Work Plan Part II:
Medicare Part C and Part D

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Note: Selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

Medicare Part C
(Medicare Advantage)

Beneficiaries must be enrolled in both Part A and Part B to join one of the Part C Medicare Advantage (MA) plans, which are administered by MA organizations. MA organizations are public or private organizations licensed by States as risk-bearing entities that are under contract with the Centers for Medicare & Medicaid Services (CMS) to provide covered services. MA organizations may offer one or more plans. The plans provide all Part A and Part B services and generally provide additional services not covered by traditional Medicare. Beneficiaries usually pay monthly premiums and copayments that likely will be less than the coinsurance and deductibles under the original Medicare Parts A and B. In most cases, these plans also offer Part D prescription drug coverage. Costs and benefits vary by plan. Descriptions of our continuing and planned reviews of Medicare Part C in fiscal year (FY) 2011 follow.

Enhanced Payments for Certain Beneficiary Types

We will review the appropriateness of Medicare Part C reimbursement for beneficiaries classified as institutionalized, end stage renal disease (ESRD), or Medicaid eligible. Pursuant to the Social Security Act, § 1853(a)(1)(c), CMS adjusts the payment to MA organizations for risk factors, including disability status, institutional status, and such other factors as deemed appropriate. We will determine the impact of inaccurate or invalid classification of beneficiaries on Medicare payments to MA plans.

(OAS; W-00-09-35227; W-00-11-35227; various reviews; expected issue date: FY 2011; work in progress)

Medicare Advantage Payments for Medicare Part D Drugs on Behalf of Institutionalized Beneficiaries

We will review the extent to which Medicare Part D paid for drugs that should have been covered under Medicare Part C in 2008. Under Medicare Part C, CMS contracts with MA plans to provide managed health care coverage to Medicare enrollees, including all Part A and Part B services and some drugs that the MA plan negotiates as part of its Part C bid. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), Medicare Part D coverage does not extend to drugs covered under Part A and Part B, including drugs for beneficiaries in Part A skilled nursing facility (SNF) stays. The Code of Federal Regulations (CFR) at 42 CFR § 409.25 provides that these drugs are generally covered under Part A. We will match Part D payment data for institutionalized beneficiaries against Part C negotiated drug information between MA plans and CMS to determine whether Medicare Part D paid for drugs that should have been covered under Part C payments to the MA plans. Matches in the data will represent potential duplicate payments.

(OAS; W-00-11-35550; various reviews; expected issue date: FY 2012; new start)

Enrollment of Medicare Beneficiaries With Chronic Conditions Into Special Needs Plans

We will review MA-Special Needs Plans' (SNP) compliance with chronic condition enrollment requirements. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 164, instituted additional restrictions and oversight on C-SNPs by requiring them to restrict enrollment to chronic or disabling conditions. The Secretary identified 15 conditions for 2010 that meet the MIPPA's requirement of being severe or disabling and needing specialized care management. We will also assess CMS oversight of C-SNP enrollment practices.
(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Eligibility Requirements for Medicare Advantage Plans for Special Needs Individuals

We will review MA-SNP processes for enrolling beneficiaries in Medicare managed care plans. SNPs exclusively enroll special needs individuals in accordance with Federal regulations at 42 CFR §§ 422.4(a)(1)(iv) and 422.52. Congress created SNPs as a new type of Medicare managed care plan focused on certain vulnerable groups of Medicare beneficiaries: those who are institutionalized, determined to be dual-eligibles, and beneficiaries who have severe or disabling chronic conditions. These beneficiaries are typically older, with multiple comorbid conditions, and thus are more challenging and costly to treat. The Medicare program typically pays more per beneficiary enrolled in a SNP than for a beneficiary enrolled in an FFS Medicare or other MA plan. The Secretary identified 15 conditions for 2010 that meet the statutory requirement of being severe or disabling and needing specialized care management. We will determine whether SNPs complied with MA eligibility requirements. We will also assess CMS oversight of MA-SNP enrollment practices.
(OAS; W-00-11-35551; various reviews; expected issue date: FY 2011; new start.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

Duplicate Fee-for-Service Billings for Beneficiaries Enrolled in Medicare Advantage

