

Medicare Part A and Part B

Medicare Part A covers certain inpatient services in hospitals and skilled nursing facilities (SNF) and some home health services. Medicare Part B covers designated practitioners' services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover. The Centers for Medicare & Medicaid Services (CMS) uses Medicare Administrative Contractors (MACs) to administer Medicare Part A and Medicare Part B and to process claims for both parts.

The Office of Inspector General (OIG) has identified reducing waste in Medicare Parts A and B and ensuring quality, including in nursing home, hospice care, and home- and community-based care, as top management challenges facing the Department. OIG has focused its efforts on reducing improper payments, improving quality and access, and fostering economical payment policies. Work planning for fiscal year (FY) 2015 and beyond will consider the following:

Quality of Care: Planned work will examine settings in which OIG has identified gaps in program safeguards intended to ensure medical necessity, patient safety, and quality of care. We will also continue our focus on access to care, including beneficiary access to durable medical equipment, prosthetics, orthotics, and supplies in the context of new programs involving competitive bidding.

Appropriate Payments: Planning is ongoing to expand OIG's portfolio examining inefficient payment policies or practices, including comparison among Government programs to identify instances when Medicare paid significantly different amounts for the same or similar services or when less efficient payment methodologies were used. Planning is ongoing for work addressing Medicare costs incurred because of deficiencies in services or defective medical devices, as well as noncompliance or other vulnerabilities in care settings with high payment error rates.

Oversight of Payment and Delivery Reform: Planning is underway to expand OIG's work addressing changes to Medicare programs designed to improve efficiency and quality of care and to promote program integrity and transparency. OIG will consider work examining the transition from volume- to value-based payments and the soundness and effectiveness of the payment structures, care coordination, and administration of these new payment models. Work expected to begin in 2015 and beyond includes examinations of data and metrics to document and measure quality and performance.

Hospitals

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
CoP—conditions of participation (in Medicare)
DRG—diagnosis related group
FTE—full-time-equivalent

GME—graduate medical education
IME—indirect medical education
PPS—prospective payment system
SNF—skilled nursing facility

Hospital-Related Policies and Practices

➤ Reconciliations of outlier payments

We will review Medicare outlier payments to hospitals to determine whether CMS performed necessary reconciliations in a timely manner to enable Medicare contractors to perform final settlement of the hospitals' associated cost reports. We will also determine whether the Medicare contractors referred all hospitals that meet the criteria for outlier reconciliations to CMS. Outliers are additional payments that Medicare provides to hospitals for beneficiaries who incur unusually high costs. CMS reconciles outlier payments on the basis of the most recent cost-to-charge ratio from hospitals' associated cost reports. Outlier payments also may be adjusted to reflect the time value of money for overpayments and underpayments. Without timely reconciliations and final settlements, the cost reports remain open and funds may not be properly returned to the Medicare Trust Fund. (42 CFR, § 412.84(i)(4).) (OAS; W-00-13-35451; W-00-14-35451; various reviews; expected issue date: FY 2015)

➤ New inpatient admission criteria

We will determine the impact of new inpatient admission criteria on hospital billing, Medicare payments, and beneficiary copayments. This review will also determine how billing varied among hospitals in FY 2014. Previous OIG work identified millions of dollars in overpayments to hospitals for short inpatient stays that should have been billed as outpatient stays. Beginning in FY 2014, new criteria state that physicians should admit for inpatient care those beneficiaries who are expected to need at least 2 nights of hospital care (known as the "two midnight policy"). Beneficiaries whose care is expected to last fewer than 2 nights should be treated as outpatients. The criteria represent a substantial change in the way hospitals bill for inpatient and outpatient stays. (OEI; 00-00-00000; expected issue date: FY 2016)

➤ Medicare costs associated with defective medical devices

We will review Medicare claims to identify the costs resulting from additional use of medical services associated with defective medical devices and determine the impact of the cost on the Medicare Trust Fund. CMS has previously expressed concerns about the impact of the cost of replacement devices, including ancillary cost, on Medicare payments for inpatient and outpatient services. (OAS; W-00-13-35516; various reviews; expected issue date: FY 2015)

➤ Analysis of salaries included in hospital cost reports

We will review data from Medicare cost reports and hospitals to identify salary amounts included in operating costs reported to and reimbursed by Medicare. We will determine the potential impact on the Medicare Trust Fund if the amount of employee compensation that could be submitted to Medicare for reimbursement on future cost reports had limits. Employee compensation may be included in allowable provider costs only to the extent that it represents reasonable remuneration for managerial, administrative, professional, and other services related to the operation of the facility and furnished in connection with patient care. (CMS's *Provider Reimbursement Manual*, Part 1, Pub. No. 15-1, Ch. 9 § 902.2.) Medicare does not provide any specific limits on the salary amounts that can be reported on the hospital cost report. (OAS; W-00-14-35713; expected issue date: FY 2015)

➤ Medicare oversight of provider-based status

We will determine the extent to which provider-based facilities meet CMS's criteria. Provider-based status allows facilities owned and operated by hospitals to bill as hospital outpatient departments. Provider-based status can result in higher Medicare payments for services furnished at provider-based facilities and may increase beneficiaries' coinsurance liabilities. In 2011, the Medicare Payment Advisory Commission (MedPAC) expressed concerns about the financial incentives presented by provider-based status and stated that Medicare should seek to pay similar amounts for similar services. (OEI; 04-12-00380; expected issue date: FY 2015)

➤ Comparison of provider-based and free-standing clinics

We will review and compare Medicare payments for physician office visits in provider-based clinics and free-standing clinics to determine the difference in payments made to the clinics for similar procedures and assess the potential impact on the Medicare program of hospitals' claiming provider-based status for such facilities. Provider-based facilities often receive higher payments for some services than do freestanding clinics. The requirements to be met for a facility to be treated as provider based are at 42 CFR § 413.65(d). (OAS; W-00-14-35724; W-00-15-35724; expected issue date: FY 2015)

➤ Critical access hospitals—Payment policy for swing-bed services

We will compare reimbursement for swing-bed services at critical access hospitals (CAHs) to the same level of care obtained at traditional SNFs to determine whether Medicare could achieve cost savings through a more cost effective payment methodology. Swing beds are inpatient beds that can be used interchangeably for either acute care or skilled nursing services. The Balanced Budget Act of 1997 (BBA) created the CAH Program to ensure access to health care services in rural areas. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed CAHs to receive Medicare reimbursement equal to 101 percent of reasonable cost and have up to 25 inpatient beds that could be used for acute care or swing-bed services, with CMS approval. (Social Security Act, § 1814(l).) Neither the BBA nor the MMA established any length-of-stay limits for the use of swing-beds. Unlike CAHs, traditional SNFs are reimbursed under a prospective payment system (PPS) through case-mix, adjusted per-diem prospective payment rates for all SNFs. The payment rates represent payment in full for all costs associated with furnishing covered SNF services to Medicare beneficiaries. (OAS; W-00-12-35101; W-00-13-35101; W-00-14-35101; various reviews; expected issue date: FY 2015)

