2011, OIG and its government partners provided in-person provider compliance training in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C. The training sessions focused on the realities of Medicare and Medicaid fraud and the importance of implementing an effective compliance program. To expand access to providers nationwide, we

broadcasted a free online live Webcast of the May 18 training in Washington. A [complete video](#) of the training as well as [16 video modules](#) containing individual presentations from May 18 are available on OIG's [Provider Compliance Training Web site](#) along with slides and written handouts corresponding to each session. Our provider compliance training effort continues.

### **Provider Self-Disclosure**

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abusive practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. In doing so, the self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in being overpaid by a Federal program). After making an initial disclosure, the provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action.

- The self-disclosure guidelines are available on the OIG Web site at <http://www.oig.hhs.gov/fraud/selfdisclosure.asp>.
- See also: Open Letters at <http://www.oig.hhs.gov/fraud/openletters.asp>

## **Investigative Activities**

To safeguard programs, protect beneficiaries, and ensure that personnel and contractors uphold the highest level of integrity, OIG reviews and investigates allegations of fraud and misconduct. Investigations lead to 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 OIG's attention for review, investigation, and resolution. The nature and volume of complaints and priority of issues vary from year to year. We describe some of the more significant investigative outcomes in OIG's *Semiannual Report(s) to Congress*, which are available on our Web site at: <http://www.oig.hhs.gov/publications.asp>.

### **Medicare Strike Force Teams and Other Collaboration**

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

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and DOJ to strengthen programs and invest in new resources and technologies to prevent and



combat health care fraud, waste, and abuse. Using a collaborative model, Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud. The Strike Force teams began in March 2007 and are operating in nine major cities. The effectiveness of the Strike Force model is enhanced by interagency collaboration within the Department of Health & Human Services (HHS). For example, we refer credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so it can suspend payments to perpetrators. During Strike Force operations, OIG and CMS work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets.

OIG and its partners investigate individuals, facilities, or entities that, for example, bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes to inflate reimbursement amounts, and false claims submitted to obtain program funds. We also investigate business arrangements that allegedly violate the Federal health care antikickback statute and the statutory limitation on self-referrals by physicians.

OIG also examines quality-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which the programs may have been billed for medically unnecessary services, for services either not rendered or not rendered as prescribed, or for substandard care that is so deficient that it constitutes “worthless services.”

Other areas of investigation include Medicare and Medicaid drug benefit issues and assisting CMS in identifying program vulnerabilities and schemes such as prescription shorting (a pharmacy dispensing fewer doses of a drug than prescribed, charging the full amount, and then instructing the customer to return to pick up the remainder). Working with law enforcement partners at the Federal, State, and local levels, we investigate schemes to illegally market, obtain, and distribute prescription drugs. In doing so, we seek to protect Medicare and Medicaid from making improper payments, deter the illegal use of prescription drugs, and to curb the danger associated with street distribution of highly addictive medications. We assist State MFCUs to investigate allegations of false claims submitted to Medicaid and will continue to strengthen coordination between OIG and organizations such as the National Association of Medicaid Fraud Control Units and the National Association for Medicaid Program Integrity.

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

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Part V:

Public Health Reviews

## Part V: Public Health Reviews

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED ORGANIZATIONS AND TERMS USED IN PART V:

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| AHRQ—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY        | IHS—INDIAN HEALTH SERVICE   |
| AIDS—ACQUIRED IMMUNODEFICIENCY SYNDROME                | IND— INVESTIGATIONAL NEW DRUG                                       |
| ASPR—ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE | NIH—NATIONAL INSTITUTES OF HEALTH                                   |
| CDC—CENTERS FOR DISEASE CONTROL AND PREVENTION         | OASH—OFFICE OF THE ASSISTANT SECRETARY OF HEALTH                    |
| CFR—CODE OF FEDERAL REGULATIONS                        | OMB—OFFICE OF MANAGEMENT AND BUDGET                                 |
| FAR—FEDERAL ACQUISITION REGULATION                     | PHEP—PUBLIC HEALTH EMERGENCY PREPAREDNESS                           |
| FDA—FOOD AND DRUG ADMINISTRATION                       | PSO—PATIENT SAFETY ORGANIZATIONS                                    |
| HIV—HUMAN IMMUNODEFICIENCY VIRUS                       | RN—RADIOLOGICAL AND NUCLEAR [INCIDENTS]                             |
| HRSA—HEALTH RESOURCES AND SERVICES ADMINISTRATION      | SAMHSA—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES<br>ADMINISTRATION |

## Public Health Agencies

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Our reviews of public health agencies within the Department of Health & Human Services (HHS) generally include the following:

- Agency for Healthcare Research and Quality (AHRQ). AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access.
- Centers for Disease Control and Prevention (CDC). CDC operates a health surveillance system to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.
- Food and Drug Administration (FDA). FDA is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.
- Health Resources and Services Administration (HRSA). HRSA maintains a safety net of health services for people who 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 American Indians and Alaska Natives.
- National Institutes of Health (NIH). NIH supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).
- Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds services to improve the lives of people who have or are at risk for mental and substance abuse disorders.

Issues related to public health are also addressed within the Office of the Secretary. For example, the Office of the Assistant Secretary for Preparedness and Response (ASPR) serves as the

Secretary's principal advisor on matters related to Federal public health preparedness and response to public health emergencies. The functions of the Office of the Assistant Secretary for Health include overseeing the protection of volunteers involved in research.

Descriptions of the Office of Inspector General's (OIG) work in progress and work planned for fiscal year (FY) 2012 follow.

## Agency for Healthcare Research and Quality

### **Early Implementation of Patient Safety Organizations (New)**

We will review the policies and activities of Patient Safety Organizations (PSO) to determine the extent of participation among hospitals, their practices in receiving and analyzing adverse event reports, and the extent to which they provide information to providers and the Network of Patient Safety Databases maintained by AHRQ. We will evaluate PSOs' efforts to identify and resolve patient safety problems in hospitals and identify any barriers to the full and effective implementation of the PSO program. In a 2009 report, OIG found that hospitals did not identify all serious adverse events, suggesting that hospital incident-reporting systems may be an unreliable source of information for PSOs. Federal law established a national network of PSOs, nongovernmental entities certified by HHS to collect and analyze reports of adverse events from hospitals and other health care settings. (Patient Safety and Quality Improvement Act of 2005.) The Secretary delegated responsibility for establishing and operating the PSO program to AHRQ. PSOs must meet certain criteria, establish a database to analyze patient safety information submitted by providers, and provide technical assistance to providers. AHRQ may also provide technical assistance to PSOs on matters such as methodology, communication, data collection, or privacy concerns. PSOs began operating in late 2008, with more than 90 in existence. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

## Centers for Disease Control and Prevention

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

We will review the adequacy of one State's monitoring of subrecipient expenditures charged to the Public Health Emergency Preparedness (PHEP) program. We will determine whether salary charges have been made at the subrecipient level and assess the adequacy of the State's subrecipient expenditure-monitoring process. 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 PHEP program. The purpose of the program is to upgrade and integrate State and local public health jurisdictions' preparedness for and response to terrorism and other public health emergencies. The Office of Management and Budget (OMB) and Federal regulations require State grantees of the PHEP program to provide time and effort certifications for employees who are expected to work solely on the PHEP Federal award. (OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, App. B, § h(3), and 2 CFR pt. 225.) Regulations require grantees to manage and monitor day-to-day operations of subgrantees to ensure compliance with Federal requirements. (45 CFR § 92.40.) (OAS; W-00-12-58140; expected issue date: FY 2012; new start)

### **States' 24/7 Reporting Systems**

We will review the status of States' systems for receiving urgent reports of bioterrorism agents and other public health emergencies. We will evaluate States' 24/7 systems to assess State preparedness for receiving urgent reports and the functionality of the systems. Pursuant to Federal law, CDC funds PHEP Cooperative Agreements that include critical tasks that States must accomplish to improve the timeliness and accuracy of communications about threats to the public's health and to decrease the time needed to classify health events, such as terrorism or naturally occurring disasters. (Public Health Service Act (PHS Act), § 319C-1, and 42 U.S.C. §§ 247d-3a.) The State must operate urgent disease and public health emergency reporting systems 24 hours per day, 7 days per week (24/7 systems). The 24/7 systems enable health care providers to report to or consult State or local health department staff at any time about suspected or confirmed diseases that require urgent reporting. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **Radiological and Nuclear Preparedness: Assessing Selected Local Public Health Emergency Response Plans**

We will determine whether and how selected localities identified radiological and nuclear (RN) incidents to be high-risk threats and have engaged in public health planning to prepare for RN incidents. We will also determine whether and how selected localities used HHS guidance. According to CDC and Department of Homeland Security guidance documents, localities will be the first to respond to an RN incident. HHS provides guidance to States and localities on how to develop RN preparedness plans. (OEI; 04-10-00250; expected issue date: FY 2012; work in progress)

### **Prevention and Public Health Fund Recipient Capability Audits (New)**

We will perform limited-scope reviews to determine whether CDC's grantees have the capability to manage and account for Federal funds, including Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) funds, in accordance with Federal regulations. We will also determine whether Prevention and Public Health Fund grantees are able to fulfill program requirements. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015, to support the Prevention and Public Health Fund. (Affordable Care Act § 4002.) Pursuant to Federal regulations, grantees receiving Federal funds must ensure that they are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) (OAS; W-00-12-59003; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

### **Grantees' Use of Funds From the Prevention and Public Health Fund (New)**

We will determine whether CDC grantees' use of funds from the Prevention and Public Health Fund were properly used for the purposes outlined in Federal laws and directives. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015, to support the Prevention and Public Health Fund. (Affordable Care Act § 4002.) Pursuant to Federal regulations, grantees receiving Federal funds must ensure that the funds are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) The use of funds from the Prevention and Public Health Fund is governed by Federal award letters; program requirements; the Affordable Care Act; and OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*. (OAS; W-00-12-59014; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

**Internal Controls for Awarding Affordable Care Act Grants (New)**

We will review and test CDC's internal controls for awarding Affordable Care Act grants. We will also determine whether selected CDC Affordable Care Act grantees complied with grants administration requirements and terms and conditions of the funding opportunity announcements. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015. (Affordable Care Act, § 4002.) CDC awarded grants for prevention activities to States, local governments, and community-based organizations. (OAS; W-00-11-59000; expected issue date: FY 2012; work in progress; Affordable Care Act)

**Payment of Invoices for Affordable Care Act Purchases (New)**

We will review and test CDC's controls over payments for goods and services, including purchases made with Affordable Care Act, § 4002, funds. We will determine whether CDC's Financial Management Office obtains proper validation that goods or services were received before payment of invoices. We will determine whether a previously identified control deficiency has been corrected. A previous internal CDC risk assessment found that receiving validations were not obtained for 9 of 10 invoices over \$2,500 during 4th quarter FY 2009. The Financial Management Office attributed this deficiency to the high volume of bills received and processed and stated that it had added additional controls to correct the problem. (OAS; W-00-12-59015; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

**Contracting Activities Within CDC's Procurement and Grants Office (New)**

We will review CDC's compliance with Federal laws and regulations in the use of service contracts awarded to assist its Procurement and Grants Office (PGO). We will focus on whether PGO contracts avoided functions that were inherently governmental in nature and whether contracts were issued and administered in a manner that did not create personal services contracts. We will also determine whether CDC funded these service contracts in accordance with requirements of the bona fide needs statute. In prior audits, OIG found that CDC employees had, in some cases, directed or controlled contractor employees' daily activities and had performed supervisory activities, such as reviewing contractor employee time cards and approving leave requests. The relationship between CDC employees and contractor personnel created a personal services contract. CDC's PGO is responsible for administering CDC grants and contracts for activities identified in the Federal Acquisition Regulation (FAR) as inherently governmental in nature. Contractors make up a significant portion of employees at CDC offices and often work side by side with CDC personnel. The FAR prohibits service contracts that are for inherently governmental functions and contracts that are for personal services. (FAR 7.503(a) and FAR 37.104(b).) In addition, the bona fide needs statute requires agencies to fund severable service contracts with funds that are current and available for the year in which performance takes place. (31 U.S.C. § 1502.) (OAS; W-00-12-58202; expected issue date: FY 2012; new start)

**CDC Oversight of High-Risk Grantees (New)**

We will examine current CDC processes for designating and monitoring high-risk grantees. We will determine the extent to which CDC designates its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) grantees as high risk, whether CDC includes special conditions and restrictions in high-risk grantees' contracts, and the extent to which CDC high-risk grantees comply with special conditions and restrictions in their contracts. Increased funding through the American Recovery and Reinvestment Act of 2009 (Recovery Act) for CDC's NCCDPHP increases potential vulnerabilities in CDC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal

regulations, operating divisions are allowed to include special conditions and restrictions in the contracts of grantees designated as high risk if the grantees meet certain criteria (e.g., history of poor performance, financial instability). (42 CFR § 74.14 and 45 CFR § 92.12.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

## Food and Drug Administration

### **Complaint Investigation Process**

We will determine the adequacy of FDA's complaint investigation process. We will determine whether complaints are properly recorded in the Consumer Complaint System and investigated expeditiously. We will also review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries. FDA relies on its complaint investigation process in its efforts to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Guidelines for investigations are in FDA's *Investigations Operation Manual*, ch. 8, § 8.2. (OAS; W-00-12-51010; expected issue date: FY 2012; new start)

### **Oversight of Food Safety Operations**

We will review FDA's oversight and operations related to imported pet food and feed products, including 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. We will review FDA's policies to determine whether it requires imported pet food and feed to be produced under the same safety standards as those that apply 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, we will determine why. (OAS; W-00-12-51002; expected issue date: FY 2012; new start)

### **Oversight of State Food Facility Inspections**

We will review FDA's oversight of food facility inspections conducted by States under contract with FDA. We will also determine the extent to which FDA is meeting its program guidelines and the extent to which deficiencies are identified and corrected. FDA created the Contract Inspection Audit Program in 2006 in response to an OIG report recommending that FDA take steps to address shortcomings in its oversight system. Under this program, 7 percent of each State's inspectors are audited by FDA or the State each year to ensure that the State's contract inspections are adequate and that the State is complying with contract requirements. When audits identify deficiencies in the State inspector's performance or systemic deficiencies in the State's inspection program, FDA and the State take action to ensure that deficiencies are corrected. (OEI; 02-09-00430; expected issue date: FY 2012; work in progress)

### **FDA Reportable Food Registry**

We will determine the extent to which food facilities comply with key requirements of FDA's Reportable Food Registry. We will also determine whether there are any known instances of reportable foods that facilities did not report to FDA, as required. Beginning in September 2009, FDA began requiring facilities to report all instances in which there is a reasonable probability that the use of, or exposure to, an article of food will cause severe health problems or death. FDA refers to such foods as "reportable foods." When a facility discovers that it has a reportable food, the facility must

report the adulteration in FDA's reportable food registry within 24 hours and submit supplemental information as required by FDA, investigate the cause of the adulteration if the adulteration originated with the facility, and work with FDA to follow up as needed. Federal law required FDA to create the registry to provide a reliable mechanism to track outbreaks of foodborne illness. (Food and Drug Administration Amendments Act of 2007, § 1005.) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **FDA's Oversight of Investigational New Drug Applications**