We will determine whether Medicare Administrative Contractors (MAC) and/or fiscal intermediaries (FI) improperly reimbursed providers for inpatient hospital services provided to beneficiaries enrolled in MA plans. For beneficiaries enrolled in MA plans, Medicare makes payments directly to the plans. The managed care plans are to arrange and pay for all necessary medical services. Pursuant to Federal regulations at 42 CFR § 412.20(e)(3) inpatient hospital services should not be paid on a fee-for-service (FFS) basis on behalf of Medicare beneficiaries enrolled in an MA plan. We will determine whether the MACs and FIs complied with Federal regulations in making FFS payments to hospitals for inpatient services furnished to MA plan beneficiaries.
(OAS; W-00-11-35552; various reviews; expected issue date: FY 2011; new start)

Duplicate Medicare Payments to Cost-Based Health Maintenance Organization Plans

We will identify duplicate Medicare capitation and FFS payments to selected cost-based Health Maintenance Organization (HMO) plans. Governing Federal regulations for costs claimed for

Medicare payments to cost-based HMO plans are at 42 CFR pt. 417, subpart O, and CMS's *Medicare Managed Care Manual*, Pub. 100-16 ch. 17, subchapter B. Generally, under capitation agreements, health care providers are paid for services furnished to a cost plan's Medicare enrollees through monthly per capita payments from the cost plan. Accordingly, any Medicare FFS billings that the capitated providers submit for services provided to the cost plan's Medicare enrollees will result in duplicate payments to the providers.
(OAS; W-00-11-35553; various reviews; expected issue date: FY 2011; new start)

Medicare Advantage Plans and Durable Medical Equipment

We will review MA plans' oversight of contractors that provide durable medical equipment (DME) services to enrollees. The Social Security Act, § 1834(a), and Federal regulations at 42 CFR pt. 414, subpart. D, allows Medicare coverage of medically necessary DME that is prescribed by a physician and furnished to enrollees. DME is part of the basic Medicare-covered services that MA plans provide, mostly by subcontracting with DME suppliers. We will determine the effectiveness of MA plans' controls over the selection of suppliers, assessing medical need for DME, and validating service delivery to prevent fraud, waste, and abuse for payments to DME suppliers servicing MA enrollees.
(OAS; W-00-10-35515; W-00-11-35515; various reviews; expected issue date: FY 2011; work in progress)

Investment Income Earned by Medicare Advantage Plans

We will review the effect of using computations that include income earned by MA organizations from their investments of current Medicare funds. Pursuant to the Social Security Act, § 1854, MA organizations are required to provide additional services in an amount equal to any excess amount remaining in their plans for the contract year and to return any remaining funds to the Medicare trust fund. However, neither the Social Security Act nor Federal regulations require MA organizations to include investment income earned on monthly capitation payments before their expenditure in developing the benefit packages or calculating the excess for the purposes of section 1854. In responding to prior Office of Inspector General (OIG) audits, CMS has agreed that policies and procedures are needed to ensure that investment income funds are used to benefit Medicare enrollees, but no such requirement has been implemented. We will determine the financial impact of requiring MA organizations to factor investment income earned on current Medicare funds in computing the annual bid proposal for estimated revenues needed to provide the Medicare benefit package. We will also determine the impact of investment income in computing additional benefits and Medicare payments.
(OAS; W-00-10-35426; various reviews; expected issue date: FY 2011; work in progress)

Disenrollments From Medicare Advantage Plans

We will review the financial impact on the Medicare program when beneficiaries disenroll from MA plans. A previous OIG review showed that under Medicare FFS, the costs of providing medical services to disenrollees increased by about 800 percent in the first 6 months

after disenrollment. Following our work, CMS initiated various election periods that limit the windows of opportunity for enrollees to disenroll from MA plans. We will examine the cost of providing health services in the FFS and managed care arenas for Medicare beneficiaries who were enrolled in MA plans and subsequently disenrolled during 2004–2007. We will also review MA plans' compliance with the election of coverage periods.
(OAS; W-00-11-35427; various reviews; expected issue date: FY 2011; work in progress)