Hospitals—Billing and Payments

➤ Inpatient claims for mechanical ventilation

We will review Medicare payments for inpatient hospital claims with certain Medicare Severity-Diagnosis Related Group (MS-DRG) assignments that require mechanical ventilation to determine whether hospitals' DRG assignments and resultant Medicare payments were appropriate. Mechanical ventilation is the use of a ventilator or respirator to take over active breathing for a patient. Claims must be completed accurately to be processed correctly and promptly. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, § 80.3.2.2.) For certain DRGs to qualify for Medicare coverage, a patient must receive 96 or more hours of mechanical ventilation. Our review will include claims for beneficiaries who received over 96 hours of mechanical

ventilation. Previous OIG reviews identified improper payments made because hospitals inappropriately billed for beneficiaries who did not receive 96 or more hours of mechanical ventilation. (OAS; W-00-14-35575; various reviews; expected issue date: FY 2015)

➤ Selected inpatient and outpatient billing requirements

We will review Medicare payments to acute care hospitals to determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments. Prior OIG audits, investigations, and inspections have identified areas at risk for noncompliance with Medicare billing requirements. Our review will focus on those hospitals with claims that may be at risk for overpayments. (OAS; W-00-12-35538; W-00-13-35538; W-00-14-35538; W-00-15-35538; various reviews; expected issue date: FY 2015)

➤ Duplicate graduate medical education payments

We will review provider data from CMS's Intern and Resident Information System to determine whether hospitals received duplicate or excessive graduate medical education (GME) payments. We will also assess the effectiveness of IRIS in preventing duplicate payments for GME costs. If duplicate payments were claimed, we will determine which payment was appropriate. Prior OIG reviews have determined that hospitals have received duplicate reimbursement for GME costs. Medicare pays teaching hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs. When payments for DGME and IME costs are being calculated, no intern or resident may be counted by Medicare as more than one full-time-equivalent (FTE) employee. (42 CFR §§ 413.78(b) and 412.105(f)(1)(iii).) The primary purpose of IRIS is to ensure that no intern or resident is counted as more than one FTE. (OAS; W-00-13-35432; various reviews; expected issue date: FY 2015)

➤ Indirect medical education payments

We will review provider data to determine whether hospitals' IME payments were made in accordance with Federal regulations and guidelines. We will determine whether the IME payments were calculated properly. Prior OIG reviews have determined that hospitals have received excess reimbursement for IME costs. Teaching hospitals with residents in approved GME programs receive additional payments for each Medicare discharge to reflect the higher indirect patient care costs of teaching hospitals relative to those of nonteaching hospitals. (42 U.S.C. § 1395ww(d)(5)(B).) The additional payments, known as the IME adjustments, are calculated using the hospital's ratio of resident FTEs to available beds. (OAS; W-00-14-35722; W-00-15-35722; expected issue date: FY 2015)

➤ Outpatient dental claims

We will review Medicare hospital outpatient payments for dental services to determine whether such payments were made in accordance with Medicare requirements. Current OIG audits have indicated that hospitals received Medicare reimbursement for noncovered dental services, resulting in significant overpayments. 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. No. 100-02, ch. 15, § 150). (OAS; W-00-14-35603; various reviews; expected issue date: FY 2015)

➤ **Outpatient evaluation and management services billed at the new-patient rate**

We will review Medicare outpatient payments made to hospitals for evaluation and management (E/M) services for clinic visits billed at the new-patient rate to determine whether they were appropriate and will recommend recovery of overpayments. Preliminary work identified overpayments that occurred because hospitals used new-patient codes when billing for services to established patients. The rate at which Medicare pays for E/M services requires hospitals to identify patients as either new or established, depending on previous encounters with the hospital. According to Federal regulations, the meaning of “new” and “established” pertains to whether the patient has been seen as a registered inpatient or outpatient of the hospital within the past 3 years. (73 Fed. Reg. 68679 (November 18, 2008).) (OAS; W-00-14-35627; expected issue date: FY 2015)

➤ **Nationwide review of cardiac catheterizations and endomyocardial biopsies**

We will review Medicare payments for right heart catheterizations (RHC) and endomyocardial biopsies billed during the same operative session and determine whether hospitals complied with Medicare billing requirements. Previous OIG reviews have identified inappropriate payments when hospitals were paid for separate RHC procedures when the services were already included in payments for endomyocardial biopsies. To be processed correctly and promptly, a bill must be completed accurately. (CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, §80.3.2.2.) (OAS; W-00-14-35721; various reviews; expected issue date: FY 2015)

➤ **Payments for patients diagnosed with kwashiorkor**

We will review Medicare payments made to hospitals for claims that include a diagnosis of kwashiorkor to determine whether the diagnosis is adequately supported by documentation in the medical record. To be processed correctly and promptly, a bill must be completed accurately. (CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 1, §80.3.2.2.) A diagnosis of kwashiorkor on a claim substantially increases the hospitals’ reimbursement from Medicare. Kwashiorkor is a form of severe protein malnutrition that generally affects children living in tropical and subtropical parts of the world during periods of famine or insufficient food supply. It is typically not found in the United States. Prior OIG reviews have identified inappropriate payments to hospitals for claims with a kwashiorkor diagnosis. (OAS; W-00-13-35715; W-00-14-35715; various reviews; expected issue date: FY 2015)

➤ **Bone marrow or stem cell transplants**

We will review Medicare payments to hospitals for bone marrow or stem cell transplants to determine whether the payments were made in accordance with Federal rules and regulations. Bone marrow or peripheral blood stem cell transplantation includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high-dose chemotherapy or radiotherapy before the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. (CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, §90.3.) Bone marrow or stem cell transplants are covered under Medicare only for specific diagnoses. Procedure codes must be accompanied by the diagnosis codes that meet specified coverage criteria. Prior OIG reviews have identified hospitals that have incorrectly billed for bone marrow or stem cell transplants. (OAS; W-00-14-35723; expected issue date: FY 2015)