We will review FDA's process for evaluating investigational new drug (IND) applications. We will assess FDA's timeliness and identify challenges in the IND review process. Drug sponsors submit IND applications to FDA for review, and the agency has 30 days from receipt of the applications to review them, after which the sponsors may start clinical trials without FDA's approval. Federal law governs FDA's authority to oversee INDs used in clinical trials to assess their safety and effectiveness. (Food, Drug, and Cosmetic Act (FDCA) of 1938, § 505(i).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **FDA's Policies and Procedures for Resolving Scientific Disputes**

We will describe the extent and nature of formal internal scientific disputes that occurred during the approval of medical devices at the FDA Center for Devices and Radiological Health's (CDRH). We will assess the extent to which regulations, policies, and procedures were followed during the dispute resolution process. We will also assess CDRH's implementation of its new policies and procedures for addressing scientific disputes. Such disputes may arise between FDA and industry or within the FDA (e.g., reviewer and management). Federal regulations require FDA reviewers to maintain an administrative file documenting their product recommendations and decisions, including significant controversies or differences of opinion and the resolution. (21 CFR § 10.70.) Regulations provide for supervisory review of a decision if requested by the FDA reviewer or an outside stakeholder or if initiated by the supervisor, using information in the administrative file. (21 CFR § 10.75(a).) In October 2009, CDRH issued new policies and procedures for addressing internal disputes related to regulatory decisions. (OEI; 01-10-00470; expected issue date: FY 2012; work in progress)

### **510(k) Process for Device Approval**

We will review documentation of devices that FDA cleared using the Premarket Notification process, known as the 510(k) process, and describe characteristics of the cleared devices. Certain devices may be approved under the 510(k) process. (FDCA, §§ 510(k) and 513(f), and 21 CFR § 807.92.) The 510(k) process is a faster and less expensive method to market lower-risk medical devices than the more stringent Premarket Approval process. We will conduct our review pursuant to documentation requirements at 21 CFR § 10.70. (OEI; 04-10-00480; expected issue date: FY 2012; work in progress)

### **The Food and Drug Administration's Implementation of the Risk Evaluation and Mitigation Strategies Program (New)**

We will examine the extent to which FDA ensures drug manufacturer compliance with the requirements of the Risk Evaluation and Mitigation Strategies (REMS) program. We will also review drug manufacturer assessments of the REMS program's efficacy in minimizing risk to consumers. Ensuring the effectiveness of REMS plans is an important component of drug safety oversight, which is one of the Top Management and Performance Challenges that OIG identified for HHS. FDA may require a REMS plan for a high-risk drug, the safety of which depends on successful communication of risks and benefits. Drug manufacturers are required to submit assessments of the effectiveness



of the REMS plan at scheduled intervals. (OEI; 04-11-00510; expected issue date: FY 2013; work in progress)

### **FDA Oversight of Claims Made on Dietary Supplement Labels (New)**

We will review a sample of dietary supplements to determine the extent to which their labeling complies with FDA regulations regarding structure function claims. Structure function claims describe the role of a dietary supplement on the structure and function of human bodies. We will also determine the extent to which manufacturers of supplements are listed in FDA's Food Facility Registry as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). We will review the accuracy of the information in the FDA's registry of manufacturers of supplements and determine how FDA monitors and responds to claims that do not comply with the regulations. FDA regulates claims made on the labels of dietary supplements but relies on manufacturers to substantiate these claims and does not require approval before marketing. Manufacturers must also register with FDA under the Bioterrorism Act. (OEI; 01-11-00210; expected issue date: FY 2012; work in progress)

## **Health Resources and Services Administration**

### **Ryan White CARE Act Payer of Last Resort Provision**

We will review States' compliance with the payer of last resort requirement in their administration of the AIDS Drugs Assistance Program (ADAP) funds. 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. FY 2006, ADAP grant awards totaled more than \$750 million. Federal law stipulates that these grant funds not be used to make payments for items or services eligible for coverage by any other Federal or State program or by any health insurance policy. (Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990.) This requirement, commonly referred to as the payer-of-last-resort provision, is outlined in the Public Health Service Act of 1944 (PHS Act), § 2617(b)(7)(F). (OAS; W-00-10-54260; various reviews; expected issue date: FY 2012; work in progress)

### **Human Immunodeficiency Virus Testing in Health Centers**

We will describe HIV testing practices of HRSA-funded health centers. We will review health center service sites to determine their HIV testing practices and the factors that influence health center staff decisions. CDC estimates that 56,300 new HIV infections occurred in the United States in 2006. In an effort to reduce this number, CDC issued new recommendations to make HIV testing a routine part of medical care. Health centers are critical to this effort because they provide health services to populations that are disproportionately affected by HIV. However, HRSA estimates that only 5.8 percent of health center patients were tested in 2010, and little information exists regarding health center HIV testing practices. (OEI; 06-10-00290; expected issue date: FY 2012; work in progress)

### **Community Health Centers' Compliance With Affordable Care Act Grant Requirements (New)**

We will determine whether community health centers that received Affordable Care Act, § 10503, funds are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems and assessing the accounting

for program income. The review is based in part on requirements of the Public Health Service Act, § 330, and Federal regulations. (OAS; W-00-12-58303; various reviews, expected issue dates: FYs 2012-13; new start; Affordable Care Act)

### **Community Health Center Limited-Scope Capability Audits (New)**

We will determine the capacity of community health centers receiving Affordable Care Act, § 10503, funds to manage and account for Federal funds and to operate community health service delivery sites in accordance with Federal requirements. Funding provided to community health centers has increased under the Affordable Care Act. Community health service delivery sites are operated in accordance with the PHS Act, § 330, and Federal regulations. (OAS; W-00-12-58204; various reviews, expected issue dates: FYs 2012-14; new start; Affordable Care Act)

### **HRSA's Monitoring of Recipients' Fulfillment of National Health Services Corps's Obligations (New)**

We will determine the effectiveness of National Health Service Corps (NHSC) monitoring of recipients to ensure timely fulfillment of their contract obligations or timely recognition and referral of defaults to a Treasury-designated Debt Collection Center (HHS Program Support Center) when recipients breach their obligations. We will assess the accuracy of HRSA's default rate (2 percent) and the adequacy of its followup with health care professionals who default on their service commitments. Under the PHS Act, NHSC provides loan repayments and scholarships for health professionals who agree to work for a specified period in Health Professional Shortage Areas. In FY 2010, NHSC received \$141 million in funding. The Affordable Care Act, § 5207, and the Recovery Act provided increased funding for the NHSC Loan and Scholarship Programs. (OAS; W-00-12-58205; expected issue date: FY 2012; new start; Affordable Care Act)

### **HRSA Oversight of High Risk Grantees (New)**

We will examine HRSA processes for designating and monitoring high-risk grantees. We will determine the extent to which HRSA designates Bureau of Primary Health Care (BPHC) grantees as high risk, whether BPHC includes special conditions and restrictions in high-risk grantees' contracts, and the extent to which HRSA high-risk grantees comply with the special conditions and restrictions in their contracts. The Increased funding that BPHC receives through the Recovery Act and the Affordable Care Act increases vulnerabilities in BPHC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal regulations, HHS operating divisions are allowed to include special conditions and restrictions in the contracts of grantees designated as high risk if the grantees meet certain criteria, e.g., a history of poor performance or financial instability. (42 CFR § 74.14 and 45 CFR § 92.12.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

## **Indian Health Service**

### **IHS Medicaid Reimbursements**

We will review IHS's expenditure of Medicaid reimbursements. Federal law allows IHS and tribal facilities to bill State Medicaid programs for services provided to Indian beneficiaries enrolled in Medicaid. (Social Security Act, § 1911.) Tribal facilities bill for services using OMB encounter rates, which are set payment amounts for inpatient and outpatient services (visitations). Unlike the Medicaid program, whereby the States provide some of the funds for Medicaid services, the Federal Government reimburses 100 percent of the services provided to Indian beneficiaries who are

enrolled in Medicaid. (Social Security Act, § 1905(b).) States may lack incentive to require accountability for expenditures of Medicaid reimbursements that, according to law, must be used exclusively to make improvements in IHS and tribal health care facilities. (OAS; W-00-12-55065; expected issue date: FY 2012; new start)

### **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, which requires that all IHS employees and contractors who have regular contact with, or control over, Indian children be investigated for any history of certain criminal acts. We will determine whether IHS and tribal organizations have completed required background investigations. Previous OIG work found inconsistent practices in staff background investigations. (OAS; W-00-12-50020; various reviews; expected issue date: FY 2012; new start)

## **National Institutes of Health**

### **Superfund Financial Activities for Fiscal Year 2010**

We will review payments, obligations, reimbursements, and other uses of Superfund amounts by NIH's National Institute of Environmental Health Sciences. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities. (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, codified at 42 U.S.C. § 9611(k).)

(OAS; W-00-12-56030; expected issue date: FY 2012; new start)

### **Colleges' and Universities' Compliance With Cost Principles**

We will assess colleges' and universities' compliance with selected cost principles issued by OMB Circular A-21, *Cost Principles for Educational Institutions*. We will conduct reviews at selected schools on the basis of the dollar value of Federal grants received and on input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration. (OAS; W-00-11-50037; various reviews; expected issue date: FY 2012; work in progress)

### **Review of Extra Service Compensation Payments Made by Educational Institutions**

We will determine whether payments for extra compensation charged to federally sponsored grants, contracts, and cooperative agreements by educational institutions complied with Federal regulations. We will determine whether extra compensation payments were properly calculated and approved by the sponsoring agency. Recent OIG work has identified problems with extra compensation payments charged to federally sponsored agreements at several colleges and universities. Pursuant to OMB requirements, charges for work performed on sponsored agreements by an individual faculty member will be based on the faculty member's regular compensation. (OMB Circular A-21, *Cost Principles for Education Institutions*, Att., § J.8.d(1).) Any charges for work representing "extra compensation" above the faculty member's base salary are allowable provided that arrangements are specifically provided for in the agreement or are approved in writing by the sponsoring agency. (OAS; W-00-12-50040; expected issue date: FY 2012; new start)

### **Recharge Centers at Colleges and Universities**

We will determine whether specialized service facilities (called recharge centers) at colleges and universities have rate schedules that ensure that amounts charged are reasonable and consistent and comply with the standards for such facilities. We will also determine the necessity for and reasonableness of the recharge centers' expenses. Recent OIG work identified problems in this area. Recharge centers at universities operate as in-house enterprises and are used to finance, account for, and report on the provision of goods and services to other university operating units. Standards for specialized service facilities are found in OMB Circular A-21, *Cost Principles for Educational Institutions*, Att., § J.44. (OAS; W-00-11-50041; expected issue date: FY 2012; work in progress)

### **Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (New)**

We will determine the extent to which NIH grantees conducting genetic research comply with regulations and guidance on informed consent procedures. We will also assess the informed consent and privacy protection procedures used by these grantees and determine the extent to which they ensure that human subjects' private information stored in biobanks is protected in future research. Regulations at 45 CFR part 46 address human subject protections, including informed consent, for HHS-funded research. The growth of genetic research involving human subjects has raised many ethical questions surrounding privacy, confidentiality, and unintended harms. Regulations at 45 CFR part 160 and 45 CFR part 164, subparts A and E, address privacy protections. (OEI; 01-11-00520; expected issue date: FY 2012; work in progress)

### **Use of Data and Safety Monitoring Boards in Clinical Trials**

We will determine the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. 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. A DSMB is made up of individuals who have pertinent expertise and who regularly review accumulated data from one or more clinical trials to ensure the safety of participants and the validity and integrity of the scientific data generated. A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial. NIH requires that all NIH-funded clinical trials establish data- and safety-monitoring plans. (NIH's "Policy for Data and Safety Monitoring," June 1998.) This requirement sets minimum responsibilities that sponsoring Institutes and centers must meet to ensure and oversee data and safety monitoring. (OEI; 12-11-00070; expected issue date: FY 2013; work in progress)

### **NIH Oversight of Grants Management Policy Implementation**

We will examine the NIH Office of Extramural Research's (OER) oversight of the grants administration processes implemented by the 24 Institutes and Centers (IC) that award extramural grants. We will also examine OER's oversight of each IC's compliance with regulations, department directives, and agency policies. NIH is the largest Federal funder of health research and development, having awarded \$22.2 billion in FY 2010 for extramural research awards. Regulations at 45 CFR Parts 74 and 92 establish uniform administrative requirements governing HHS grants. The HHS Grants Policy Directives and the NIH Grants Policy Statement provide guidance on implementing these regulations. OER issues grants administration policy to the ICs and has oversight responsibility for ICs' compliance with both Federal regulations and departmental guidance. Each IC maintains a Grants Administration Office that is responsible for implementing its own procedures. (OEI; 07-11-00190; expected issue date: FY 2012; work in progress)

### **National Center for Research Resources' Oversight of 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. We will also examine NCRR's monitoring of programmatic involvement with CTSA, particularly awardee-generated goals and milestones. 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. The CTSA program began in 2006 to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at 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 regulations at 45 CFR pt. 74. (OEI; 07-09-00300; expected issue date: FY 2012; work in progress)

### **Inappropriate Salary Draws From Multiple Universities (New)**

We will determine whether faculty members working on NIH grants were inappropriately drawing salaries from multiple universities. A recent indictment alleged that two professors were inappropriately drawing salaries from two universities. Extensive and swift funding under the Recovery Act may have provided an opportunity for similar actions by other researchers. The Recovery Act provided \$10.4 billion in new funding for NIH. (OAS; W-00-12-58206; expected issue date: FY 2012; new start)

### **Cost Sharing Claimed by Universities (New)**

We will determine how universities are meeting cost-sharing requirements. During a recent audit, we noted that to meet cost-sharing requirements, a university waived its claim for Facilities and Administrative (F&A) costs. The university then relied on a Cost Accounting Standards (CAS) exemption to directly claim costs that are normally treated as F&A costs. A CAS exemption allows, in exceptional circumstances, normally indirect costs, such as clerical salaries, postage, memberships, subscriptions, telephone charges, and office supplies, to be charged as direct costs. However, by waiving F&A costs to meet cost-sharing requirements and claiming the costs directly, the university is not complying with the intent of cost sharing. Indirect costs may be claimed in matching or cost-sharing instances only with the prior approval of the Federal awarding agency. (OMB Circular A-110, *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Non-Profit Organizations*, subpart C, section .23(b).) (OAS; W-00-12-58207; expected issue date: FY 2012; new start)

### **Awardee Eligibility for Small Business Innovation Research Awards (New)**

We will determine the extent to which HHS improperly funds ineligible Small Business Innovation Research (SBIR) awardees. We will also determine the extent to which HHS uses a required Governmentwide database and other management controls to prevent the funding of ineligible awardees. Within HHS, NIH manages SBIR applications for awards from NIH, CDC, FDA, and the Administration for Children and Families. The SBIR Program, created by the Small Business Innovation Development Act of 1982, is a highly competitive, three-phase award system providing qualified small businesses with opportunities to propose innovative ideas that meet the specific research and development needs of the Federal Government. Eligible awardees must meet the definition of a small business and not already receive Federal funding for the proposed research.