Managed Care Encounter Data

We will review the accuracy of Part A encounter data for Medicare beneficiaries' contacts with MA plans for health care services related to one or more medical conditions. All MA plans are required to submit these data for CMS's use in developing a portion of each organization's monthly capitation rate. CMS's *Medicare Managed Care Manual*, Pub. No. 100-16, ch. 7, §§ 110 and 111, requires that medical records substantiate all diagnostic information provided in the encounter data to CMS. The portion of the monthly rate that relates to the encounter data is the risk-adjusted portion, which represents 10 percent of the rate in 2003. Risk adjustments are processes that minimize financial incentives that MA plans may have to select healthier-than-average enrollees. The risk-adjusted portion increased to 50 percent in 2005 and 75 percent in 2006; it will eventually be 100 percent of the monthly rate. Thus, incorrect or incomplete encounter data could affect future Medicare reimbursement significantly.
(OAS; W-00-09-35078; W-00-10-35078; W-00-11-35078; various reviews; expected issue date: FY 2011; work in progress)

Medicare Advantage Risk Adjustment Data Validation

We will determine whether CMS adjusted payments to MA plans in accordance with Federal regulations at 42 CFR §§ 422.308(c) and 422.310(e) based on the results of their data validation reviews. Risk adjustment data validation is an annual process of verifying diagnosis codes; the process affects payments to MA plans. CMS contracts with Quality Improvement Organizations (QIO) (or QIO-equivalent contractors) to verify whether diagnosis codes are supported by medical record documentation. We will review the CMS contractors' calendar year (CY) 2007 data validation results and determine whether CMS appropriately adjusted payments.
(OAS; W-00-11-35554; various reviews; expected issue date: FY 2012; new start)

Credentialing by Medicare Advantage Plan Sponsors

We will reiew the extent to which MA plan sponsors have contracted with providers that are not qualified or are ineligible to participate in the Medicare program. Regulations at 42 CFR § 422.204, requires MA plan sponsors to credential providers with whom they contract. The credentialing process should include verification of licensure, education or certification, and eligibility for payment under Medicare. We will also examine the processes that MA plan sponsors have in place to ensure that only qualified and eligible providers are allowed into their plans.
(OEI; 00-00-00000; expected issue date: FY 2011; work in progress)

Medicare Advantage Plans' Oversight of Contractors

We will review MA plans' oversight of contractors that provide enrollees various benefits, such as prescription drugs and mental health services. MA plans are accountable for the performance of related entities, subcontractors, and first-tier and downstream entities. Pursuant to Federal regulations at 42 CFR § 422.504(i)(4), MA organizations that delegate responsibilities under their contracts with CMS to other entities must include in their contracts with those entities provisions specifying that the entities must comply with all applicable Medicare laws, regulations, and CMS instructions. We will determine the extent to which MA plans oversee and monitor their contractors' compliance with 42 CFR § 422.504 and examine the processes that they use to ensure that contractors fulfill their contractual obligations.
(OEI; 00-00-00000; expected issue date: FY 2012, new start)

Oversight of CMS's Medicare Advantage Bid Review Process

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

Medicare Advantage Plans' Identification of Potential Fraud and Abuse

We will review the extent to which potential fraud and abuse incidents were identified and addressed by MA plan sponsors in 2009. Pursuant to regulations at 42 CFR § 422.503, each MA plan sponsor is required to have a compliance plan that includes measures to detect, correct, and prevent fraud, waste, and abuse. Previous OIG work found that 28 percent of stand-alone Part D sponsors did not identify any potential fraud and abuse incidents in 2007. We will also determine whether MA plan sponsors conducted inquiries, initiated corrective actions, or referred for further investigation incidents with potential for fraud and abuse.
(*OEI; 03-10-00310; expected issue date: FY2011; work in progress*)

Medicare Advantage Organizations' Reporting Requirements

We will review Medicare Advantage Organizations' (MAOs) compliance with CMS's reporting requirements for plan year 2009. Pursuant to regulations at 42 CFR 422.516(a), CMS requires MAOs to develop, compile, evaluate, and report certain information to CMS and others. The information is necessary for CMS to assess and report on MAOs' operations, costs, availability and utilization of services. In the past, CMS has been unable to complete such assessments and reports because of lack of data. We will also review CMS's oversight of MAOs' reporting requirements and the actions CMS has taken to enforce reporting requirements.
(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Medicare Part D
(Prescription Drug Program)