➤ **Review of hospital wage data used to calculate Medicare payments (new)**

We will review hospital controls over the reporting of wage data used to calculate wage indexes for Medicare payments. Prior OIG wage index work identified hundreds of millions of dollars in incorrectly reported wage data and resulted in policy changes by CMS with regard to how hospitals reported deferred compensation cost. Hospitals must accurately report wage data to CMS annually to develop wage index rates. (Social Security Act, §1886(d)(3) and 1886(d)(3)(E).) (OAS; W-00-14-35725; W-00-15-35725; various reviews; expected issue date: FY 2015)

Hospitals—Quality of Care and Safety

➤ **Participation in projects with quality improvement organizations**

We will determine the extent and nature of hospitals' participation in quality improvement projects with Quality Improvement Organizations (QIOs). We will also determine the extent to which QIOs' quality improvement projects in hospitals overlap with projects offered by other entities. CMS is required to enter into contracts with QIOs, formerly called utilization and quality control peer review organizations. (Social Security Act § 1862 (g).) The purpose of the QIOs is to improve the efficiency, effectiveness, economy, and quality of services delivered to Medicare beneficiaries. Medicare spent about \$1.6 billion for QIOs' recently completed 3-year contract period, and each contract specifies clinical areas for quality improvement projects. (OEI; 01-12-00650; expected issue date: FY 2015)

➤ **Oversight of pharmaceutical compounding**

We will determine the extent to which Medicare's oversight of Medicare-participating acute care hospitals addresses recommended practices for pharmaceutical compounding oversight. Pharmaceutical compounding is the creation of a prescription drug tailored to meet the needs of an individual patient. Most hospitals compound at least some pharmaceuticals onsite. Medicare oversees the safety of pharmaceuticals compounded at Medicare-participating hospitals through the accreditation and certification process. This work is particularly important in view of a 2012 meningitis outbreak resulting from contaminated injections of compounded drugs. (OEI; 01-13-00400; expected issue date: FY 2015)

➤ **Oversight of hospital privileging**

We will determine how hospitals assess medical staff candidates before granting initial privileges, including verification of credentials and review of the National Practitioner Databank. Hospitals that participate in Medicare must have an organized medical staff that operates under bylaws approved by a governing body. (42 CFR § 482.22). A hospital's governing body must ensure that the members of the medical staff, including physicians and other licensed independent practitioners, are accountable for the quality of care provided to patients. Robust hospital privileging programs contribute to patient safety. (OEI; 06-13-00410; expected issue date: FY 2016)

➤ **Inpatient rehabilitation facilities—Adverse events in post-acute care for Medicare beneficiaries**

We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving postacute care in inpatient rehabilitation facilities (IRF). We will also identify factors contributing to these events, determine the extent to which the events were preventable,

and estimate the associated costs to Medicare. IRFs are inpatient facilities that provide intensive rehabilitation therapy to patients recovering from illness, injury, or surgery, typically consisting of at least 3 hours of therapy per day. Upon discharge from the hospital, IRF residents often require extensive services to improve functioning before returning home. IRFs provide 11 percent of postacute facility care and have experienced rapid growth over the last decade. IRF care accounted for \$7 billion in Medicare expenditures in 2011. (OEI; 06-14-00110; expected issue date: FY 2015)

➤ **Long-term-care hospitals—Adverse events in post-acute care for Medicare beneficiaries (new)**

We will estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries receiving care in long-term-care hospitals (LTCHs). We will also identify factors contributing to these events, determine the extent to which the events were preventable, and estimate the associated costs to Medicare. LTCHs are inpatient hospitals that provide long-term care to clinically complex patients, such as those with multiple acute or chronic conditions. Medicare beneficiaries typically enter LTCHs following an acute-care hospital stay to receive intensive rehabilitation and medical care. LTCHs are the third most common type of post-acute care facility after SNFs and independent rehabilitation facilities (IRFs), accounting for nearly 11 percent of Medicare costs for post-acute care (\$5.4 billion in FY 2011). (OEI; 06-14-00530; expected issue date: FY 2015)

Nursing Homes

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services

SNF—skilled nursing facility

➤ **Medicare Part A billing by skilled nursing facilities**

We will describe changes in SNF billing practices from FYs 2011 to 2013. Prior OIG work found that SNFs increasingly billed for the highest level of therapy even though beneficiary characteristics remained largely unchanged. OIG also found that SNFs billed one-quarter of all 2009 claims in error; this erroneous billing resulted in \$1.5 billion in inappropriate Medicare payments. CMS has made substantial changes to how SNFs bill for services for Medicare Part A stays. (OEI; 02-13-00610; various reviews; expected issue date: FY 2015)

➤ **Questionable billing patterns for Part B services during nursing home stays**

We will identify questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to nursing home residents during stays not paid under Part A (for example, stays during which benefits are exhausted or the 3-day prior-inpatient-stay requirement is not met). A series of studies will examine several broad categories of services, such as foot care. Congress directed OIG to monitor Part B billing for abuse during non-Part A stays to ensure that no excessive services are provided. (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, § 313.) (OEI; 06-14-00160; various reviews; expected issue date: FY 2015)

➤ State agency verification of deficiency corrections

We will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. A prior OIG review found that one State survey agency did not always verify that nursing homes corrected deficiencies identified during surveys in accordance with Federal requirements. Federal regulations require nursing homes to submit correction plans to the State survey agency or CMS for deficiencies identified during surveys. (42 CFR § 488.402(d).) CMS requires State survey agencies to verify the correction of identified deficiencies through onsite reviews or by obtaining other evidence of correction. (*State Operations Manual*, Pub. No. 100-07, § 7300.3.) (OAS; W-00-13-35701; W-00-14-35701; various reviews; expected issue date: FY 2015)

➤ Program for national background checks for long-term-care employees

We will review the procedures implemented by participating States for long-term-care facilities or providers to conduct background checks on prospective employees and providers who would have direct access to patients and determine the costs of conducting background checks. We will determine the outcomes of the States' programs and determine whether the programs led to any unintended consequences. Section 6201 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary of Health and Human Services to carry out a nationwide program for States to conduct national and State background checks for prospective direct patient access employees of nursing facilities and other long-term-care providers. The program is administered by CMS. To carry out the nationwide program, CMS has issued solicitations for grant awards. All States, the District of Columbia, and U.S. territories are eligible to be considered for a grant award. OIG is required under the ACA to submit a report to Congress evaluating this program. This mandated work is ongoing and will be issued at the program's conclusion, as required. (ACA, § 6401.) (OEI; 07-10-00420; expected issue date: FY 2015; ACA)

➤ Hospitalizations of nursing home residents for manageable and preventable conditions