The Small Business Innovation Research Program Reauthorization Act of 2000 required creation of a Governmentwide database to assist with monitoring of SBIR awards across Departments. (OEI; 04-11-00530; expected issue date: FY 2013; work in progress)

## Substance Abuse and Mental Health Services Administration

### **Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program**

We will review SAMHSA's progress in identifying performance goals for the Substance Abuse Treatment Block Grant program. We will also assess the extent to which States are reporting and meeting performance goals for this program. The program's goal is to improve access, reduce barriers, and promote effective treatment and recovery services for people who have alcohol and drug abuse problems. Federal law requires Federal agencies to develop long-term strategic plans defining goals and objectives for their programs. (Government Performance and Results Act of 1993 (GPRA).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

### **SAMHSA Oversight of Grantees**

We will determine the extent to which SAMHSA maintains grant files in accordance with Federal regulations. We will also identify characteristics of SAMSHA's interactions (e.g., frequency and types of communication) with grantees. A number of regulations and policies govern how HHS administers grants. Federal regulations, departmental directives, and agency policies govern the administration of discretionary grants at SAMHSA. (45 CFR pts. 74 and 92.) (OEI; 07-10-00220; expected issue date: FY 2012; work in progress)

### **SAMHSA Grantees' Use of Funds From the Prevention and Public Health Fund (New)**

We will review grantees' use of Prevention and Public Health Fund awards to determine whether the funds were properly used for the purposes outlined in Federal award letters, program requirements, and Affordable Care Act regulations. The Affordable Care Act, § 4002, authorized funds for the Prevention and Public Health Fund. From these funds, SAMHSA awarded, in FY 2010, \$20.9 million to help 43 community behavioral health agencies integrate primary care into their services. Up to \$500,000 per year will be available for 4 years to each grantee, depending on the availability of funds, need, and the progress achieved by the grantee. Pursuant to 45 CFR §§ 74.21(b)(3) and 92.20(b)(3), grantees receiving Affordable Care Act funds must ensure that the funds are used for authorized purposes. (OAS; W-00-11-59005; W-00-12-59005; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

## Cross-Cutting and Other Public-Health-Related Reviews

### **Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation**

We will review States' use of Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. We will determine whether States have inappropriately used program funding to compensate State employees. This review cross-cuts the

bioterrorism program funding and oversight of CDC and ASPR. The program provides funding to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. (PHS Act, §§ 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2.) States may not use Federal funds to compensate State employees for non-Federal services that States have provided in the immediately prior years. (OAS; W-00-12-57228; various reviews; expected issue date: FY 2012; new start)

### **HHS' Federal Response Capabilities for Public Health and Medical Services Emergency Support (New)**

We will determine the extent to which HHS has participated in preparedness activities to fulfill its public health and medical services emergency support responsibilities. The National Response Framework's (NRF) Emergency Support Functions (ESF) establishes a comprehensive approach that can be adapted for a variety of disasters and emergencies (i.e., incidents). NRF is used by the Federal Government to coordinate designated agencies' response efforts when an incident occurs. Fifteen ESFs are outlined in the NRF, and agencies are assigned to fulfill responsibilities as the Coordinator, Primary, or Support agency for each ESF. The Secretary of HHS, through ASPR, coordinates HHS's Federal response for ESF #8, public health and medical services. (OEI; 04-11-00260; expected issue date: FY 2012; work in progress)

### **Pandemic Influenza Planning**

We will review HHS's implementation of high-risk areas of its pandemic influenza plan. We will also determine the extent to which States are reporting and meeting performance goals and determine how CDC's Division of Strategic National Stockpile provides countermeasures to the States. We will review areas pertaining to appropriate supplies of prepandemic vaccines, postpandemic vaccines, and antivirals and vaccine and antiviral distribution. HHS's pandemic-related activities are coordinated by CDC and ASPR. HHS's pandemic influenza plan is the blueprint for responding to the next pandemic, which has the potential to overwhelm current public health and medical care capabilities. In the 2009-H1N1 pandemic, during which 11 million doses of antivirals were released, many doses of antivirals remained unused because they were released without regard to the sufficiency of existing State stockpiles. (OAS; W-00-12-57229; expected issue date: FY 2012; new start)

## **Public Health Legal Activities**

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

## **Public Health Investigations**

### **Violations of Select Agent Requirements**

We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of the Bioterrorism Act, which governs the registration, storage, and transfer of select agents and toxins. Federal regulations authorize OIG to

conduct investigations and impose civil monetary penalties against individuals or entities for violations of select agent requirements. (42 CFR pt. 73.) The regulations apply to the possession, use, and transfer of select (biological) agents and toxins by academic institutions and biomedical centers; commercial manufacturing facilities; and Federal, State, and local laboratories.

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The [Work Plan](#) is one of OIG's three core publications. OIG's [Semiannual Report to Congress](#) summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations that when implemented will save tax dollars and improve programs.



Part VI:  
Human Services Reviews

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## ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN PART VI:

ACF—ADMINISTRATION FOR CHILDREN AND FAMILIES  
 AoA—ADMINISTRATION ON AGING  
 CCDF—CHILD CARE AND DEVELOPMENT FUND

CSE—CHILD SUPPORT ENFORCEMENT  
 FFP—FEDERAL FINANCIAL PARTICIPATION  
 TANF—TEMPORARY ASSISTANCE FOR NEEDY FAMILIES [PROGRAM]

## Human Services Agencies

The principal Department of Health and Human Services (HHS) agencies that administer human services programs are the:

- Administration on Aging (AoA), 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
- 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.

Descriptions of the Office of Inspector General's (OIG) human services work in progress and planned new starts for fiscal year (FY) 2012 follow.

## Administration on Aging

### Performance Data for the Senior Medicare Patrol Projects

We will review Medicare and Medicaid monetary recoveries attributable to the Senior Medicare Patrol projects, including documentation supporting amounts recovered for the Medicare and Medicaid programs, beneficiaries, and providers. This information will support AoA's efforts to evaluate and improve the performance of the projects. In 1997, AoA established demonstration projects that recruit retired professionals to serve as educators and counselors to help beneficiaries detect fraud, waste, and abuse in the Medicare and Medicaid programs. The initiative stemmed from recommendations in a congressional committee report accompanying the Omnibus Consolidated Appropriations Act of 1997.

*(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

### **State Long-Term-Care Ombudsman Programs: Efforts To Identify, Investigate, and Resolve Elder Abuse Cases (New)**

We will determine whether Ombudsmen follow statutory requirements to identify, investigate, and resolve elder abuse cases. (42 U.S.C. § 3058g(a)(3)(A).) We will also assess AoA's oversight of the ombudsman programs. Ombudsman responsibilities include identifying, investigating, and resolving cases made by or on behalf of residents in long-term-care facilities, including cases involving elder abuse. (42 U.S.C. § 3058g(a)(3)(A).) AoA's data on elder abuse show significant variation between State Long-Term-Care Ombudsman programs. AoA administers the State Long-Term-Care Ombudsman programs pursuant to 42 U.S.C. § 3058g, as set forth by the Older Americans Act Amendments of 2000, § 704. (OEI; 00-00-00000; expected issue date: FY 2012; new start)

## **Administration for Children and Families**

### **Oversight of System Design of Statewide Automated Child Welfare Information Systems**

We will review ACF's oversight of and guidance and assistance to States directed to ensuring that States' new Statewide Automated Child Welfare Information System initiatives are appropriately focused and successfully implemented with risks minimized. We will determine whether the costs claimed by States for the systems are allowable. Federal regulations require that ACF continually review, assess, and inspect the planning, design, and operation of the systems to determine how such systems meet the requirements imposed by law, regulations, and guidelines. (45 CFR § 95.621.) States may receive 50-percent Federal Financial Participation (FFP) for the costs of planning, design, development, and installation of a statewide child welfare information system. (45 CFR § 1355.52.) (OAS; W-00-12-25040; expected issue date: FY 2012; new start)

### **Adoption Assistance Subsidies**

We will review States' claims for Federal reimbursement of adoption assistance subsidies to determine compliance with eligibility requirements. A previous OIG review of one State's adoption assistance subsidies found payments to families that did not meet eligibility requirements. Adoption assistance eligibility requirements were established by the Social Security Act, §§ 473(a) and 473(c). 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. (OAS; W-00-11-24009; expected issued date: FY 2012; work in progress and new start)

### **Foster Care and Adoption Assistance Training Costs and Administrative Costs**

We will review foster care and adoption assistance training costs and other administrative costs claimed under Title IV-E of the Social Security Act to determine whether current and retroactive claims were allowable and reasonable and were supported in accordance with laws and regulations and States' cost allocation plans. Title IV-E training costs 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. Federal reimbursement of training and administrative costs, respectively, are provided by the Social Security Act, §§ 474(a)(3)(A) – (B) and 474(a)(3)(E). (OAS; W-00-11-24100; various reviews; expected issue date: FY 2012; work in progress and new start)

**Foster Care: Training Costs Charged by One County Probation Department**

We will review one State's county probation department's claims for Title IV-E training costs charged to the Foster Care Program. Federal regulations provide that FFP is available at the enhanced rate of 75 percent for the costs of training personnel employed or preparing for employment by the State or local agency administering the State's foster care training plan and providing short-term training to current or prospective foster or adoptive parents, as well as personnel of childcare institutions. (45 CFR § 1356.60(b)(1).) (OAS; W-00-12-24121; expected issue date: FY 2012; new start)

**Foster Care: Administrative Costs Charged by One County Probation Department**

We will review one State's county probation department's claims for Title IV-E administrative costs charged to the Foster Care program. A prior OIG review disclosed instances in which a county probation department charged administrative costs to the Foster Care program for activities that were not listed in the Federal regulation or closely related to those listed in Federal regulations. Federal regulations list the costs that are necessary for the administration of the Foster Care program, and therefore allowable. (45CFR § 1356.60(c)(2).) (OAS; W-00-12-24120; expected issue date: FY 2012; new start)

**Foster Care: Per Diem Rates**

We will determine whether State agencies claimed foster care maintenance payments and administrative costs under Title IV-E of the Social Security Act in accordance with Federal requirements. A prior OIG review found that some services included in per diem rates were not eligible for Title IV-E foster care maintenance payments. Federal law 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. (Social Security Act, § 475(4)(A).) (OAS; W-00-12-24101; expected issue date: FY 2012; new start)

**Foster Care: 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 to determine whether the rates were accurate. Federal regulations provide that FFP 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. (45 CFR §§ 1356.60(a)(1)(i) and 1356.71(d)(2).) The auditee State requires 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. (OAS; W-00-12-24111; expected issue date: FY 2012; new start)

**Foster Care: Claims for the Placement of Delinquent Children**

We will determine whether foster care maintenance costs claimed by several States pursuant to Title IV-E of the Social Security Act for the placement of delinquent children complied with Federal requirements. A prior OIG review found that claims were submitted for ineligible children, some services were not provided, and some services were ineligible. Maintenance costs include room and board payments to licensed foster parents, group homes, and residential childcare facilities for children who meet Title IV-E program requirements. (Social Security Act, § 475(4)(A).) (OAS; W-00-12-25023; various reviews; expected issue date: FY 2012; work in progress and new start)

**Foster Care: Preplacement Candidacy Costs**

We will determine whether State claims for foster care candidate costs in several States were properly claimed. Federal law allows States to claim administrative costs for allowable preplacement activities on behalf of foster care candidates. (Social Security Act, § 472(i)(2).) Federal regulations state that administrative costs cover staff members' activities, such as case management and supervision of children placed in foster care and children considered to be candidates pursuant to Title IV-E of the Social Security Act. (45 CFR § 1356.60(c)(2).) A candidate for foster care is a child who must be documented, through one of three allowable methods, as being at imminent risk of placement in foster care.

*(OAS; W-00-12-24112; expected issue date: FY 2012; new start)*

**Foster Care: Children Over 19 Years Old**

We will determine whether foster care maintenance payments were made on behalf of children age 19 and over. Children age 19 and over are ineligible for such payments. Federal law limits Title IV-E eligibility to children under age 18 or over age 18 but under age 19 if they are full-time students (Title IV-A State plan option). (Social Security Act, § 472.) The Adoption and Foster Care Analysis and Reporting System database, maintained by ACF, listed more than 9,900 of 513,000 children who were 19 years old or over as of September 30, 2005.

*(OAS; W-00-12-24113; various reviews; expected issue date: FY 2012; new start)*

**Foster Care: Program 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. 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. Federal regulations 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. (45 CFR 302.52.) To facilitate offsets, Foster Care program agencies are required to report identifying information for children in foster care to States' CSE agencies. *(OAS; W-00-12-25041; expected issue date: FY 2012; new start)*

**Foster Care: Monitoring the Health and Safety of Foster Children**

We will review case files of foster children in one State to determine whether county social workers are monitoring foster care placements to ensure the health and safety of children. A State must have a plan approved by the Secretary that provides for development of a case plan for each child receiving foster care maintenance payments and provides for a case review system. (Social Security Act, § 471(a)(16).) Federal law defines "case review system" as a procedure for ensuring that the status of each child is reviewed periodically, but no less frequently than once every 6 months, by a court or by administrative review. (Social Security Act, § 475(5)(B).)

*(OAS; W-00-12-24122; expected issue date: FY 2012; new start)*

**Child Care and Development Fund: Integrity of Child Care Payments (New)**

For the Child Care and Development Fund (CCDF), we will determine what controls States have to identify and prevent fraudulent claims for federally subsidized childcare payments. We will also determine, for a sample of childcare reimbursement claims, the number and dollar amount of claims having characteristics indicative of fraud. CCDF is authorized by the Child Care and Development Block Grant Act and section 418 of the Social Security Act. Grantees (States, territories, and tribes) must use the funds they receive under CCDF to pay for childcare services provided to eligible

children. (42 U.S.C. § 9858c(c)(3).) CCDF may be vulnerable to submission of claims for children not under care or for more hours of care than were provided.  
(OEI; 00-00-00000; expected issue date: FY 2012; new start)

### **Child Care and Development Fund: Monitoring of Licensing and Health and Safety Requirements for Childcare Providers**

We will describe childcare-licensing and health and safety requirements for each State, States' monitoring of providers' compliance in each State, and ACF's monitoring of licensing and health and safety requirements for each State. Additionally, we will review outcomes in selected States in more detail (i.e., deficiencies, complaints, and safety issues). A previous OIG review of one Head Start grantee that also provided CCDF daycare services found several instances in which childcare facilities did not comply with the health and safety requirements. Federal Head Start performance standards require that Head Start facilities comply with State and local childcare-licensing requirements. (45 CFR pt. 1304 and pt. 1306.) 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 regulations at 45 CFR § 1304.53(a). Federal regulations for the CCDF require States to certify that they have licensing and health and safety requirements applicable to childcare services pursuant to 45 CFR §§ 98.40 and 98.41. (45 CFR § 98.15(b)(4)-(6).)  
(OEI; 07-10-00230; expected issue date: FY 2012; work in progress)

### **Head Start and Child Care and Development Fund: Licensing Standards and Health and Safety Monitoring at Federally Funded Facilities**

We will review licensing, health, and safety standards at selected childcare facilities that received Federal Head Start funding and/or Federal funding from the CCDF. We will determine the extent to which Head Start grantees and States have demonstrated that the childcare facilities have complied with requirements. We will also assess ACF's oversight of States' licensing, health, and safety requirements for CCDF-funded childcare facilities. A previous OIG review of one Head Start grantee that also provided CCDF daycare services found several instances in which childcare facilities did not comply with the health and safety requirements. Federal Head Start performance standards require that Head Start facilities comply with State and local childcare licensing requirements. (45 CFR pt. 1304 and pt. 1306.) 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 regulations at 45 CFR § 1304.53(a). Federal regulations for the CCDF require States to certify that they have licensing and health and safety requirements applicable to childcare services pursuant to 45 CFR §§ 98.40 and 98.41. (45 CFR § 98.15(b)(4)-(6).)  
(OAS; W-00-12-22005; various reviews; expected issue date: FY 2012; new start)

