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Medicare
Part A and Part B

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Part I: Medicare Part A and Part B

Medicare Part A and 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-forservice (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

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;

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)

work in progress)

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 nusing 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

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CAH—CRITICAL ACCESS HOSPITALS

COP—CONDITIONS OF PARTICIPATION (IN MEDICARE)

DGME—DIRECT GRADUATE MEDICAL EDUCATION (COSTS)

DRA—DEFICIT REDUCTION ACT OF 2005

FTE—FULL TIME EQUIVALENT

GME—GRADUATE MEDICAL EDUCATION (PAYMENTS)

HAC—HOSPITAL-ACQUIRED CONDITIONS

IPPS—INPATIENT PROSPECTIVE PAYMENT SYSTEM

IRF—INPATIENT REHABILITATION FACILITIES

IRIS—INTERN AND RESIDENT INFORMATION SYSTEM

POA—PRESENT ON ADMISSION

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 Execessive 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 Beneficiearies 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(I)(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

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' implemention 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; oo-oo-oooo; 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

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

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

DME—DURABLE MEDICAL EQUIPMENT
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 Lo631. Medicare beneficiaries receive their Lo631 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 Lo631 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; 00-00-0000; 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

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; oo-oo-ooooo; 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, \S 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; oo-oo-oooo; 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

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 Feb.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 areusually 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

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CAS—Cost Accounting Standards

DME—DURABLE MEDICAL EQUIPMENT

DMEPOS—DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS,

DMERC—DURABLE MEDICAL EQUIPMENT REGIONAL CARRIERS

FAR—FEDERAL ACQUISITION REGULATION

FI—FISCAL INTERMEDIARY

LCD—LOCAL COVERAGE DETERMINATION

MAC—MEDICARE ADMINISTRATIVE CONTRACTOR

MEDIC—MEDICARE DRUG INTEGRITY CONTRACTOR

MSP—MEDICARE SECONDARY PAYER

NSC—National Supplier Clearinghouse

PCA—PROGRESSIVE CORRECTIVE ACTION (PROVIDER EDUCATION AND

TRAINING)

QASP—Quality Assurance Surveillance Plan

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; 00-00-0000; 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

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, \S 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, whichcontains 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 Identifer 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)

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