We will determine the extent to which Medicare beneficiaries residing in nursing homes are hospitalized as a result of conditions thought to be manageable or preventable in the nursing home setting. A 2013 OIG review found that 25 percent of Medicare beneficiaries were hospitalized for any reason in FY 2011. Hospitalizations of nursing home residents are costly to Medicare and may indicate quality-of-care problems in nursing homes. (OEI; 06-11-00041; expected issue date: FY 2015)

Hospices

Acronyms and Abbreviations for Selected Terms:

ALF—assisted living facility
CMS—Centers for Medicare & Medicaid Services

MedPAC—Medicare Payment Advisory Commission

➤ Hospices in assisted living facilities

We will review the extent to which hospices serve Medicare beneficiaries who reside in assisted living facilities (ALFs). We will determine the length of stay, levels of care received, and common terminal illnesses of beneficiaries who receive hospice care in ALFs. Pursuant to the ACA, § 3132, CMS must reform the hospice payment system, collect data relevant to revising hospice payments, and develop quality measures for hospices. Our work is intended to provide HHS with information relevant to these requirements. Medicare covers hospice services for eligible beneficiaries under Medicare Part A. (Social Security Act, § 1812(a).) Hospice care may be provided to individuals and their families in various settings, including the beneficiary's place of residence, such as an ALF. ALF residents have the longest lengths of stay in hospice care. MedPAC has said that these long stays bear further monitoring and examination. (OEI; 02-14-00070; expected issue date: FY 2015; ACA)

➤ Hospice general inpatient care

We will review the use of hospice general inpatient care. We will assess the appropriateness of hospices' general inpatient care claims and the content of election statements for hospice beneficiaries who receive general inpatient care. We will also review hospice medical records to address concerns that this level of hospice care is being misused. Hospice care is palliative rather than curative. When a beneficiary elects hospice care, the hospice agency assumes the responsibility for medical care related to the beneficiary's terminal illness and related conditions. Federal regulations address Medicare conditions of participation (CoP) for hospices. (42 CFR Part 418.) Beneficiaries may revoke their election of hospice care and return to standard Medicare coverage at any time. (42 CFR § 418.28.) (OEI; 02-10-00491; 02-10-00492; expected issue date: FY 2015)

Home Health Services

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
HHA—home health agency

PPS—prospective payment system

➤ 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. We will determine whether home health claims were paid in accordance with Federal laws and regulations. A prior OIG report found that one in four home health agencies (HHAs) had questionable billing. Further, CMS designated newly enrolling HHAs as high-risk providers, citing their record of fraud, waste, and abuse. Since 2010, nearly \$1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit. Home health services include part-time or intermittent skilled nursing care, as well as other skilled care services, such as physical, occupational, and speech therapy; medical social work; and home health aide services. (OAS; W-00-13-35501; W-00-14-35501; various reviews; expected issue date: FY 2015)

➤ Employment of individuals with criminal convictions

We will determine the extent to which HHAs employed individuals with criminal convictions. We will also examine the criminal convictions of selected employees with potentially disqualifying convictions. Federal law requires that HHAs comply with all applicable State and local laws and regulations. (Social Security Act, §1891(a)(5), implemented at 42 CFR § 484.12(a).) Nearly all States have laws prohibiting certain health-care-related entities from employing individuals with certain types of criminal convictions. (OEI; 07-14-00130; expected issue date: FY 2015)

Medical Equipment and Supplies

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
E/M—evaluation and management (services)

LCD—local coverage determination
PMD—power mobility device

Equipment and Supplies—Policies and Practices

➤ Power mobility devices—Lump-sum purchase versus rental

We will determine whether potential savings can be achieved by Medicare if certain power mobility devices (PMDs) are rented over a 13-month period rather than acquired through a lump-sum purchase. (OAS; W-00-14-35461; expected issue date: FY 2015)

➤ Competitive bidding for medical equipment items and services—Mandatory postaward audit

We will review the process CMS used to conduct competitive bidding and to make subsequent pricing determinations for certain medical equipment items and services in selected competitive bidding areas under rounds 1 and 2 of the competitive bidding program. Federal law requires OIG to conduct postaward audits to assess this process. (Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 154(a)(1)(E).) (OAS; W-00-13-35241; various reviews; expected issued date: FY 2015)

➤ Competitive bidding for diabetes testing supplies—Market share review

We will determine the market share of different types of diabetes test strips for the 3-month period of October through December 2013. MIPPA requires that, in rounds subsequent to the round 1 rebid of the competitive bidding program, contracts for mail order diabetes test strips be awarded to suppliers that provide at least 50 percent, by volume, of all types of diabetic testing strips. CMS requested this study and may use the results for program analysis purposes and for evaluating the effect of the competitive bidding program on test strip choice. (OEI; 04-13-00682; expected issue date: FY 2015)

Equipment and Supplies—Billing and Payments

➤ Power mobility devices—Supplier compliance with payment requirements

We will review Medicare Part B payments for suppliers of PMDs to determine whether such payments were in accordance with Medicare requirements. We will focus particularly on whether PMDs are medically necessary and whether Medicare payments for PMD claims submitted by medical equipment suppliers are supported in accordance with requirements at 42 CFR § 410.38. (OAS; W-00-14-35703; various reviews; expected issue date: FY 2015)

➤ Power mobility devices—Add-on payment for face-to-face examination

We will review Medicare Part B payments for PMDs to determine whether the Medicare requirements for a face-to-face examination were met. Medicare requires that the treating physician, when prescribing a PMD, conduct a face-to-face examination to determine the medical necessity of the PMD and write a prescription for the PMD. (42 CFR § 410.38(c)(2).) To receive compensation for conducting the face-to-face examination, the prescribing physician can bill for an E/M service and has the option of billing Medicare for an add-on payment for the sole purpose of documenting the need for the PMD. Prior OIG work found that when the prescribing physician did not bill the code for the add-on payment in addition to the E/M code, the resulting PMD claim was likely to be unallowable. (OAS; W-00-14-35460; expected issue date: FY 2015)

➤ Lower limb prosthetics—Supplier compliance with payment requirements

We will review Medicare Part B payments for claims submitted by medical equipment suppliers for lower limb prosthetics to determine whether the requirements of CMS's *Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 120, were met. A national OIG review of suppliers of lower limb prosthetics identified 267 suppliers that had questionable billing. Earlier OIG work found that suppliers frequently submitted claims that did not meet certain Medicare requirements; were for beneficiaries with no claims from their referring physicians; and had other questionable billing characteristics (e.g., billing for lower limb prostheses for a high percentage of beneficiaries with no history of amputations or missing limbs). Such claims are questionable and, if determined to be improper, should not be paid by Medicare. Payments to service providers are precluded unless the provider has and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, §1833(e).) Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-13-35702; W-00-14-35702; various reviews; expected issue date: FY 2015)