### **Head Start: Oversight of Eligibility and Enrollment (New)**

We will assess ACF oversight of income eligibility to enroll in the Head Start program and determine the extent to which ACF has implemented recent changes intended to improve oversight. In May 2010, a Government Accountability Office (GAO) investigation revealed that grantees inappropriately enrolled families who did not meet eligibility requirements. In response, the Office of Head Start committed to a variety of changes intended to improve oversight, such as performing unannounced monitoring visits and developing a fraud hotline. (GAO-10-733T, p. 14 (May 18, 2010).) Federal regulations contain requirements and procedures for eligibility determination, recruitment, selection, enrollment, and attendance of children in Head Start programs. (45 CFR § 1305.)  
(OEI; 05-11-00140; expected issue date: FY 2012; work in progress)

**TANF Recipient Social Security Numbers**

We will determine whether a State agency's TANF records contain valid Social Security numbers and whether the State agency verified the numbers with the Social Security Administration. A Federal regulation requires that applicants and recipients of certain programs, including TANF, provide their Social Security numbers to State agencies as a condition of eligibility for the program and that State agencies submit the numbers to the Social Security Administration for verification. (45 CFR § 205.52.) (OAS; W-00-12-25050; expected issue date: FY 2012; new start)

**TANF: Use of Smart Card Technology To Reduce Payment Errors**

We will determine the extent which whether States have adopted or are contemplating adoption of Smart Card technology in their TANF programs. We will survey a number of States to quantify the impact of using the technology. Smart cards can validate the identity of TANF recipients and ensure that payments are allowed only for authorized items. This technology could greatly reduce fraud and abuse in the TANF program. (OAS; W-00-12-25051; expected issue date: FY 2012; new start)

**TANF: ACF Oversight of Work Participation and Verification Requirements**

We will review ACF oversight of States' compliance with requirements for verifying TANF program work participation. We will also assess ACF oversight of tribes' compliance with Tribal Family Assistance Plan requirements under TANF. TANF provides assistance and work opportunities to needy families by granting States Federal funds and wide flexibility to develop and implement their own welfare programs. Regulations implementing the TANF program include, among other things, the requirement that States ensure that 50 percent of all families and 90 percent of two-parent families are working and that States report and verify work activities. (45 CFR pts. 261-265.) (OEI; 09-11-00490; 09-11-00491; expected issue date: FY 2012; work in progress)

**Refugee Resettlement: Services for Recently Arrived Refugees**

We will determine whether grantees have met the terms and conditions of grants and contracts. Federal law allows the Director of Refugee Resettlement to make grants to and enter into contracts with public or private nonprofit agencies for projects 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. (The Refugee Act of 1980, § 412(c).) (OAS; W-00-12-25042; expected issue date: FY 2012; new start)

**Community Action Agencies: Pension Costs Claimed on HHS-Funded Programs (New)**

We will determine whether costs for retirement benefits for Community Action Agency employees have been appropriately charged to ACF-sponsored grants. We will also determine whether retirement benefit costs claimed are reasonable and allowable and comply with Federal requirements. Retirement benefits are allowable under Federal cost principles provided that the costs are incurred in accordance with the organization's policies and such policies meet the test of reasonableness, the methods of cost allocation are not discriminatory and are in accordance with generally accepted accounting principles and the American Institute of Certified Public Accountants' Accounting Principles Board Opinion No. 8, and costs assigned to a given fiscal year are funded for all plan participants within 6 months after the end of that year. (2 CFR § 225 (applicable to State and local governments) and 2 CFR § 230 (applicable to nonprofit organizations).) (OAS; W-00-12-28020; expected issue date: FY 2012; new start)

**Low-Income Home Energy Assistance Program: Duplicate Payments (New)**

We will examine the extent to which Low-Income Home Energy Assistance Program (LIHEAP) grantees made duplicate payments or payments that exceed benefit thresholds. We will also review ACF's oversight of LIHEAP grantees. LIHEAP provides States, territories, and tribal organizations with funding to assist low-income households in meeting their immediate home energy needs. On September 30, 2008, Federal law appropriated \$5.1 billion to LIHEAP. (The Consolidated Appropriations Act for FY 2009, § 155, appropriated the amount under the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009.) Program requirements codified in the statute include the purpose of LIHEAP funds, eligibility criteria, and annual application requirements. (42 U.S.C. §§ 8621 et seq.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

**Child Support: Increasing Collections**

We will review States' procedures for collecting child support 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 legislation to identify earnings and collect child-support from self-employed individuals whose families are receiving TANF. A prior review in one State disclosed that the State increased child support collections by more than \$1 million as a result of enacting legislation to identify earnings from self-employed noncustodial parents. (OAS; W-00-12-20032; expected issue date: FY 2012; new start)

**Child Support: Investigations Under the Child-Support Enforcement Task Force Model**

Project Save Our Children seeks to identify, investigate, and prosecute individuals who fail to meet their court-ordered support obligations. We plan to continue to encourage and coordinate, in FY 2012, enforcement efforts in States, particularly in States that have not pursued prosecutions of nonsupport cases. The project brings together OIG, the U.S. Marshals Service, the Departments of Justice and State, local law enforcement agencies and prosecutors, State child-support agencies, and others to enforce Federal and State criminal child-support statutes.

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The [Work Plan](#) is one of OIG's three core publications. OIG's [Semiannual Report to Congress](#) summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations that when implemented will save tax dollars and improve programs.



Part VII:  
Other HHS-Related Reviews

## Part VII: Other HHS-Related Reviews

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN PART VII:

ACF—ADMINISTRATION FOR CHILDREN AND FAMILIES

AICPA—AMERICAN INSTITUTE OF CERTIFIED PUBLIC ACCOUNTANTS

AIDS—ACQUIRED IMMUNODEFICIENCY SYNDROME

CMS—CENTERS FOR MEDICARE &amp; MEDICAID SERVICES

FAR—FEDERAL ACQUISITION REGULATION

FISMA—FEDERAL INFORMATION SECURITY MANAGEMENT ACT  
OF 2002

OMB—OFFICE OF MANAGEMENT AND BUDGET

PEPFAR—PRESIDENT’S EMERGENCY PLAN FOR AIDS RELIEF

## Cross-Cutting and Mandatory Work

Certain financial, performance, and investigative issues cut across Department of Health & Human Services (HHS) programs. The Office of Inspector General’s (OIG) work in progress and its planned work address departmentwide matters, such as financial statement audits; financial accounting; information systems management; and other departmental issues, including discounted airfares and protections for people in residential settings who have disabilities.

Although we have discretion in allocating most of our non-Medicare and non-Medicaid resources, a portion is used for mandatory reviews, including financial statement audits conducted pursuant to the Government Management Reform Act of 1994 (GMRA), § 405(b); the Chief Financial Officers Act of 1990 (CFO Act); and information systems reviews required by the Federal Information Security Management Act of 2002 (FISMA).

The GMRA seeks to ensure that Federal managers have the financial information and flexibility necessary to make sound policy decisions and manage scarce resources. The GMRA broadened the CFO Act by requiring annual audited financial statements for all accounts and associated activities of HHS and other Federal agencies and components of Federal agencies, including the Centers for Medicare & Medicaid Services (CMS).

Summaries of OIG’s reviews of departmentwide matters in fiscal year (FY) 2012 follow.

## Financial Statement Audits

### **Audits of Fiscal Years 2011 and 2012 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 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 2011 financial statements are due to the Office of Management and Budget (OMB) by November 15, 2011; for FY 2012, they are due by November 15, 2012.

The following FY 2011 financial statement audits will be completed and reports will be issued during FY 2012:

- Consolidated HHS – This audit covers all operating divisions, including CMS, which will also receive a separate audit report (listed below). (OAS; W-00-11-40009; A-17-11-00001)
- CMS – (OAS; W-00-11-40008; A-17-11-02010)

The following FY 2012 financial statement audits will be completed and reports will be issued during FY 2013:

- Consolidated HHS – This audit will cover all operating divisions, including those that will also receive separate audit reports (listed below). (OAS; W-00-12-40009; A-17-12-00001)
- CMS – (OAS; W-00-12-40008; A-17-12-02010)

### **Fiscal Year 2012 Statement on Standards for Attestation Engagements**

We will review an independent auditor's workpapers to determine whether examinations of HHS's service organizations were conducted in accordance with laws and regulations. Such examinations are conducted in accordance with Generally Accepted Government Auditing Standards and the American Institute of Certified Public Accountants' (AICPA) *Statement on Standards for Attestation Engagements (SAE) No. 16, Reporting on Controls at a Service Organization*, commonly referred to as SAE 16 examinations. SAE 16 examinations report on the controls of service organizations that may be relevant to the user organizations' internal control structures. The following SAE 16 examinations of HHS service organizations will support FY 2012 financial statement audits and will be issued during FY 2012:

- Center for Information Technology (National Institutes of Health Computer Center) (OAS; W-00-12-40012; A-17-12-00010)
- Division of Payment Management (OAS; W-00-12-40012; A-17-12-00009)

### **Fiscal Years 2011 and 2012 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*, §§ 6.11 and 13.

The FY 2011 financial-related reviews that will be issued during FY 2012 are:

- 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-00-11-40009; A-17-11-00006)
- Department of State Agreed Upon Procedures. These procedures focus on reviewing certain financial information for allocation transfers from the Department of State to HHS under the President's Emergency Plan for AIDS Relief (PEPFAR) program. OMB requires auditors to work together to ensure that allocation transfers receive audit coverage that, in the transferring

agency auditor's professional judgment, is required as part of the annual financial statement audit. (OMB Bulletin 07-04, paragraph 6.05.) The procedures are performed in accordance with the AICPA's attestation standards. (OAS; W-00-11-40009; A-17-11-00015)

The FY 2012 financial-related reviews that will be issued in FY 2012 is:

- Payroll Agreed-Upon Procedures. These procedures focus on reviewing the official personnel files for selected HHS employees to assist the Department of Defense OIG in performing the OMB Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, Section 11, Agreed-Upon Procedures. (OAS; W-00-12-40009; A-17-12-00008)

The FY 2012 financial-related reviews that will be issued during FY 2013 are:

- Department of State Agreed Upon Procedures. These procedures focus on reviewing certain financial information for allocation transfers from the Department of State to HHS under the PEPFAR program. OMB requires auditors to work together to ensure that allocation transfers receive audit coverage that, in the transferring agency auditor's professional judgment, is required as part of the annual financial statement audit. (OMB Bulletin 07-04, paragraph 6.05.) The procedures are performed in accordance with the AICPA's attestation standards. (OAS; W-00-12-40009; A-17-12-00015)
- 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-00-12-40009; A-17-12-00006)

## Other Financial Accounting Reviews

### **The President's Emergency Plan for AIDS Relief Funds**

We will review the effectiveness of HHS's accounting for and control of funds received under the PEPFAR program. HHS received PEPFAR funds from the annual HHS appropriation and the Foreign Operations appropriation. PEPFAR funds support international programs for acquired immunodeficiency syndrome (AIDS) prevention, treatment, and care. (OAS; W-00-10-52300; W-00-11-52300; expected issue date: FY 2012; work in progress and new start)

### **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. We will determine whether State agency costs have been allocated correctly among various Federal programs and whether claims submitted by the State and based on the cost allocation plan were supported and claimed in accordance with Federal criteria pertinent to the State agency. The Administration for Children and Families (ACF) has informed us that the State's plan may be unsupportable and that the State has been required to revise it. Federal regulations 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*. (45 CFR pt. 95, subpart E.) (OAS; W-00-12-52310; expected issue date: FY 2012; new start)

### **Annual Accounting of Drug Control Funds**

We will review HHS agencies' compliance with the requirement that agencies expending funds on National Drug Control Program activities submit to the Office of National Drug Control Policy an annual accounting of the expenditure of drug control funds. (21 U.S.C. § 1704.) The policy also requires that an agency submit with its annual accounting an authentication by the agency's OIG in which OIG expresses a conclusion on the reliability of the agency's assertions in its accounting. We will submit this authentication with respect to HHS's FY 2010 annual accounting. (OAS; W-00-12-52312; expected issue date: FY 2012; 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 obtains through contracts to ensure that appropriated funds were used only during the period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and were used only for a bona fide need arising in the fiscal year for which the appropriation was made. (31 U.S.C. § 1502.) We will review contracts and contract modifications issued by the Program Support Center to determine whether appropriated funds were used in accordance with the Anti-Deficiency Act. Key provisions of the Anti-Deficiency Act prohibit the Government from obligating or expending funds in advance of an appropriation unless authorized by law as required by 31 U.S.C. § 1341(a)(1). (OAS; W-00-12-52313; expected issue date: FY 2012; new start)

### **Reasonableness of Prime Contractor Fees**

We will determine whether the Government negotiated reasonable fees for prime contracts that involve significant subcontractor efforts, taking into consideration any fees the prime contractor expected to pay subcontractors. Federal acquisition laws and regulations limit the amount of the fee that can be negotiated with a contractor. (10 U.S.C. 2306(d), 41 U.S.C. 254(b), and Federal Acquisition Regulation (FAR) 15.404-4(b)(4)(i).) Subcontractor fees are typically considered "costs" to the prime contractor and may not be considered during the Government's negotiations with the prime contractor. This "fee on fee" situation may result in fees that exceed the limits established in Federal laws and regulations. (OAS; W-00-12-52321; expected issue date: FY 2012; work in progress)

### **Contracting Procedures**

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. HHS's contracting procedures are subject to the FAR and the HHS Acquisition Regulation. (OAS; W-00-12-52314; various reviews; expected issue date: FY 2012; 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*. As part of our reviews of A-133 audits, we will ensure that the auditors have audited and reported in compliance with the American Recovery and Reinvestment Act of 2009 (Recovery Act). State, local, and Indian tribal governments; colleges and universities; and nonprofit organizations receiving Federal awards are required to have annual organizationwide audits of all Federal funds that they receive. Our reviews ensure that the audits and reports meet applicable standards, identify any followup work needed, and identify issues that may require management attention. OIG also provides upfront technical assistance to non-Federal auditors to ensure that they understand Federal audit requirements and to promote effective audit

work. We analyze and record electronically the audit findings reported by non-Federal auditors for use by HHS managers. Our reviews assure HHS managers about the management of Federal programs and identify significant areas of internal control weaknesses, noncompliance with laws and regulations, and questioned costs that require formal resolution by Federal officials.

### **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, OMB establishes audit cognizance, that is, it designates which Federal agency has primary responsibility for audit of all Federal funds the entity receives. Accordingly, HHS OIG has audit cognizance over all State governments and most major research colleges and universities. Agreements are reached with other Federal audit organizations or other Federal agencies to reimburse HHS OIG as the cognizant audit organization for audits that HHS OIG performs of non-HHS funds. (OAS; W-00-12-50012; various reviews; expected issue date: FY 2012; new start)

### **Requested Audit Services**

Throughout the year, Congress, HHS, and other Federal organizations request that we perform a variety of audit services including

- 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 evaluate requests as we receive them, considering such factors as why the audit is being requested, how the results will be used, when the results are needed, and whether the work is cost beneficial.