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

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

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

Duplicate Drug Claims for Hospice Beneficiaries

We will review the appropriateness of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D. Pursuant to its *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 11, § 30.2, CMS publishes the hospice payment rates, which include prescription drugs (used for pain relief and symptom control) related to the beneficiary's terminal illness. Hospice providers are paid per diem amounts, which include payments for these drugs. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), a drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. Therefore, Medicare Part D drug plans should not pay for drugs that are covered under the Part A hospice benefit. We will determine whether payments under Part D are correct, are supported, and are not duplicated in hospice per diem amounts. We will also determine the extent of duplication between Part D payments and Part A hospice payments and identify controls to prevent duplicate drug payments.
(OAS; W-00-10-35307; W-00-11-35307; various reviews; expected issue date: FY 2011; work in progress)

Medicare Part D Claims Duplicated in Part A and Part B

We will review Medicare Part D claims to determine whether they were duplicated in Part A or Part B. Pursuant to the Social Security Act, § 1860D-2(e)(2)(B), a drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. Medicare Part A covers drugs for beneficiaries who are

receiving treatments as hospital inpatients. Drugs covered under Medicare Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with DME, and some vaccines. Medicare Part A and Part B do not cover most outpatient prescription drugs that may be covered under Part D. We will also determine the extent to which payments for the sampled Part D claims were correct and supported.
(OAS; W-00-11-35409; various reviews; expected issue date: FY 2011; new start)

Part D Billing in 2009

We will review Part D drugs billed in 2009 to identify characteristics of associated pharmacies, prescribers, and beneficiaries. Pursuant to the Social Security Act, § 1860(D)-15(f)(1), drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans, and the Department of Health & Human Services (HHS) has the right to inspect and audit the sponsors' records pertaining to the information. We will also identify the pharmacies, prescribers, and beneficiaries associated with atypically high billing and determine what, if any, characteristics they have in common.
(OEI; 02-09-00600; expected issue date: FY 2011; work in progress)

Aberrant Part D Claims

We will review Medicare Part D claims to identify aberrant claims (those that deviate from the usual patterns) and determine how they relate to pharmacies, physicians, and/or beneficiaries. We will determine whether Part D sponsors are appropriately processing Medicare Part D claims for Schedule II drugs (drugs with an accepted medical use and a high potential for abuse and dependency). Pursuant to the Social Security Act, § 1860(D)-15(f)(1), sponsors must submit the information necessary for the Secretary to determine payments to the plans, and HHS has the right to inspect and audit the sponsors' records pertaining to the information.
(OAS; W-00-10-35411; W-00-11-35411; various reviews; expected issue date: FY 2011; work in progress)

Excluded Category of Drugs in Part D

We will review prescription drug event (PDE) data to determine the extent to which sponsors submitted data for drugs used for the treatment of sexual dysfunction or erectile dysfunction (ED) in Part D drug claims. Pursuant to the Social Security Act § 1860D-2(e), Part D drugs do not include those used for the treatment of sexual dysfunction or ED that are excluded from coverage under Part D. CMS's *Medicare Prescription Drug Manual*, Pub. 100-18, ch. 6, § 20.1, says that ED drugs meet the definition of a Part D drug when prescribed for medically accepted indications approved by the Food and Drug Administration (FDA) other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label. Part D claims for these drugs could indicate a lack of edits in place at sponsors that would identify this particular excluded category of drugs.
(OAS; W-00-10-35525; W-00-11-35525; various reviews; expected issue date: FY 2011; work in progress)

Off-Formulary Drugs in Part D

We will review PDE data to determine the extent to which selected sponsors submitted data for drugs that were not included on their approved Part D formularies. Federal regulations at 42 CFR § 423.100 define a "covered Part D drug" as one that is included in a plan's formulary or treated as being included in a plan's formulary as a result of a coverage determination or appeal. We will examine Part D payment data and CMS-approved Part D formularies to determine whether costs submitted by sponsors were for drugs that were not included in their approved formularies.