➤ Nebulizer machines and related drugs—Supplier compliance with payment requirements

We will review Medicare Part B payments for nebulizer machines and related drugs to determine whether medical equipment suppliers' claims for nebulizers and related drugs are medically necessary and are supported in accordance with Medicare requirements. Prior OIG work found that suppliers were overpaid approximately \$46 million for inhalation drugs used with nebulizer machines. Medicare requires that such items be "reasonable and necessary." (Social Security Act § 1862(a)(1)(A).) Further, the local coverage determinations (LCDs) issued by the four Medicare contractors that process medical equipment and supply claims contain utilization guidelines and

documentation requirements. (OAS; W-00-14-35465; W-00-15-35465; expected issue date: FY 2015)

➤ **Frequently replaced supplies—Supplier compliance with medical necessity, frequency, and other requirements**

We will review claims for frequently replaced medical equipment supplies to determine whether medical necessity, frequency, and other Medicare requirements are met. Prior OIG work found that suppliers automatically shipped continuous positive airway pressure system and respiratory-assist device supplies when no physician orders for refills were in effect. Such claims are improper and should not be submitted to Medicare for payment. For supplies and accessories used periodically, orders or certificates of medical necessity must specify the type of supplies needed and the frequency with which they must be replaced, used, or consumed. (CMS's *Medicare Program Integrity Manual*, Pub. 100-08, ch. 5, §§ 2.3 and 5.9.) Beneficiaries or their caregivers must specifically request refills of repetitive services and/or supplies before suppliers dispense them. (CMS's, *Medicare Claims Processing Manual*, Pub. 100-04, ch. 20, § 200.) Suppliers may not initiate refills of orders, and suppliers 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-00-15-35420; various reviews; expected issue date: FY 2015)

➤ **Diabetes testing supplies—Supplier compliance with payment requirements for blood glucose test strips and lancets**

We will review Medicare Part B payments for home blood glucose test strips and lancet supplies to determine their appropriateness. Prior OIG reviews determined that suppliers of diabetic-related supplies did not always comply with Federal requirements. As reflected in the LCDs issued by the Medicare contactors that process medical equipment and supply claims, physicians' orders for items billed to Medicare must include certain elements and be retained by the suppliers to support billing for the services. Suppliers of diabetes testing supplies are required to add a modifier code on the claim 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 service code modifier. Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-12-35407; W-00-14-35407; various reviews; expected issue date: FY 2015)

➤ **Diabetes testing supplies—Effectiveness of system edits to prevent inappropriate payments for blood glucose test strips and lancets to multiple suppliers**

We will review Medicare's claims processing edits (special system controls) designed to prevent payments to multiple suppliers of home blood glucose test strips and lancets and determine whether they are effective in preventing inappropriate payments. Prior OIG work found that inappropriate payments were made to multiple medical equipment suppliers for test strips and lancets dispensed to the same beneficiaries with overlapping service dates. The LCDs issued by the pertinent claims processing contractors state that medical equipment suppliers may not dispense test strips and lancets until beneficiaries have nearly exhausted the previously dispensed supplies. The LCDs also require that beneficiaries or their caregivers specifically request the refills before the

suppliers dispense them. Medicare does not pay for items or services that are not “reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-13-35604; W-00-14-35604; various reviews; expected issue date: FY 2015)

Other Providers and Suppliers

Acronyms and Abbreviations for Selected Terms:

ASC—ambulatory surgical center

CMS—Centers for Medicare & Medicaid Services

ESRD—end-stage renal disease

PHP—partial hospitalization program

PPS—prospective payment system

RHC—rural health clinic

Other Providers—Policies and Practices

➤ Ambulatory surgical centers—Payment system

We will review the appropriateness of Medicare’s methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. We will also determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. A change in Federal law required the Secretary to implement a revised payment system for payment of surgical services furnished in ASCs beginning January 1, 2008. Accordingly, CMS implemented a revised ASC payment system modeled on the Outpatient Prospective Payment System. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), § 626.) (See also 42 CFR § 416.171.) (OAS; W-00-13-35423; W-00-14-35423; various reviews; expected issue date: FY 2015)

➤ End-stage renal disease facilities—Payment system for renal dialysis services and drugs

We will review Medicare payments for and utilization of renal dialysis services and related drugs pursuant to the new bundled end-stage renal disease (ESRD) prospective payment system (PPS). We will compare facilities' acquisition costs for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed. Previous OIG work found that data from the Bureau of Labor Statistics (BLS) did not accurately measure changes in facilities’ acquisition costs for high-dollar ESRD drugs. However, CMS has based the ESRD PPS price updates on wage and price proxy data from BLS. Effective January 1, 2011, Federal law required CMS to begin implementation of 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. (75 Fed. Reg. 49030 at page 49151 (Aug. 12, 2010).) (OAS; W-00-14-35608; various reviews; expected issue date: FY 2015)

Other Providers—Billing and Payments

➤ Ambulance services—Questionable billing, medical necessity, and level of transport

We will examine Medicare claims data to assess the extent of questionable billing for ambulance services, such as transports that potentially never occurred or potentially were medically unnecessary transports to dialysis facilities. We will also determine whether Medicare payments for ambulance services were made in accordance with Medicare requirements. Prior OIG work found that Medicare made inappropriate payments for advanced life support emergency transports. Medicare pays for emergency and nonemergency ambulance services when a beneficiary's medical condition at the time of transport is such that other means of transportation 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; 09-12-00351; 09-12-00353; expected issue date: FY 2015; and OAS; W-00-11-35574; W-00-12-35574; W-00-13-35574; W-00-14-35574; various reviews; expected issue date: FY 2015)

➤ Ambulance services—Portfolio report on Medicare Part B payments

We will analyze and synthesize OIG evaluations, audits, investigations, and compliance guidance related to ground ambulance transport services paid by Medicare Part B to identify vulnerabilities, inefficiencies, and fraud trends and offer recommendations to improve detected vulnerabilities and minimize inappropriate payments for ambulance services. Prior OIG work identified fraud schemes and trends indicating overuse and medically unnecessary payments. The planned portfolio will offer recommendations to address the vulnerabilities that we have identified and improve efficiency. Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Specifically, ambulance services are covered "where the use of other methods of transportation is contraindicated by the individual's condition..." (§ 1861(s)(7).) The *Medicare Benefit Policy Manual*, § 10.2.1, more specifically states that Medicare covers ambulance transports when a beneficiary's medical condition at the time of the transport is such that using other means of transportation would endanger the beneficiary's health. Coverage requirements and requirements for ambulance suppliers are in 42 CFR §§ 410.40 and 41. (OIG; OIG-12-14-02; expected issue date: FY 2016)