### **Compliance With Executive Order 13520: Reducing Improper Payments**

We will review certain aspects of HHS's compliance with Executive Order 13520 on reducing improper payments. The Executive Order requires Federal agencies to reduce improper payments by intensifying efforts to eliminate payment errors, waste, fraud, and abuse in major programs administered while continuing to ensure that Federal programs serve and provide access to the intended beneficiaries. Pursuant to the Executive Order, HHS is required to provide to OIG a quarterly report of high-dollar overpayments. OIG is reviewing how the Department is compiling these reports. We will assess the data presented in the reports and provide HHS any recommendations for modifying its methodology, improper-payment reduction plans, or program access and participation plans. (OAS; W-00-11-40047; various reviews; expected issue date: FY 2011; work in progress)

## 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 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 security program requirements. (OAS; W-00-11-42000; various reviews; expected issue date: FY 2012; work in progress and new start)

### **Federal Information Security Management Act of 2002**

We will review various HHS operating divisions' compliance with FISMA. We will also follow up on the unresolved findings from prior reviews of information systems controls. FISMA and OMB Circular A-130, *Management of Federal Information Resources*, Appendix III, require that agencies and their contractors maintain programs that provide adequate security for all information collected, processed, transmitted, stored, or disseminated in general support systems and major applications. (OAS; W-00-11-42001; various reviews; expected issue date: FY 2012; work in progress and new start)

### **Information Technology Systems' General Controls**

We will review the adequacy of information technology security general controls of selected HHS systems using Departmental, OMB, and FISMA guidance and regulations. Recent legislation and OMB directives have focused on safeguards for critical systems' assets and infrastructures. (OAS; W-00-11-42002; various reviews; expected issue date: FY 2012; work in progress and new start)

### **Fraud Vulnerabilities Presented by Electronic Health Records (NEW)**

We will identify fraud and abuse vulnerabilities in electronic health records (EHR) systems as articulated in literature and by experts and determine how certified EHR systems address these vulnerabilities. The Health Information Technology for Economic and Clinical Health Act provides \$36 billion in incentives for adopting EHRs. Medicare and Medicaid EHR incentive programs require providers to use EHR systems that have been certified by a Department-authorized testing and certification body. The Office of the National Coordinator establishes the requirements and oversees the certification process. Regulations at 45 CFR part 170 provide the initial set of standards, implementation specifications, and certification criteria for EHR systems. (OEI; 01-11-00570; expected issue date FY 2012; work in progress)

## Other Departmental Issues

### **State Protections for People in Residential Settings Who have Disabilities**

We will review actions taken by CMS, ACF, the Substance Abuse and Mental Health Services Administration, and the Food and Drug Administration on OIG recommendations to work cooperatively to provide information and technical assistance to States for strengthening State protections for people in residential settings who have disabilities. Several HHS operating divisions fund programs or services that play a role in protecting people who have disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid funds, 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-00-12-58126; expected issue date: FY 2012; new start)

### **Classifications of Federal Pass-Through Funding Recipients**

We will review the appropriateness of States' classifications of recipients of Federal pass-through funds. In one State, we will determine why the State awarded funds to a university as a vendor when the State had previously treated the university as a subrecipient. State agencies determine whether they are passing through Federal funds in the form of Federal financial assistance to subgrantees or whether they are contracting with vendors. OMB provides guidance on distinguishing between subrecipients and vendors in OMB Circular A-133, subpart B, § 210. There is an advantage to the recipient of the pass-through funds if the recipient is treated as a vendor. Vendors may enter into fixed-price contracts that allow retention of unused funds, whereas subgrantees must return unspent Federal funds to the State agency. (OAS; W-00-12-58127; expected issue date: FY 2012; new start)

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# Appendix A: Affordable Care Act Reviews

## Appendix A

# Affordable Care Act Reviews

The reviews described in Appendix A address:

- New programs and initiatives created by the Affordable Care Act<sup>1</sup> that are national in scope and significantly engage the Department of Health and Human Services (HHS).
- Existing HHS programs and operations (Medicare, Medicaid, and public health) that relate directly or indirectly to Affordable Care Act provisions.

## New Programs and Initiatives Created by the Affordable Care Act

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CCIO— CENTER FOR CONSUMER INFORMATION AND INSURANCE  
OVERSIGHT  
CLASS— COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS  
[PROGRAM]

CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES  
ERRP— EARLY RETIREE REINSURANCE PROGRAM  
EXCHANGES—AFFORDABLE INSURANCE EXCHANGES  
PCIP—PRE-EXISTING CONDITION INSURANCE PLANS

The Affordable Care Act created new programs and initiatives and expanded and modified a number of existing HHS programs. The Secretary of HHS is responsible for many of the new programs in the Affordable Care Act. HHS programs created by the Affordable Care Act for which the Office of Inspector General (OIG) has work in progress or plans to start reviews in fiscal year (FY) 2012 are:

- Pre-existing Condition Insurance Plans (PCIP), § 1101
- Early Retiree Reinsurance Program (ERRP), § 1102
- Health Insurance Web Portal, § 1103
- Affordable Insurance Exchanges, § 1311
- National Background Check program, § 6201
- Community Living Assistance Services and Supports (CLASS) program, § 8002

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<sup>1</sup> Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act).

## Pre-Existing Condition Insurance Plans, § 1101

**WHY WAS THE PROGRAM CREATED?** The PCIP program was created to provide a temporary high-risk health insurance pool program for eligible individuals with pre-existing conditions. PCIPs will operate until 2014, when individuals and small businesses will be able to purchase private health insurance through insurance exchanges called Affordable Insurance Exchanges (Exchanges). Insurance plans offered under the Exchanges may not discriminate on the basis of a pre-existing condition.

**WHAT DOES THE PROGRAM DO?** The law appropriates \$5 billion of Federal funds to support PCIPs that offer comprehensive insurance coverage to individuals with pre-existing conditions. A State may choose to operate its own PCIP or to be covered under the Federal PCIP.

**WHO IS RESPONSIBLE?** The Center for Consumer Information and Insurance Oversight (CCIIO), part of the Centers for Medicare & Medicaid Services (CMS), is responsible for administering the PCIP program. HHS, through arrangements with the Office of Personnel Management and the Department of Agriculture's National Finance Center, operates a Federal PCIP for those States that choose not to operate their own PCIPs.

**HOW IS THE RELATED ASSISTANCE RECEIVED AND USED?** Funding for PCIPs became available on July 1, 2010, and States applied to CCIIO for funding. To ensure the integrity of the program, each PCIP is required to develop, implement, and execute procedures to prevent, detect, and recover inappropriate payments, as well as to promptly report to HHS incidences of waste, fraud, and abuse.

The objective of our initial review of the PCIP program follows.

### **Controls Over Pre-Existing Condition Insurance Plans and Collaborative Administration**

We will review the controls HHS and States have in place to prevent and identify fraudulent health care claims for individuals covered by PCIPs. We will also examine the effectiveness of Federal agencies in working together to administer the PCIP program. (OEI; 00-00-00000; expected issue date: FY 2013; new start; Affordable Care Act)

## Early Retiree Reinsurance Program, § 1102

**WHY WAS THE PROGRAM CREATED?** The ERRP is a temporary reinsurance program to reimburse participating employment-based plans for a portion of the cost of providing health insurance to early retirees (and to certain eligible family members). The ERRP will end on January 1, 2014, when the Affordable Insurance Exchanges under § 1311 of the Affordable Care Act are implemented.

**WHAT DOES THE PROGRAM DO?** The \$5 billion ERRP will reimburse participating employment-based plans for a portion of health care costs incurred by the plans for certain early retirees that are not less than \$15,000 nor more than \$90,000.

**WHO IS RESPONSIBLE?** The program is being implemented by the CCIIO, a part of CMS.

HOW IS THE ASSISTANCE RECEIVED AND USED? Employment-based plans apply to CCIIO to participate in the ERRP. CCIIO made applications available until early May 2011. Employers may use ERRP payments to reduce premium costs for employment-based plans or to reduce premium contributions, co-payments, deductibles, co-insurance, or other out-of-pocket costs for plan participants.

The objectives for our initial ERRP-related reviews follow.

### **CCIIO's Internal Control Structure for the Early Retiree Reinsurance Program (New)**

We will determine whether CCIIO's internal controls for the ERRP provide reasonable assurance that the program is in compliance with the requirements of the Affordable Care Act.

(OAS; W-00-12-59008; expected issue dates: FYs 2012-14; new start Affordable Care Act)

### **CCIIO's Certification Procedures for Employment-Based Plans and Plan Sponsor's Use of Federal Funds**

We will determine whether CCIIO's procedures for certifying employment-based plans for participation in the ERRP and plans use of ERRP reimbursements are in compliance with the requirements of the Affordable Care Act. (OAS; W-00-12-59009; expected issue dates: FYs 2012-14; new start; Affordable Care Act)

### **CCIIO's System Security Controls Over Protected Health Information**

We will review CCIIO's system security controls over claims that employment-based plans submit for reimbursement to determine whether CCIIO's claims system contains vulnerabilities that could affect the confidentiality, integrity, and availability of the claims' protected health information.

(OAS; W-00-12-59010; expected issue dates: FYs 2012-14; new start; Affordable Care Act)

### **CCIIO's Reimbursements to Plans**

We will review CCIIO's ERRP reimbursements to participating employment-based plans to determine whether CCIIO's payments for the costs of health benefits for early retirees complied with Federal requirements. A plan receives reimbursement for 80 percent of the costs net of negotiated price concessions for health benefits within certain cost thresholds. (OAS; W-00-12-59011; expected issue dates: FYs 2012-14; new start; Affordable Care Act)

### **Employment-Based Plans' Costs for Items and Services Reimbursed**

We will determine whether the costs for items and services that employment-based plans reported on their claims for reimbursement complied with Federal requirements. Claims are to be based on the actual amount expended by the plans for the health benefits provided to early retirees and eligible spouses, surviving spouses, and dependents. (OAS; W-00-12-59012; various reviews; expected issue dates: FYs 2012-14; new start; Affordable Care Act)

### **Employment-Based Plan Sponsors' Use of Early Retiree Reinsurance Program Funds**

We will determine whether employment-based plans sponsors' use of ERRP Federal funds complied with Federal requirements. (OAS; W-00-12-59013; various reviews; expected issue dates: FYs 2012-14; new start; Affordable Care Act)

## Health Insurance Web Portal, § 1103

**WHY WAS THE PROGRAM CREATED?** The portal provides a mechanism through which residents of, and small businesses in, any State may identify affordable health insurance coverage options in that State and receive information about coverage options. The Affordable Care Act required the portal to be available not later than July 1, 2010.

**WHAT DOES THE PROGRAM DO?** The program enables individuals and consumers to access information on coverage options, including private health insurance, Medicaid coverage, State high-risk pools, and other types of insurance.

**WHO IS RESPONSIBLE?** CCIIO, a part of CMS, is responsible for operating the portal.

The objective of our initial review of the Health Insurance Web Portal follows.

### **Oversight of Private Health Insurance Submissions to the Health Insurance Web Portal**

We will assess CCIIO's oversight of the health insurance Web portal (portal). We will also review the procedures CCIIO has established to determine and protect the integrity of data submitted by private insurers for the portal and will assess private insurer compliance with reporting requirements. The portal can be found at <http://www.healthcare.gov/>. (OEI; 03-11-00560; expected issue date: FY 2012; work in progress)

## Affordable Insurance Exchanges, § 1311 and 1413

**WHY WAS THE PROGRAM CREATED?** Starting in 2014, individuals and small businesses will be able to purchase qualified health plans through State-based insurance Exchanges. The Affordable Care Act requires HHS to streamline the procedures for enrolling through an Exchange and State Medicaid, Children's Health Insurance Program (CHIP), and health insurance subsidy programs.

**WHAT WILL THE PROGRAM DO?** The streamlined eligibility procedures will ensure that an individual applying to an Exchange who is found to be eligible for enrollment under a State Medicaid program or CHIP will be enrolled under such plan or program.

**WHO IS RESPONSIBLE?** HHS's Exchange responsibilities (including funding, regulations, and other guidance to States) are being implemented by CCIIO with the assistance of the National Coordinator for Health Information Technology.

**HOW IS RELATED ASSISTANCE RECEIVED AND USED?** Although Exchanges are not required to be operational until 2014, States have applied to CCIIO for initial grants that can be used in a variety of initial planning activities, including planning the coordination of eligibility and enrollment systems across Medicaid, CHIP, and the Exchanges.

The objective for our initial review of Affordable Insurance Exchanges follows.

### **States' Readiness To Comply With Exchange and Medicaid Eligibility and Enrollment System Requirements**

We will review States' progress toward complying with new eligibility and enrollment requirements for the Exchanges, Medicaid, CHIP, and health subsidy programs. We will also identify what steps States have already taken to meet these requirements, what additional steps States plan to take, and challenges or barriers that States report regarding the implementation of eligibility and enrollment systems. We will also determine the extent to which CMS has provided guidance and technical assistance to States to meet the streamlined eligibility and enrollment requirements. (OEI; 07-10-00530; expected issue date: FY 2012; work in progress; Affordable Care Act)

## **National Background Check Program, § 6201**

**WHY WAS THE PROGRAM CREATED?** The program is designed to address continued problems of patient abuse and neglect and misappropriation of patient funds in long-term-care facilities through background checks of employees with direct access to patients.

**WHAT WILL THE PROGRAM DO?** Under the program, the Secretary is required to identify, on a nationwide basis, efficient, effective, and economical procedures for long-term-care facilities or providers to conduct background checks on prospective employees and providers that would have direct access to patients. The program authorizes matching funds to participating States that have a plan to implement a section 6201 compliant program statewide in all specified types of long-term-care entities.

**WHO IS RESPONSIBLE?** The program will be administered by CMS, in consultation with the Department of Justice and the Federal Bureau of Investigation. The program will be evaluated by OIG.

**HOW IS RELATED ASSISTANCE RECEIVED AND USED?** Federal 3-to-1 matching funds are available to all States and territories that apply to CMS and meet all the program requirements. Although CMS will fully fund grant awards under this program, CMS will impose drawdown restrictions as necessary to ensure that State program preapproved milestones are met.

The objective of our initial review of the National Background Check Program follows.

### **Program for National Background Checks for Long-Term-Care Employees**

We will review the procedures implemented by participating States for long-term-care facilities or providers to conduct background checks on prospective employees and providers who would have direct access to patients and determine the costs of conducting background checks. (OEI; 07-10-00420; expected issue date: FY 2013; work in progress; Affordable Care Act)

## Community Living Assistance Services and Supports Program, § 8002

**WHY WAS THE PROGRAM CREATED?** The Community Living Assistance and Supports Program (CLASS) is a national voluntary insurance program for purchasing community living assistance services and supports to provide individuals having functional limitations with tools that will enable them to maintain their personal and financial independence and live in the community.

**WHAT WILL THE PROGRAM DO?** Those who are eligible and who enroll will receive benefits to purchase long-term services and supports.

**WHO IS RESPONSIBLE?** CLASS will be administered by the Administration on Aging (AoA) through the Office of Community Living Assistance Services and Supports (CLASS Office).

The objective for our initial review of CLASS follows.

### **Development of the Community Living Assistance Services and Supports Program**

We will describe AoA's progress in developing the CLASS program requirements of the Affordable Care Act. The law requires OIG to annually report on the CLASS program with regard to eligibility determination; provision of cash benefits; quality assurance and protection against waste, fraud, and abuse; and recouping of unpaid and accrued benefits. (OEI; 04-11-00450; multiple reports; expected issue date: FY 2012; work in progress; Affordable Care Act)

# Existing Programs Related to Affordable Care Act Provisions

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## ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CDC—CENTERS FOR DISEASE CONTROL AND PREVENTION  
HRSA—HEALTH RESOURCES AND SERVICES ADMINISTRATION

MA—MEDICARE ADVANTAGE

The major parts of the OIG *Work Plan* for FY 2012 that precede the appendixes include descriptions of Affordable Care Act-related reviews in progress or planned to start in FY 2012. Below are shortened descriptions of those reviews and the major Part in which each appears in full.

## Medicare

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

We will review hospitals' controls for ensuring the accuracy and validity of data related to quality of care that they submit to CMS for Medicare reimbursement. The Affordable Care Act expands Medicare's existing quality initiative. (*Work Plan Part I.*)

### **Accuracy of Present-on-Admission Indicators Submitted on Medicare Claims**

We will determine the accuracy of present on admission (POA) indicators on inpatient claims submitted by hospitals nationally in October 2008. The Affordable Care Act provides that hospitals with high rates of hospital-acquired conditions receive reduced payments. Accurate POA indicators are needed for CMS to implement requirements in the Deficit Reduction Act of 2005 (DRA) and the Affordable Care Act. (*Work Plan Part I.*)

### **Hospital Same-Day Readmissions**

We will review Medicare claims to determine trends in the number of same-day hospital readmissions. This work, which pertains to an existing system edit, may also be helpful to CMS in implementing provisions of the Affordable Care Act. (*Work Plan Part I.*)

### **Nursing Home Compliance Plans**

We will review Medicare- and Medicaid-certified nursing homes' incorporation of compliance plans into their day-to-day operations and determine whether the plans contain elements identified in OIG's compliance program guidance. Starting in 2013, we will determine whether CMS has incorporated compliance requirements into Requirements of Participation and oversees provider implementation of plans. (*Work Plan Part I.*)

### **Recovery Audit Contractors' Performance and Identification and Recoupment of Improper Payments**

We will review the performance of the Recovery Audit Contractor (RAC) program and CMS's oversight of the program. Congress expanded the RAC program, giving it additional responsibilities



to address improper payments in Medicare (including Part C and Part D), and Medicaid. (*Work Plan Part I.*)

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

We will determine the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, as having end stage renal disease, or as Medicaid eligible. We will also determine the impact of inaccurate or invalid classification of beneficiaries on Medicare payments to Medicare Advantage (MA) plans. (*Work Plan Part II.*)

### **Enrollment of Medicare Beneficiaries With Chronic Conditions in Special-Needs Plans**

We will review Special-Needs Plans' compliance with chronic condition enrollment requirements and will assess CMS's oversight of the enrollment practices. (*Work Plan Part II.*)

### **Quality-Based Bonus Payments to Unrated Plans in 2011 and 2012**

We will determine the amounts of quality-based bonus payments made to unrated MA plans in 2011 and 2012 and will determine the extent to which CMS collects data for MA plans that are unrated. (*Work Plan Part II.*)

### **Part D and Medicaid Payments for High-Volume Prescription Drugs**

We will review prices paid by Medicare Part D plans and State Medicaid agencies for 200 high-volume prescription drugs, compare prices paid under the programs (including discounts and rebates), and assess the impact of any price discrepancies on the Federal Government and beneficiaries. (*Work Plan Part II.*)

### **Quality of Sponsor Data Used in Calculating Coverage-Gap Rebates**

We will review data submitted by Part D sponsors used in calculating coverage-gap rebates to ensure that beneficiary payments were correct. (*Work Plan Part II.*)

### **Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts**

We will review data submitted by Part D sponsors used in calculating the coverage gap discount. We will determine the accuracy of the sponsor-submitted data to ensure that beneficiary payments are correct and amounts paid to sponsors are supported. (*Work Plan Part II.*)

## **Medicaid**

### **Appropriateness of Federal Upper Limit Amounts**

We will compare Federal Upper Limit (FUL) amounts under the 2010 Affordable Care Act methodology (which changed the FUL calculation to no less than 175 percent of the designated pricing point) to estimates of pharmacy acquisition costs for selected drugs. (*Work Plan Part III.*)

### **States' Collection of Rebates for Drugs Paid by Managed Care Organizations**

We will determine whether Medicaid Managed Care Organizations ((MCO) are providing State Medicaid agencies with the utilization data needed to collect rebates for drugs used by Medicaid MCO enrollees. The Affordable Care Act, § 2501, expanded Medicaid rebate requirements to include

drugs dispensed to MCO enrollees and required Medicaid MCOs to report enrollees' drug utilization data to the State for the purpose of collecting rebates from manufacturers. (*Work Plan Part III.*)

### **Federal Share of Rebates**

We will review States' reporting of the Federal share of Medicaid rebate collections to determine whether States are correctly identifying and reporting the increases in rebate collections. (*Work Plan Part III.*)

### **Rebates on New Formulations**

We will review drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs. We will also determine whether manufacturers have correctly identified all their drugs that are subject to a new provision in law. (*Work Plan Part III.*)

### **Payments for Health-Care-Acquired Conditions**

We will determine whether selected State agencies made Medicaid payments for health-care-acquired conditions and provider-preventable conditions and will quantify the amount of Medicaid payments for such conditions. (*Work Plan Part III.*)

### **State Agencies' Terminations of Providers Terminated Under Medicare or by Other States**

We will review States' compliance with a new requirement that State Medicaid agencies terminate providers that have been terminated under Medicare or by another State. We will also determine whether such providers are terminated by all States, assess the status of the supporting information-sharing system, determine how CMS is ensuring that States share complete and accurate information, and identify obstacles States face in complying with the termination requirement. (*Work Plan Part III.*)

### **Medicaid National Correct Coding Initiative Effectiveness**

We will review selected States' implementation of National Correct Coding Initiative (NCCI) edits for Medicaid claims. Pursuant to the Affordable Care Act, State Medicaid programs were required to incorporate "NCCI methodologies" into their claims processing systems by October 1, 2010. (*Work Plan Part III.*)

### **Completeness and Accuracy of Managed Care Encounter Data**

We will determine the extent to which Medicaid managed care encounter data included in Medicaid Statistical Information System (MSIS) submissions to CMS accurately represent all services provided to beneficiaries. We will also determine the extent to which CMS acted to enforce Federal requirements that mandate the inclusion of Medicaid managed care encounter data in MSIS. (*Work Plan Part III.*)

## **Public Health**

### **Prevention and Public Health Fund Recipient Capability Audits**

We will perform limited-scope reviews to determine whether Centers for Disease Control and Prevention (CDC) grantees can manage and account for Federal funds, including Affordable Care Act

funds, in accordance with Federal regulations. We will also determine whether Prevention and Public Health Fund grantees can fulfill program requirements. (*Work Plan Part V.*)

### **CDC Grantees' Use of Funds From the Prevention and Public Health Fund**

We will determine whether CDC grantees' use of funds from the Prevention and Public Health Fund were properly used for the purposes outlined in Federal laws and directives. (*Work Plan Part V.*)

### **Internal Controls for Awarding Affordable Care Act Grants**

We will review and test CDC's internal controls for awarding Affordable Care Act grants. We will also determine whether selected CDC Affordable Care Act grantees complied with grants administration requirements and terms and conditions of the funding opportunity announcements. (*Work Plan Part V.*)

### **Payment of Invoices for Affordable Care Act Purchases**

We will review and test CDC's controls over payments for goods and services, including Affordable Care Act-related purchases. We will also determine whether CDC's Financial Management Office obtains proper validation that goods or services were received before payment of invoices and whether a previously identified control deficiency has been corrected. (*Work Plan Part V.*)

### **Community Health Centers' Compliance With Affordable Care Act Grant Requirements**

We will determine whether community health centers that received Affordable Care Act funds through the Health Resources and Services Administration (HRSA) are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems and assessing the accounting for program income. (*Work Plan Part V.*)

### **Community Health Center Limited-Scope Capability Audits**

We will determine the capacities of community health centers receiving Affordable Care Act funds through HRSA to manage and account for Federal funds and to operate community health service delivery sites in compliance with Federal requirements. (*Work Plan Part V.*)

### **HRSA's Monitoring of Recipients' Fulfillment of National Health Services Corps's Obligations**

We will review the effectiveness of National Health Service Corps monitoring of recipients to ensure timely fulfillment of their contract obligations or timely recognition and referral of defaults to a Treasury-designated Debt Collection Center (HHS Program Support Center) if the recipients breach their obligations. We will determine the accuracy of HRSA's default rate (2 percent) and the adequacy of its followup with health care professionals who default on their service commitments. The Affordable Care Act and the Recovery Act provided increased funding for National Health Service Corps Loan and Scholarship Programs. (*Work Plan Part V.*)

### **SAMHSA Grantees' Use of Funds From the Prevention and Public Health Fund**

We will review Substance Abuse and Mental Health Services Administration grantees' use of funds from the Prevention and Public Health Fund to determine whether such funds were properly used for the purposes outlined in Federal laws and directives. (*Work Plan Part V.*)

# Appendix B: Recovery Act Reviews

## Appendix B

# Recovery Act Reviews: Medicare and Medicaid

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THE MEDICARE AND MEDICAID SECTION:

|   |   |
|---|---|
| CBO—CONGRESSIONAL BUDGET OFFICE                                   | HIT—HEALTH INFORMATION TECHNOLOGY                           |
| CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES                      | OCR—OFFICE FOR CIVIL RIGHTS                                 |
| FORM CMS-64—MEDICAID QUARTERLY EXPENDITURE REPORT                 | PHI—PROTECTED HEALTH INFORMATION                            |
| HIPAA—HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 | RECOVERY ACT—AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009 |

## Medicare Part A and Part B

### Medicare Incentive Payments for Electronic Health Records

We will review Medicare incentive payments to eligible health care professionals and hospitals for adopting electronic health records (EHR) and the Centers for Medicare & Medicaid Services' (CMS) safeguards to prevent erroneous incentive payments. An EHR is an electronic record of health-related information for an individual that is generated by health care providers. It may include a patient's health history, along with other items. The American Recovery and Reinvestment Act of 2009 (Recovery Act) authorized Medicare incentive payments over a 5-year period to physicians and hospitals that demonstrate meaningful use of certified EHR technology. (§§ 4101 and 4102.) Incentive payments are scheduled to begin in 2011 and continue through 2016, with payment reductions to health care professionals who fail to become meaningful users of EHRs beginning in 2015. (§ 4101(b).) According to Congressional Budget Office (CBO) estimates, CMS's net spending for incentives will total about \$20 billion. We will review Medicare incentive payment data from 2011 to identify payments to providers that should not have received incentive payments (e.g., those not meeting selected meaningful use criteria). We will also assess CMS's plans to oversee incentive payments for the duration of the program and actions taken to remedy erroneous incentive payments. (OEI; 05-11-00250; expected issue date: fiscal year (FY) 2012; work in progress; Recovery Act)

## Medicaid Administration

### Medicaid Incentive Payments for Electronic Health Records

We will review Medicaid incentive payments to providers and hospitals for adopting EHRs and CMS's safeguards to prevent erroneous incentive payments. The Recovery Act establishes 100-percent Federal financial participation for allowable expenses for eligible Medicaid providers to purchase, implement, and operate certified EHR technology. (§ 4201.) The section also provides a 90-percent Federal match for State administrative expenses for the adoption of certified EHR technology by Medicaid providers. According to CBO estimates, Medicaid spending for incentives will total about \$12 billion between 2011 and 2019. We will determine whether incentive payments to Medicaid providers to purchase, implement, and operate EHR technology were claimed in accordance with

Medicaid requirements. We will also assess CMS's actions to remedy erroneous incentive payments and its plans for securing the payments for the duration of the incentive program, as well as review payments to States for administrative expenses. (OAS; W-00-11-31351; various reviews; expected issue date: FY 2012; new start; Recovery Act))

### **Reconciliation of Expenditure Reports to Claim Data**

We will review and reconcile reported line items on the Medicaid quarterly expenditure report (Form CMS-64) in selected States to determine whether the amounts claimed are adequately supported. The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time a claim is filed. Our prior audit work revealed concerns about expenditures claimed on Form CMS-64. (OAS; W-00-10-31359; W-00-11-31359; various reviews; expected issue date: FY 2012; work in progress, Recovery Act)

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

### **Health Information Technology System Enhancements**

We will review health information technology (HIT) enhancements to CMS systems to ensure that they include standards adopted by the Department of Health and Human Services (HHS) and that adequate information technology (IT) security controls are in place to protect sensitive EHR and personal information. The Recovery Act provides financial incentives through Medicare and Medicaid to encourage doctors, hospitals, health clinics, and other entities to adopt and use certified EHRs. Medicare incentive payments are being phased out over time and replaced with financial penalties for providers that are not using EHR. CMS systems require modification to manage the new requirements. (OAS; W-00-10-27109; various reviews; expected issue date: FY 2012; work in progress; Recovery Act)

### **Contractor System Enhancements**

We will review HIT enhancements to IT systems used by Medicare and Part D contractors to ensure that adequate IT security controls are in place to protect sensitive EHR and personal information that is being added as a result of the Federal HIT initiatives. CMS contractor systems require modification to comply with the new requirements. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

### **Breaches and Medical Identity Theft Involving Medicare Identification Numbers**

We will review CMS's policies and procedures on breaches and medical identity theft. The Recovery Act defines a "breach" as an "unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of the protected health information." (§13400.) The Recovery Act requires covered entities, including CMS, to notify individuals whose unsecured protected health information (PHI) has been or is reasonably believed to have been accessed, acquired, or disclosed as a result of a breach. Breaches of PHI increase Medicare beneficiaries' and providers' vulnerability to medical identity theft. We will also assess the actions CMS has taken to address medical identity theft in the Medicare program. (OEI; 02-10-00040; expected issue date: FY 2012; work in progress; Recovery Act)

### OCR Oversight of the HIPAA Privacy Rule (New)

We will review Office for Civil Rights (OCR) oversight of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The Privacy Rule establishes Federal minimum standards for safeguarding individually identifiable health information referred to as PHI. The Recovery Act requires that OCR investigate all privacy complaints filed against covered entities if a preliminary investigation indicates willful neglect of the Privacy Rule. Covered entities include health plans, health care clearinghouses, and health care providers that electronically transmit health information in connection with certain HIPAA transactions and technical standards. The Recovery Act also strengthened OCR's enforcement of the HIPAA Privacy Rule by increasing the civil monetary penalties for covered entities' noncompliance. (74 Fed. Reg. 56123.) We will review OCR's investigation policies and assess OCR's oversight to ensure that covered entities are complying with the Privacy Rule. (OEI; 09-10-00510; expected issue date: FY 2012; work in progress; Recovery Act)

### OCR Oversight of the HITECH Breach Notification Rule (New)

We will review OCR's oversight of the Health Information Technology for Economic and Clinical Health Act (HITECH) Breach Notification Rule, which requires that covered entities, as defined by HIPAA, notify affected individuals; the Secretary of HHS; and when required, the media, following the discovery of a breach in unsecured PHI. A breach is the unauthorized acquisition, access, use, or disclosure of PHI that compromises the security or privacy of such information. Unsecured PHI is individually identifiable health information that is unencrypted or not destroyed in a way that renders the PHI unusable or unreadable by unauthorized individuals. HHS provided additional guidance on what is considered to be unsecured PHI in its issuances at 74 Fed. Reg. 19006 and 74 Fed. Reg. 42741. The Secretary of HHS delegated oversight responsibility to OCR. We will review OCR's policies for investigating breaches reported by covered entities and determine whether Medicare Part B-covered entities have policies or plans in place to mitigate breaches. (OEI; 09-10-00511; expected issue date: FY 2012; work in progress; Recovery Act)

## Recovery Act Reviews: Public Health Programs

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#### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THE PUBLIC HEALTH PROGRAMS SECTION:

CDC—CENTERS FOR DISEASE CONTROL AND PREVENTION  
EHR—ELECTRONIC HEALTH RECORDS  
HRSA—HEALTH RESOURCES AND SERVICES ADMINISTRATION  
IHS—INDIAN HEALTH SERVICE

NIH—NATIONAL INSTITUTES OF HEALTH  
ONC—OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH  
INFORMATION TECHNOLOGY

### Centers for Disease Control and Prevention

#### Recipient Compliance With Grant and Cooperative Agreement Requirements

We will review compliance with the Recovery Act and Federal regulations by recipients of the Centers for Disease Control and Prevention's (CDC) grants and cooperative agreements. The Recovery Act provides \$1 billion, primarily through grants and cooperative agreements, for prevention and wellness strategies. The funds will be awarded and spent in a short period.