➤ Anesthesia services—Payments for personally performed services

We will review Medicare Part B claims for personally performed anesthesia services to determine whether they were supported in accordance with Medicare requirements. We will also determine whether Medicare payments for anesthesia services reported on a claim with the "AA" service code modifier met Medicare requirements. Physicians report the appropriate anesthesia modifier code to denote whether the service was personally performed or medically directed. (CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 12, § 50) Reporting an incorrect service code modifier on the claim as if services were personally performed by an anesthesiologist when they were not will result in Medicare's paying a higher amount. The service code "AA" modifier is used for anesthesia services personally performed by an anesthesiologist, whereas the QK modifier limits payment to 50 percent of the Medicare-allowed amount for personally performed services claimed with the AA modifier. Payments to any service provider are precluded unless the provider has furnished the information necessary to determine the amounts due. (Social Security Act, §1833(e).)

(OAS; W-00-13-35706; W-00-14-35706; W-00-15-35706; various reviews; expected issue date: FY 2015)

➤ **Chiropractic services—Part B payments for noncovered services**

We will review Medicare Part B payments for chiropractic services to determine whether such payments were claimed in accordance with Medicare requirements. Prior OIG work identified inappropriate payments for chiropractic services furnished during calendar year (CY) 2006. Subsequent OIG work (CY 2013) also identified unallowable Medicare payments for chiropractic services. Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if there is a neuro-musculoskeletal condition for which such manipulation is appropriate treatment. (42 CFR § 410.21(b).) Chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. (CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 30.5B.) Medicare will not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) (OAS; W-00-12-35606; W-00-13-35606; W-00-14-35606; various reviews; expected issue date: FY 2015)

➤ **Chiropractic services—Questionable billing**

We will determine and describe the extent of questionable billing for chiropractic services. Previous OIG work has demonstrated a history of vulnerabilities relative to inappropriate payments for chiropractic services, including recent work that identified a chiropractor with a 93-percent claim error rate and inappropriate Medicare payments of about \$700,000. Although chiropractors may submit claims for any number of services, Medicare reimburses claims only for manual manipulations or treatment of subluxations of the spine that provides "a reasonable expectation of recovery or improvement of function." (CMS's *Medicare Benefit Policy Manual*, Pub. No. 100 02, ch. 15, § 240.1.3.) (OEI; 01-14-00200; expected issue date: FY 2015)

➤ **Chiropractic services—Portfolio report on Medicare Part B payments**

We will compile the results of prior OIG audits, evaluations, and investigations of chiropractic services paid by Medicare to identify trends in payment, compliance, and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities. Prior OIG work identified inappropriate payments for chiropractic services that were medically unnecessary, were not documented in accordance with Medicare requirements, or were fraudulent. Medicare does not pay for items or services that are not "reasonable and necessary." (Social Security Act, § 1862(a)(1)(A).) Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if there is a neuro-musculoskeletal condition for which such manipulation is appropriate treatment. (42 CFR § 410.21(b).) CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 30.5, states that chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is therefore not payable. Further, § 240.1.2 of the manual establishes Medicare requirements for documenting chiropractic services. This planned work will offer recommendations to reduce Medicare chiropractic vulnerabilities detected in prior OIG work. (OAS; OIG-12-14-03; expected issue date: FY 2015)

➤ **Diagnostic radiology—Medical necessity of high-cost tests**

We will review Medicare payments for high-cost diagnostic radiology tests to determine whether the tests were medically necessary and to determine the extent to which use has increased for these tests. Medicare will not pay for items or services that are not "reasonable and necessary." (Social

Security Act, § 1862 (a)(1)(A).) (OAS; W-00-13-35454; W-00-14-35454; various reviews; expected issue date: FY 2015)

➤ **Imaging services—Payments for practice expenses**

We will review Medicare Part B payments for imaging services to determine whether they reflect the expenses incurred and whether the utilization rates reflect industry practices. For selected imaging services, we will focus on the practice expense components, including the equipment utilization rate. Practice expenses may include office rent, wages, and equipment. 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 insurance costs, and practice expenses. (Social Security Act, § 1848(c)(1)(B).) (OAS; W-00-13-35219; W-00-14-35219; various reviews; expected issue date: FY 2015)

➤ **Selected independent clinical laboratory billing requirements (new)**

We will review Medicare payments to independent clinical laboratories to determine laboratories' compliance with selected billing requirements. We will use the results of these reviews to identify clinical laboratories that routinely submit improper claims and recommend recovery of overpayments. Prior OIG audits, investigations, and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements. Payments to service providers are precluded unless the provider has and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, §1833(e).) We will focus on independent clinical laboratories with claims that may be at risk for overpayments. (OAS; W-00-14-35726; W-00-15-35726; various reviews; expected issue date: FY 2015)

➤ **Ophthalmologists—Inappropriate and questionable billing**

We will review Medicare claims data to identify potentially inappropriate and questionable billing for ophthalmology services during 2012. We will also determine the locations and specialties of providers with questionable billing. Medicare payments for Part B physician services, which include ophthalmologists, are authorized by the Social Security Act, § 1832(a)(1), and 42 CFR § 410.20. In 2010, Medicare allowed more than \$6.8 billion for services provided by ophthalmologists. (OEI; 04-12-00280; 04-12-00281; expected issue date: FY 2015)

➤ **Physicians—Place-of-service coding errors**

We will review physicians' coding on Medicare Part B claims for services performed in ASCs and hospital outpatient departments to determine whether they properly coded the places of service. Prior OIG reviews determined that physicians did not always correctly code nonfacility places of service on Part B claims submitted to and paid by Medicare contractors. 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 ASC. (OAS; W-00-13-35113; W-00-14-35113; various reviews; expected issue date: FY 2015)

➤ **Physical therapists—High use of outpatient physical therapy services**

We will review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations. Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable or were not properly documented or that the therapy services were not medically necessary. Our focus is on independent therapists who have a high utilization rate for outpatient physical therapy services. Medicare will not pay for items or services that are not “reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) Documentation requirements for therapy services are in CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 220.3. (OAS; W-00-11-35220; W-00-12-35220; W-00-13-35220; W-00-14-35220; W-00-15-35220; various reviews; expected issue date: FY 2015)

➤ **Portable x-ray equipment—Supplier compliance with transportation and setup fee requirements**

We will review Medicare payments for portable x-ray equipment services to determine whether payments were correct and were supported by documentation. We will also assess the qualifications of the technologists who performed the services. Prior OIG work found that Medicare may have improperly paid portable x-ray suppliers for return trips to nursing facilities (i.e., multiple trips to a facility in 1 day). Medicare generally reimburses for portable x-ray services if the conditions for coverage are met. (42 CFR §§ 486.100–486.110.) (OAS; W-00-14-35464; various reviews; expected issue date: FY 2015)

➤ **Sleep disorder clinics—High use of sleep-testing procedures**

We will examine Medicare payments to physicians, hospital outpatient departments, and independent diagnostic testing facilities for sleep-testing procedures to assess the appropriateness of Medicare payments for high-use sleep-testing procedures and determine whether they were in accordance with Medicare requirements. An OIG analysis of CY 2010 Medicare payments for Current Procedural Terminology¹ codes 95810 and 95811, which totaled approximately \$415 million, showed high utilization associated with these sleep-testing procedures. Medicare will not pay for items or services that are not “reasonable and necessary.” (Social Security Act, § 1862(a)(1)(A).) To the extent that repeated diagnostic testing is performed on the same beneficiary and the prior test results are still pertinent, repeated tests may not be reasonable and necessary. Requirements for coverage of sleep tests under Part B are in CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 70. (OAS; W-00-10-35521; W-00-12-35521; W-00-13-35521; W-00-14-35521; various reviews; expected issue date: FY 2015)

¹ The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright [2011] by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

Prescription Drugs

Acronyms and Abbreviations for Selected Terms Used in This Section:

AMP—average manufacturer price

ASP—average sales price

CMS—Centers for Medicare & Medicaid Services

FDA—Food and Drug Administration

LCD—local coverage determination

MAC—Medicare Administrative Contractor

Prescription Drugs—Policies and Practices

➤ Comparison of average sales prices to average manufacturer prices

We will review Medicare Part B drug prices by comparing average sales prices (ASPs) to average manufacturer prices (AMPs) and identify drug prices that exceed a designated threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The enabling law required that OIG compare ASPs with AMPs. (Social Security Act, § 1847A(d)(2)(B).) Pursuant to the requirement, OIG conducts such reviews and issues quarterly and annual reports of its findings. When OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent), OIG notifies the Secretary, who may disregard the ASP for the drug when setting reimbursement amounts (e.g., apply a price substitution policy). (OEI; 03-14-00520; various studies; expected issue date: FY 2015)

➤ Part B payments for drugs purchased under the 340B Program

We will determine how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs. We will calculate the amount by which ASP-based payments exceed 340B prices and estimate potential savings on the basis of various shared-benefit methodologies. Previous OIG work revealed that some Medicaid State agencies have developed strategies to take advantage of the discounts on 340B drugs. The 340B Program requires drug manufacturers to provide discounted outpatient drugs to approximately 10,000 covered entities, including tribal health centers, children’s hospitals, and tuberculosis clinics. Medicare Part B reimburses for almost all covered outpatient drugs (including those purchased by 340B entities) on the basis of the ASP, regardless of the amount paid for the drug. Medicare Part B providers that purchase drugs under the 340B program can fully retain the difference between the ASP-based payment amount and the 340B purchase price. (OEI; 12-14-00030; expected issue date: FY 2015)

Prescription Drugs—Billing and Payments

➤ Payments for immunosuppressive drug claims with KX modifiers

We will determine whether Part B payments for immunosuppressive drugs that were billed with a service code modifier “KX” met Medicare documentation requirements. Medicare claims for immunosuppressive drugs reported with the KX modifier may not always meet documentation requirements for payment under Part B. Medicare Part B covers Food and Drug Administration (FDA)-approved immunosuppressive drugs and drugs used in immunosuppressive therapy when a beneficiary receives an organ transplant for which immunosuppressive therapy is appropriate. (Social Security Act, § 1861(s).) Since July 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary annotate the Medicare claim with the KX modifier to signify that the

supplier retains documentation of the beneficiary's transplant date and that such transplant date preceded the date of service for furnishing the drug. (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 17, § 80.3.) (OAS; W-00-14-35707; W-00-15-35707; various reviews; expected issue date: FY 2015)

➤ Payments for outpatient drugs and administration of the drugs

We will review Medicare outpatient payments to providers for certain drugs (e.g., chemotherapy drugs) and the administration of the drugs 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 *Claims Processing Manual*, Pub. No. 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. (Chapter 5, § 20.2, and ch. 26, § 10.4.) (OAS; W-00-12-35576; W-00-13-35576; W-00-14-35576; various reviews; expected issue date: FY 2015)

Prescription Drugs—Quality of Care and Safety

➤ Covered uses for Medicare Part B drugs

We will review the oversight actions that CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria. We will also identify challenges contractors face when making coverage decisions for drugs. If Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drugs with little clinical evidence of the drugs' safety and effectiveness. Medicare Part B generally covers drugs when they are used to treat conditions approved by FDA, referred to as "on-label" uses. Part B may also cover drugs when an "off-label" use of the drug is supported in major drug compendia or when an off-label use is supported by clinical evidence in authoritative medical literature. (*Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, § 50.4.2.) (OEI; 03-13-00450; expected issue date: FY 2015)

Part A and Part B Contractors

Acronyms and Abbreviations for Selected Terms:

CMS—Centers for Medicare & Medicaid Services
FAR—Federal Acquisition Regulation

PSC—Program Safeguard Contractor
ZPIC—Zone Program Integrity Contractor

Oversight of Contracts

➤ Contract management at the Centers for Medicare & Medicaid Services

We will determine the number, types, and contract value of currently active contracts administered under the Federal Acquisition Regulation (FAR) by CMS. We also will determine the number and total value of FAR contracts that CMS has not closed out as required under FAR and will identify CMS's barriers to managing and closing of FAR contracts. CMS relies extensively on contractors to help it carry out its basic mission, including administration, management, and oversight of its health programs. In FY 2013, CMS obligated \$5.4 billion under contracts for a variety of goods and services. Previous Government Accountability Office (GAO) reports highlighted the vulnerabilities and weaknesses in the contracting environment at CMS, including problems with the contract closeout process. Given the number of contracts and the obligated dollars, oversight and monitoring are vital for ensuring effective programs and safeguarding taxpayer dollars. In addition, timely and effective contract closeouts protect the Government's financial interests and allow for recovery of excess funds. (OEI; 03-12-00680; various expected issue date: FY 2015)