As part of our oversight role in preventing fraud, waste, and abuse, we will determine whether CDC recipients spent funds in accordance with the Recovery Act and Federal regulations. (OAS; W-00-12-27102; expected issue date: FY 2012; new start and work in progress, Recovery Act)

## Health Resources and Services Administration

### **Limited-Scope Audits of Grantees' Capacities**

We will determine whether potentially high-risk recipients of Recovery Act funds for new access points are capable of managing Federal awards. Under the New Access Points Program, 50 of the 126 grantees receiving \$156 million in Recovery Act funds for new service delivery sites are new grantees. In light of the Office of Inspector General's (OIG) oversight role in preventing fraud, waste, and abuse and given the increased number of grants and the expanded revenue base of grantees, we will also conduct limited-scope audits of grants for Increased Demand for Services (\$342 million), the Capital Improvement Program (\$853 million), and the Facility Investment Program (\$520 million). The objective of the audits will be to assess grantees' capacities to manage and account for Federal funds and to operate community health service delivery sites in accordance with Federal regulations. (OAS; W-00-10-27105; W-00-11-27105; various reviews; expected issue date: FY 2012; work in progress and new start, Recovery Act)

### **Recovery Act Funding for Community Health Centers Infrastructure Development**

We will review community health centers and other facilities in two States to determine whether Recovery Act funds were spent in accordance with Federal regulations. The Recovery Act provided \$2 billion to be invested in community health centers. Of that amount, \$1.5 billion funds infrastructure development for community health centers, which includes acquisition of equipment, construction, and renovation. Another \$500 million has been provided to fund operations of health centers. Community health centers are locally directed and operated providers of preventive and primary care. Forty-six community health centers in Florida were awarded about \$88 million in Recovery Act funding. In Alabama, one community health center received about \$15 million for a competitive Facility Investment Program grant, almost half of the total amount received by the other 14 Alabama grantees. On the basis of results, audits may be performed in other States. (OAS; W-00-11-27105; expected issue date: FY 2012; new start; Recovery Act)

### **Grant Award System for Health Information Technology Funds**

We will review general and application IT security controls for the Health Resources and Services Administration's (HRSA) grant system to ensure that adequate IT security controls are in place. We will assess whether HRSA's grant award system has sufficient processes in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. HRSA has \$120 million in Recovery Act funding available for HIT systems and network grants to support EHR for health centers. The review will focus on the controls in place to safeguard HIT grant information pertaining to HRSA's distribution of the grant funds. We will also determine whether HRSA's grant awards require appropriate IT security provisions to protect sensitive EHR or personal information at the grantee level. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)



### **Community Health Centers Receiving Health Information Technology Funding**

We will review general IT security controls in place for community health center systems funded by HRSA HIT grants to ensure that adequate HIT security controls are in place to protect sensitive EHR and personal information. HRSA will expend \$120 million of \$1.5 billion in Recovery Act funding for HIT systems and network grants to support EHR for community health centers. Almost 300 community health centers are expected to benefit from the funding. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

### **HRSA Health Information Technology Grants (New)**

We will determine the extent to which HRSA Recovery Act grants supported the implementation and expansion of EHRs through health-center-controlled networks. In 2009 and 2010, HRSA awarded 99 grants totaling nearly \$121 million in Recovery Act funds for EHR implementation and other HIT initiatives. We will survey HRSA grantees about how Recovery Act grants supported the adoption, use, and sustainability of EHRs through health-center-controlled networks. (OEI; 09-11-00380; expected issue date: FY 2012; work in progress; Recovery Act)

## **Indian Health Service**

### **Facilities Construction Bid Proposal Audits**

We will review the top bidders for Indian Health Service (IHS) construction contracts to determine whether the proposed costs were supported by current, complete, and accurate cost or pricing data and determine the reasonableness and allowability of proposed costs. We will also review bid estimation procedures. The Recovery Act provides \$415 million for construction of IHS health care facilities. As part of our oversight role in preventing fraud, waste, and abuse, we will assess the bid proposals to address the risk of unreasonable or unallowable costs or inaccurately priced contracts. (OAS; W-00-12-27103; expected issue date: FY 2012; new start, Recovery Act)

### **Facilities Construction Contingency Fund Management Audits**

We will review IHS's management of construction contingency funds and determine whether they were spent on eligible project costs. The Recovery Act provides \$415 million for construction of IHS health care facilities. Our preliminary analysis indicates that 10 to 15 percent of construction funding is usually set aside as a contingency fund for major construction projects. The Recovery Act specified that funds must be obligated by the end of FY 2010. As part of our oversight role in preventing fraud, waste, and abuse, we will assess IHS's management of contingency funds to determine whether the usage was proper considering the accelerated timeframe to obligate the funds, which will then be used for construction projects lasting years afterward. (OAS; W-00-12-27103; expected issue date: FY 2012; new start, Recovery Act)

### **Internal Controls Over Equipment**

We will review IHS's internal controls for property management and equipment monitoring. The Recovery Act provides \$20 million for IHS to purchase medical equipment, computed tomography scanners, and ambulances. A recent Government Accountability Office audit found that millions of dollars worth of IHS property was lost or stolen over the past several years. The audit also found evidence of wasteful spending. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will assess internal controls and monitoring of IHS property. (OAS; W-00-12-27103; expected issue date: FY 2012; new start, Recovery Act)

### **Indian Health Service System Improvements**

We will review improvements by IHS to its applications and network infrastructure to ensure that IT security controls are in place. The Recovery Act provided \$85 million to IHS to make improvements to its HIT environment and to improve service to its constituents. Activities to be funded with the investment include application development and enhancements for the Resource and Patient Management System, which contains patient medical data, history, and payment data, and HIT infrastructure security improvements to ensure safety of health data, as well as network upgrades to provide enhanced health services to IHS constituents. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

## **National Institutes of Health**

### **Implementation of Internal Controls for Grantee Reporting**

We will review the National Institutes of Health's (NIH) internal controls for ensuring that grantee reporting processes comply with Recovery Act requirements. The Recovery Act provides \$10.4 billion in new funding to NIH. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH has a system in place to ensure that grantees capture and report necessary financial, economic, and grant/contract data in accordance with the Recovery Act. (OAS; W-00-11-27101; expected issue date: FY 2012; new start, Recovery Act)

### **Internal Controls for Extramural Construction and Shared Instrumentation**

We will review NIH's internal controls for awarding extramural construction and shared instrumentation grants. NIH's extramural construction spending plan proposes \$1 billion in Recovery Act funds for renovations, repairs, improvements, or construction of core research facilities. The shared instrumentation spending plan proposes \$300 million in Recovery Act funds to purchase major items of biomedical research equipment. As part of OIG's oversight role in preventing fraud, waste, and abuse, we will determine whether NIH's internal controls for the systems used to process and monitor Recovery Act grants are effective and efficient. (OAS; W-00-09-27101; W-00-11-27101 expected issue date: FY 2012; work in progress and new start, Recovery Act)

### **Intramural Construction Bid Proposal Audits**

We will review the top bidders for construction contracts to determine whether proposed costs were supported by current, complete, and accurate cost or pricing data, and we will determine the reasonableness and allowability of proposed costs. We will also evaluate bid estimation procedures. The Recovery Act provides \$500 million for NIH's Intramural Buildings and Facilities program. As part of our oversight role in preventing fraud, waste, and abuse, we will assess the bid proposals to determine the risk of unreasonable or unallowable costs or inaccurately priced contracts. (OAS; W-00-11-27101; expected issue date: FY 2012; new start, Recovery Act)

### **Intramural Construction Contingency Fund Management**

We will review NIH's management of construction contingency funds to ensure that they are spent on eligible project costs. The Recovery Act provides \$500 million for NIH's Intramural Buildings and Facilities program. Our preliminary analysis indicates that 10 to 15 percent of construction funding is usually set aside as a contingency fund for major construction projects. The Recovery Act specified that funds must be obligated by the end of FY 2010. As part of OIG's oversight role in preventing

fraud, waste, and abuse, we will assess NIH's management of the contingency funds to determine whether the usage was proper considering the accelerated timeline to obligate the funds, which will then be used for future construction projects. (OAS; W-00-11-27101; expected issue date: FY 2012; new start, Recovery Act)

### **College and University Indirect Costs Claimed as Direct Costs**

We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants. Prior audit work found problems in this area. A large amount of Recovery Act funds will be used for grants to colleges and universities. We will review administrative and clerical expenses claimed for reimbursement as direct charges to Federal grants and contracts when those costs should have been treated as indirect costs and recovered through negotiated facility and administrative rates. Such costs are usually treated as indirect costs. (Office of Management and Budget (OMB) Circular A-21, *Cost Principles for Educational Institutions*.) However, direct charging of the costs may be appropriate when the nature of the work performed under a specific project requires extensive administrative or clerical support. (OAS; W-00-09-27101; expected issue date: FY 2012; work in progress, Recovery Act)

### **National Institutes of Health Grant System**

We will review general and application IT security controls for NIH's Information for Management, Planning, Analysis, and Coordination (IMPAC) system to ensure that adequate controls are in place. We will determine whether NIH has processes in place or under development that are sufficient to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. The system manages grants at NIH, and its importance has increased since NIH received \$7.4 billion in Recovery Act funding for grants to and cooperative agreements with research entities, including nonprofit and for-profit organizations, universities, hospitals, research foundations, government agencies, and individuals. We will also determine whether NIH's grant awards require appropriate IT security provisions to protect sensitive EHR or personal information at the grantee level. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

## **Cross-Cutting Public Health Activities**

### **Recipient Compliance With Reporting Requirements**

We will review monitoring by HRSA, NIH, and IHS of award recipients' compliance with the reporting requirements specified in the Recovery Act and in OMB guidance. The recipients and uses of Recovery Act funds must be transparent to the public, and the public benefits of the funds must be reported clearly and accurately and in a timely manner. We will review recipients' reports for compliance with the reporting requirements, including accuracy and completeness. (OAS; W-00-11-27101; W-00-11-27103; W-00-11-27105; various reviews; expected issue date: FY 2012; new start, Recovery Act)

### **State Compliance With Grant Requirements**

We will review security controls implemented by States to safeguard electronic health information exchanges. The Office of the National Coordinator for Health Information Technology (ONC) is authorized to award planning and implementation grants to States to facilitate and expand electronic health information exchanges. (Public Health Service Act of 1944, § 3013, as added by the Recovery Act, § 13301.) To receive an implementation grant, a State must submit a plan describing

the activities to be carried out to facilitate and expand electronic health information exchange pursuant to nationally recognized standards and implementation specifications. We will use our body of work in Medicaid reviews of 24 States to identify higher risk States, assess State plans, and determine the adequacy of security controls. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

## Recovery Act Reviews: Human Services Programs

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### ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THE HUMAN SERVICES PROGRAMS SECTION:

ACF—ADMINISTRATION FOR CHILDREN AND FAMILIES

TANF—TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

GATES—GRANTS ADMINISTRATION TRACKING EVALUATION SYSTEM

## Administration for Children and Families

### Head Start Agencies' Use of Grant Funds

We will review the use of funds, including Recovery Act funds, by Head Start agencies. The Recovery Act requires that the \$1 billion in supplemental funds for Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Recipients of Head Start funds are required to ensure that the funds are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) We will determine whether Head Start funds and Recovery Act funds were properly used for the purposes outlined in Federal award letters, approved Head Start agency grant applications, and program requirements. (OAS; W-00-11-27100; expected issue date: FY 2012; new start, Recovery Act)

### Head Start Recipient Capability Audits

We will review Head Start applicants' capacity to manage and account for Federal funds, including Recovery Act funds, and to operate a Head Start program in accordance with Federal regulations. The Recovery Act requires that \$1 billion in supplemental funds awarded to Head Start grantees be used in a manner consistent with the requirements of the Head Start Act. Grantees receiving Head Start funds must ensure that the funds are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) We will determine whether Head Start applicants can adequately manage and account for Federal funds, including Recovery Act funds, and fulfill Head Start program requirements. (OAS; W-00-10-27100; W-00-11-27100; expected issue date: FY 2012; work in progress and new start, Recovery Act)

### Administration for Children and Families Grant System

We will determine whether adequate general and application IT security controls for the Administration for Children and Families' (ACF) Grants Administration Tracking Evaluation System (GATES) are in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. GATES is used by ACF grants officers and specialists to manage grant programs and process grant applications from receipt through award. ACF received \$10 billion for grants supporting Head Start, Early Head Start, Temporary Assistance for Needy Families (TANF),

child care and development, and community services. We will also determine whether ACF's grant awards require increased IT security provisions to protect sensitive EHR or personal information at the grantee level. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

### **Administration for Children and Families Health Information Technology Grants**

We will review general IT security controls for systems funded by ACF HIT grants to determine whether adequate security controls are in place to protect sensitive EHR and personal information. ACF will award HIT grants to State agencies, local governments, nonprofit organizations, and school systems administering Head Start, Early Head Start, TANF, Child Care and Community Development Block Grant, and Community Services Block Grant programs. We will also determine whether ACF grantees receiving HIT funds have sufficient processes in place to ensure that the confidentiality, integrity, and availability of sensitive data in transit and at rest are maintained. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

## Recovery Act Reviews: Departmentwide Issues

### Cross-Cutting Investigative Activities

#### **Integrity of Recovery Act Expenditures**

We will evaluate credible allegations of improper expenditures of Recovery Act funds to identify cases in which criminal investigations will be opened and enforcement actions pursued. Recovery Act funding will result in a significant increase in the number of grants and contracts awarded by HHS. Accordingly, we expect an increase in the number of complaints and referrals of grant- and contract-related fraud allegations. The Recovery Act requires transparency and accountability in the awarding and spending of funds. (OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)