➤ Administrative costs claimed by Medicare contractors

We will review administrative costs claimed by various contractors for their Medicare activities, focusing on costs claimed by terminated contractors. We will also determine whether the costs claimed were reasonable, allocable, and allowable. We will coordinate with CMS regarding the selection of the contractors we will review. Criteria include Appendix B of the Medicare contract with CMS and the FAR at 48 CFR Part 31. (OAS; W-00-13-35005; W-00-14-35005; various reviews; expected issue date: FY 2015)

➤ Executive compensation benchmark

We will review contractor employee salaries charged to Medicare to determine whether the selected contractors applied a senior executive compensation benchmark required by regulation, and we will determine the potential cost savings if contractors were required to apply the same benchmark to all employee compensation. Costs incurred after January 1, 1998, for compensation of a senior executive in excess of the benchmark compensation amount determined applicable for the contractor fiscal year by the Administrator, Office of Federal Procurement Policy (OFPP), under section 39 of the OFPP Act (41 U.S.C. 435) are unallowable. (48 CFR § 31.205-6(p).) We will determine the potential effect of expanding the executive compensation benchmark to all employees. The term "senior executive" is defined as the top five compensated employees of each organizational segment. (48 CFR § 31.205-6(p)(4)(B)(ii).) The issue of high salaries for executives of Government contractors has been examined in the news media. (OAS; W-00-13-35710; various reviews; expected issue date: FY 2015)

➤ Contractor pension cost requirements

We will determine whether Medicare contractors have calculated and claimed reimbursement for Medicare's share of various employee pension costs in accordance with their Medicare contracts and applicable Federal requirements. We will determine whether contractors have fully implemented contract clauses requiring them to determine and separately account for the employee pension assets and liabilities allocable to their contracts with Medicare. We will also review Medicare carriers and fiscal intermediaries (FIs) whose Medicare contracts have been terminated, assess Medicare's share of future pension costs, and determine the amount of excess pension assets as of the closing dates. Applicable requirements are found in the FAR at 48 CFR Subpart 31.2; Cost Accounting Standards (CAS) 412 and 413; and the Medicare contract, Appendix B, § XVI. (OAS; W-00-14-35067; W-00-14-35094; various reviews; expected issue date: FY 2015)

➤ Contractor postretirement benefits and supplemental employee retirement plan costs

We will review the postretirement health benefit costs and the supplemental employee retirement plans of Medicare FIs and carriers to determine the allowability, allocability, and reasonableness of the benefits and plans, as well as the costs charged to Medicare contracts. Criteria are in the FAR at 48 CFR §§ 31.201 through 31.205. (OAS; W-00-13-35095; W-00-14-35095; various reviews; expected issue date: FY 2015)

Contractor Functions and Performance

➤ Medicare benefit integrity contractors' activities

We will review and report the level of benefit integrity activity performed by Medicare benefit integrity contractors in CYs 2012 and 2013. CMS contracts with entities to carry out benefit integrity activities to safeguard the Medicare program against fraud, waste, and abuse. Activities that these contractors perform include analyzing data to identify aberrant billing patterns, conducting fraud investigations, responding to requests for information from law enforcement, and referring suspected cases of fraud to law enforcement for prosecution. Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs) carry out benefit integrity activities for Medicare Parts A and B, and a Medicare Drug Integrity Contractor (MEDIC) carries out benefit integrity activities for Medicare Parts C and D. (OEI; 03-13-00620; expected issue date: FY 2015)

➤ ZPICs and PSCs—Identification and collection status of Medicare overpayments

We will determine the total amount of overpayments that ZPICs and PSCs identified and referred to claims processors in 2013 and the amount of these overpayments that claims processors collected. We will also review the procedures for tracking collections on overpayments identified by ZPICs and PSCs. OIG has issued several reports regarding the tracking and collection of the overpayments that Medicare's contractors have made to providers. In response, CMS stated that it has added reporting requirements that would improve overpayment tracking among the claims processors and ZPICs and PSCs. ZPICs and PSCs are required to detect and deter fraud and abuse in Medicare Part A and/or Part B in their jurisdictions. They conduct investigations; refer cases to law enforcement; and take administrative actions, such as referring overpayments to claims processors for collection and return to the Medicare program. (OEI; 03-13-00630; expected issue date: FY 2015)

Information Technology Security, Protected Health Information, and Data Accuracy

➤ Medicare contractor information systems security programs—Annual report to Congress

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 their results. 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-00-14-41010; W-00-15-41010; expected issue date: FY 2015)

➤ Controls over networked medical devices at hospitals

We will examine whether CMS oversight of hospitals' security controls over networked medical devices is sufficient to effectively protect associated electronic protected health information (ePHI) and ensure beneficiary safety. Computerized medical devices, such as dialysis machines, radiology systems, and medication dispensing systems that are integrated with electronic medical records (EMRs) and the larger health network, pose a growing threat to the security and privacy of personal health information. Such medical devices use hardware, software, and networks to monitor a patient's medical status and transmit and receive related data using wired or wireless communications. To participate in Medicare, providers such as hospitals are required to secure medical records and patient information, including ePHI. (42 CFR § 482.24(b).) Medical device manufacturers provide Manufacturer Disclosure Statement for Medical Device Security (MDS2) forms to assist health care providers in assessing the vulnerability and risks associated with ePHI that is transmitted or maintained by a medical device. (OAS; W-00-15-42020; various reviews; expected issue date: FY 2015)

Other Part A and Part B Program Management Issues

Provider Eligibility

➤ Enhanced enrollment screening process for Medicare providers

We will determine the extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for Medicare providers pursuant to the ACA, § 6401. We will also collect data on and report the number of initial enrollments and enrollment revalidations approved and denied by CMS before and after the implementation of the enhanced screening procedures. As part of an effort to prevent fraud, waste, and abuse resulting from vulnerabilities in the Medicare enrollment process, CMS is implementing new authorities that include site visits, fingerprinting, and background checks, as well as an automated provider screening process. (OEI; 03-13-00050; expected issue date: FY 2015; ACA.)

New Models

➤ Risk Assessment of CMS' administration of the Pioneer Accountable Care Organization Model (new)

We will conduct a risk assessment of the Pioneer Accountable Care Organization (ACO) Model. An ACO is a group of providers and suppliers of services (e.g., hospitals and physicians and others involved in patient care) that will work together to coordinate care for the Medicare fee-for-service beneficiaries they serve. The Centers for Medicare & Medicaid Innovation was created to test innovative care and service delivery models and is administering the Pioneer ACO Model. (ACA, § 3021.) We will conduct a risk assessment of internal controls over administration of the Pioneer ACO Model. (OAS; W-00-00-00000; expected issue date: FY 2015; ACA)