#### **Enforcement of Whistleblower Protections**

We will evaluate credible allegations of reprisals against whistleblowers by entities or individuals receiving Recovery Act funds to identify cases in which criminal investigations will be opened and antireprisal enforcement actions pursued. The Recovery Act extends whistleblower protection to employees who reasonably believe they are being retaliated against for reporting misuse of Recovery Act funds received by their non-Federal employers. (§ 1553.) (OI; various reviews; expected issue dates: FY 2009 through FY 2012; work in progress; Recovery Act)

### Information Systems Reviews

#### **Departmentwide Network Improvements**

We will review the acquisition of staff, hardware, and software intended to improve IT security at HHS and, when applicable, test modifications to the HHS IT security environment. HHS has allocated

\$50 million in Recovery Act funds to improve IT security departmentwide. Recent compromises of systems and data in HHS's Office of the Secretary, as well as at several HHS agencies, require concerted and coordinated action across HHS that is commensurate with the sustained level of sophisticated cyber attacks that have targeted HHS computer systems. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

### **Security Controls for Grants Web Site**

We will review general and application IT security controls for the [Grants.gov](http://Grants.gov) Web site to ensure that adequate controls are in place to protect information. Our assessment will focus on controls for ensuring confidentiality, integrity, and availability of data. Grants.gov is the central grant identification and application portal for more than 1,000 Federal grant programs offered by 26 Federal agencies and organizations. On March 6, 2009, Grants.gov began posting information on specific grant opportunities provided in the Recovery Act. As a result, grant applications filed using Grants.gov have risen to an unprecedented level, reaching almost 11,500 per week, about 3 times the weekly average number of submissions during FY 2008. (OAS; W-00-11-27109; various reviews; expected issue date: FY 2012; new start; Recovery Act)

# Appendix C: Acronyms and Abbreviations

## Appendix C: Acronyms and Abbreviations

THIS APPENDIX SPELLS OUT SELECTED ACRONYMS AND ABBREVIATIONS USED IN THE WORK PLAN. They are listed in three categories:

- Terms and Titles
- Organizations
- Public Laws

### Terms and Titles

|       |  |
|-------|--|
| 340B  | section 340B discount drug pricing program                       |
| ADAP  | AIDS Drug Assistance Program                                     |
| AI/AN | American Indians and Alaska Natives                              |
| AIDS  | acquired immunodeficiency syndrome                               |
| ALF   | assisted living facility   |
| ALJ   | administrative law judge   |
| AMD   | age-related macular degeneration                                 |
| AMP   | average manufacturer price                                       |
| ASP   | average sales price  |
| AWP   | average wholesale price  |
| BERM  | Bioterrorism Epidemic Outbreak Response Model                    |
| CAA   | community action agency  |
| CAH   | critical access hospital   |
| CAS   | cost accounting standards  |
| CATT  | Comparison of age-related macular degeneration treatments trials |
| CCDF  | Child Care and Development Fund                                  |
| CDT   | continuing day treatment (providers)                             |
| CERT  | Comprehensive Error Rate Testing (program)                       |
| CFR   | Code of Federal Regulations                                      |
| CHIP  | Children's Health Insurance Program                              |
| CIA   | Corporate Integrity Agreement                                    |
| CMHC  | community mental health center                                   |
| CMP   | civil monetary penalty   |
| CNC   | currently not collectible  |
| CoP   | Conditions of Participation                                      |
| CORF  | Comprehensive Outpatient Rehabilitation Facility                 |
| CPE   | certified public expenditures                                    |
| CPG   | Compliance Program Guidance                                      |
| CSE   | child support enforcement  |
| CTSA  | Clinical and Translational Science Award (grants)                |
| CWF   | Common Working File  |



|        |   |
|--------|---|
| CY     | calendar year   |
| DGME   | direct graduate medical education                               |
| DIR    | direct and indirect remunerations                               |
| DME    | durable medical equipment                                       |
| DMEPOS | durable medical equipment, prosthetics, orthotics, and supplies |
| DMERC  | durable medical equipment regional carrier                      |
| DRG    | diagnosis-related group   |
| DSH    | disproportionate share hospital                                 |
| DSMB   | Data and Safety Monitoring Board                                |
| DSMT   | diabetes self-management training                               |
| DTS    | diabetic testing supplies                                       |
| DUA    | data use agreement  |
| EAC    | estimated acquisition cost                                      |
| ED     | erectile dysfunction  |
| E&M    | evaluation and management (services)                            |
| EHR    | electronic health records                                       |
| EPSDT  | Early and Periodic Screening, Diagnostic, and Treatment         |
| ERRP   | error rate reduction plan                                       |
| ESF    | emergency support functions                                     |
| ESRD   | end stage renal disease   |
| F&A    | facilities and administrative (costs)                           |
| FAR    | Federal Acquisition Regulation (CFR, Title 48)                  |
| FEHB   | Federal Employees Health Benefits (plan)                        |
| FFP    | Federal financial participation                                 |
| FFS    | fee-for-service (payments)                                      |
| FI     | fiscal intermediary   |
| FMAP   | Federal medical assistance percentage                           |
| FMO    | field marketing organization                                    |
| FTE    | full-time equivalent  |
| FTR    | Federal Travel Regulation                                       |
| FUL    | Federal upper limit   |
| FY     | fiscal year   |
| GAAP   | generally accepted accounting principles                        |
| GATES  | Grants Administration Tracking Evaluation System                |
| HAC    | hospital-acquired condition                                     |
| HCBS   | home- and community-based services                              |
| HCPCS  | Healthcare Common Procedure Coding System                       |
| HCPP   | health care prepayment plan                                     |
| HHA    | home health agency  |
| HHRG   | home health resource group                                      |
| HHSAR  | HHS Acquisition Regulation (CFR, Title 48)                      |
| HIT    | health information technology                                   |
| HIV    | human immunodeficiency virus                                    |
| HMO    | health maintenance organization                                 |
| HPMP   | Hospital Payment Monitoring Program                             |
| IDTF   | independent diagnostic testing facility                         |
| IGRT   | image-guided radiation therapy                                  |
| IMD    | institution for mental diseases                                 |
| IME    | indirect medical education                                      |
| IMRT   | intensity modulated radiation therapy                           |
| IND    | investigational new drug  |
| IPPS   | inpatient prospective payment system                            |

|        |   |
|--------|---|
| IRF    | inpatient rehabilitation facility                 |
| IRIS   | Intern and Resident Information System            |
| IT     | information technology                            |
| LCD    | local coverage determination                      |
| LIHEAP | Low-Income Home Energy Assistance Program         |
| MA     | Medicare Advantage                                |
| MAC    | Medicare Administrative Contractor                |
| MAO    | Medicare Advantage organization                   |
| MA-PD  | Medicare Advantage prescription drug organization |
| MCE    | Medicaid managed care entities                    |
| MCO    | managed care organization                         |
| MDS    | Minimum Data Set                                  |
| MEDIC  | Medicare drug integrity contractor                |
| MIC    | Medicaid Integrity Contractors                    |
| MIP    | Medicaid Integrity Program                        |
| MMIS   | Medicaid Management Information System            |
| MPFS   | Medicare physician fee schedule                   |
| MSIS   | Medicaid Statistical Information System           |
| MSN    | Medicare Summary Notice                           |
| MSP    | Medicare Secondary Payer                          |
| MSPRC  | Medicare Secondary Payer Recovery Contractor      |
| NCCI   | National Correct Coding Initiative                |
| NCD    | national coverage determination                   |
| NPI    | national provider identifier                      |
| NRF    | National Response Framework                       |
| NSC    | National Supplier Clearinghouse                   |
| OASIS  | Outcome and Assessment Information Set            |
| OPO    | organ procurement organization                    |
| OPPS   | outpatient prospective payment system             |
| PARIS  | Public Assistance Reporting Information System    |
| PBM    | pharmacy benefit manager                          |
| PCA    | progressive correction action                     |
| PCIP   | Pre-Existing Condition Insurance Plan             |
| PCS    | personal care services                            |
| PDE    | prescription drug event                           |
| PDP    | prescription drug plan                            |
| PECOS  | Provider Enrollment Chain and Ownership System    |
| PEPFAR | President's Emergency Plan for AIDS Relief        |
| PERM   | Payment Error Rate Measurement (program)          |
| PHEP   | Public Health Emergency Preparedness (program)    |
| PHI    | protected health information                      |
| PHP    | partial hospitalization program                   |
| PII    | personally identifiable information               |
| POA    | present on admission                              |
| PPS    | prospective payment system                        |
| PSC    | Program Safeguard Contractor                      |
| PSO    | patient safety organization                       |
| QASP   | Quality Assurance Surveillance Plan               |
| QI     | Qualifying Individual program                     |
| RAC    | Recovery Audit Contractor                         |
| RAI    | Resident Assessment Instrument                    |
| REMS   | risk evaluation and mitigation strategy           |

|        |   |
|--------|---|
| RN     | radiological and nuclear                              |
| RUG    | resource utilization group                            |
| Rx-HCC | prescription drug model used for payment under Part D |
| SAPTBG | SAMHSA-Funded Prevention and Treatment Block Grants   |
| S&C    | survey and certification                              |
| SAS    | Statement on Auditing Standards                       |
| SBIR   | Small Business Innovation Research (awards)           |
| SLEP   | Shelf-Life Extension Program                          |
| SNF    | skilled nursing facility                              |
| SNS    | Strategic Nuclear Stockpile                           |
| SOW    | Statement of Work                                     |
| TANF   | Temporary Assistance for Needy Families (program)     |
| TrOOP  | true out-of-pocket costs for Part D                   |
| UM     | utilization management                                |
| UPIN   | unique physician identifier number                    |
| URA    | unit rebate amount                                    |
| UPIN   | Unique Physician Identifier Number                    |
| UPL    | upper payment limit                                   |
| U.S.C. | United States Code                                    |
| WAC    | wholesale acquisition cost                            |
| WAMP   | widely available market price                         |
| ZPIC   | Zone Program Integrity Contractor                     |

## Organizations

|        |  |
|--------|--|
| ACF    | Administration for Children and Families                                 |
| AHRQ   | Agency for Healthcare Research and Quality                               |
| AoA    | Administration on Aging  |
| ASA    | Office of the Assistant Secretary for Administration                     |
| ASPR   | Office of the Assistant Secretary for Preparedness and Response          |
| ASFR   | Office of the Assistant Secretary for Financial Resources and Technology |
| BPHC   | Bureau of Primary Health Care  |
| CBO    | Congressional Budget Office  |
| CCIIO  | Center for Consumer Information and Insurance Oversight (see CMS)        |
| CDC    | Centers for Disease Control and Prevention                               |
| CDRH   | Center for Devices and Radiological Health                               |
| CMS    | Centers for Medicare & Medicaid Services                                 |
| DEA    | Drug Enforcement Administration  |
| DHS    | Department of Homeland Security  |
| DOJ    | Department of Justice  |
| FDA    | Food and Drug Administration   |
| GAO    | Government Accountability Office   |
| GSA    | General Services Administration  |
| HHS    | Department of Health & Human Services                                    |
| HRSA   | Health Resources and Services Administration                             |
| IHS    | Indian Health Service  |
| MFCU   | State Medicaid Fraud Control Units                                       |
| MedPAC | Medicare Payment Advisory Commission                                     |
| NCRR   | National Center for Research Resources                                   |
| NIAID  | National Institute of Allergy and Infectious Diseases                    |
| NIEHS  | National Institute of Environmental Health Sciences                      |

|        |  |
|--------|--|
| NIH    | National Institutes of Health  |
| OAS    | Office of Audit Services   |
| OCIG   | Office of Counsel to the Inspector General                           |
| OCIIO  | Office of Consumer Information and Insurance Oversight               |
| OHIT   | Office of Health Information Technology                              |
| OCR    | Office for Civil Rights  |
| OCSE   | Office of Child Support Enforcement                                  |
| OEI    | Office of Evaluation and Inspections                                 |
| OGE    | Office of Government Ethics  |
| OIG    | Office of Inspector General  |
| OMB    | Office of Management and Budget                                      |
| OMHA   | Office of Medicare Hearings and Appeals                              |
| ONC    | Office of the National Coordinator for Health Information Technology |
| PSC    | Program Support Center   |
| SAMHSA | Substance Abuse and Mental Health Services Administration            |
| USDA   | Department of Agriculture  |
| VA     | Department of Veterans Affairs                                       |

## Public Laws

The following public laws are commonly cited using acronyms or abbreviations in OIG's publications.

|                     |  |
|---------------------|--|
| Affordable Care Act | Patient Protection and Affordable Care Act of 2010, P.L. No. 111-148                                       |
| Anti-Deficiency Act | Anti-Deficiency Act of 1950, P.L. No. 82-414   |
| BBA                 | Balanced Budget Act of 1997, P.L. No. 105-33   |
| BIPA                | Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, P.L. No. 106-554            |
| CARE Act            | Ryan White Comprehensive AIDS Resources Emergency Act of 1990, P.L. No. 101-381                            |
| CERCLA              | Comprehensive Environmental Response, Compensation, and Liability Act of 1980, P.L. No. 96-510             |
| CFO Act             | Chief Financial Officers Act of 1990, P.L. No. 101-576   |
| CHIPRA              | Children's Health Insurance Program Reauthorization Act of 2009, P.L. No. 11-3                             |
| DRA                 | Deficit Reduction Act of 2005, P.L. No. 109-171  |
| EMTALA              | Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272   |
| FCA                 | False Claims Act, updated in August 2010 as an incorporating passage of P.L. No. 111-203                   |
| FCCA                | Federal Claims Collection Act of 1966, P. L. No. 89-508  |
| FDAAA               | Food and Drug Administration Amendments Act of 2007, P.L. No. 110-85                                       |
| FDAMA               | Food and Drug Administration Modernization Act of 1997, P.L. No. 105-115                                   |
| FDCA                | Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717  |
| FISMA               | Federal Information Security Management Act of 2002, Title III, E-Government Act of 2002, P.L. No. 107-347 |
| GMRA                | Government Management Reform Act of 1994, P.L. No. 103-356   |
| GPRA                | Government Performance and Results Act of 1993, P.L. No. 103-62  |
| Head Start Act      | Improving Head Start for School Readiness Act of 2007, P.L. No. 110-134                                    |
| HIPAA               | Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191                              |
| HITECH              | Health Information Technology for Economic and Clinical Health Act, enacted as part of the Recovery Act    |
| IDEA                | Individuals with Disabilities Education Act of 2004, P.L. No. 108-446                                      |
| IHCIA               | Indian Health Care Improvement Act of 1976, P.L. No. 94-437  |
| IPIA                | Improper Payments Information Act of 2002, P.L. No. 107-300  |

|              |  |
|--------------|--|
| MMA          | Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 |
| MIPPA        | Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275           |
| OCAA         | Omnibus Consolidated Appropriations Act of 1997, P.L. 104-368                            |
| PHS Act      | Public Health Service Act of 1944  |
| QI           | Qualifying Individual Program Supplemental Funding Act of 2008, P.L. No. 110-380         |
| Recovery Act | American Recovery and Reinvestment Act of 2009, P.L. No. 111-5                           |
| TEFRA        | Tax Equity and Fiscal Responsibility Act of 1982, P.L. No. 97-248                        |
| TRHCA        | Tax relief and Health Care Act of 2006, P.L. 109-432                                     |