(OAS; W-00-11-35560; various reviews; expected issue date: FY 2011; new start)

True Out-of-Pocket Costs for Part D

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

(OAS; W-00-11-35234; various reviews; expected issue date: FY 2011; new start)

Safety and Effectiveness of Part D Drugs

We will review whether the drugs used in the Part D program were previously found to be safe and effective by FDA in accordance with statute (21 United States Code (U.S.C.) § 355). To ensure that drugs are safe and effective, FDA requires that drugs used by the public be approved and registered. As part of a safety initiative, CMS instituted a policy effective January 1, 2010, to ensure that Part D beneficiaries receive only drugs that are properly registered with FDA. We will determine whether Part D beneficiaries were dispensed drugs that FDA had deemed safe and effective.

(OAS; W-00-11-35561; various reviews; expected issue date: FY 2011; new start)

Administrative Costs Included in Bid Submissions

We will review the appropriateness of Part D sponsors' documentation supporting administrative costs included in their annual bid proposals to CMS. The Social Security Act, § 1860D-11(b), and regulations at 42 CFR § 423.265(c)(1) require that Part D sponsors submit bids for the costs of providing prescription drug coverage, including administrative costs. Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums.

(OAS; W-00-11-35506; various reviews; expected issue date: FY 2011; new start)

Part D Sponsors' Audits of Pharmacies

We will review the process that Part D sponsors and their pharmacy benefit managers (PBM) use in auditing pharmacies. These audits are needed to validate payments by the sponsors to

pharmacies; the contracts between pharmacies and sponsors generally allow for these audits. We will identify amounts recouped from the pharmacies and ensure that the amounts have been properly reported as overpayments to CMS. The Medicare Part D Reporting Requirements for Contract Year 2008, section XI, "Overpayments," says: "Part D Sponsors will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D Sponsor erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit." We will determine whether recoveries by Part D sponsors or their PBMs are properly accounted for. We will also review the extent to which pharmacy audits focus on uncovering fraud, waste, and abuse versus program noncompliance.
(OAS; W-00-11-35235; various reviews; expected issue date: FY 2011; new start) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

Part D Risk Adjustment Data Validation

We will review the accuracy of data supporting diagnosis codes submitted by MA prescription drug organizations (MA-PD) that determined the final RxHCC (prescription drug model used for payment under Part D) risk scores assigned to beneficiaries. We will also review CMS risk-adjusted payments to MA-PDs as a result of the assigned risk scores. In 2006, CMS adopted the RxHCC model to calculate the risk scores of all Medicare beneficiaries eligible for Part D. As an incentive to MA-PDs to accept less healthy and higher risk beneficiaries, CMS uses a risk-adjusted payment methodology (described generally in regulations at 42 CFR § 423.329(b)) to pay a higher monthly subsidy for beneficiaries diagnosed as less healthy. The collection of medical records/diagnoses from the appropriate sources, i.e., hospital inpatient facilities, hospital outpatient facilities, and physicians, is critical in determining the appropriate diagnosis codes for accurate risk-adjusted RxHCC scores assigned to beneficiaries and determining the accurate monthly payments to MA-PDs. Federal regulations at 42 CFR §§ 422.310(b) and 423.329(b)(3)(ii) require MA organizations that offer MA-PD plans to submit to CMS the risk adjustment data that they must obtain from the providers or other practitioners that provided the service. We will determine the validity of diagnosis codes submitted by MA-PDs and the accuracy of the resultant monthly payments to MA-PDs.
(OAS; W-00-11-35540; various reviews; expected issue date: FY 2011; new start)

Medicare Part D Risk Corridors

We will review the financial impact of risk corridors on the Part D program. The MMA requires the Federal Government to share with sponsors a portion of any unexpected Part D profits and losses. Risk corridors determine the amount of unexpected profits or losses that the Federal Government and sponsors share. Pursuant to the Social Security Act § 1860D-15, CMS has the legal authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. Previous OIG reports found that in 2007 and 2008, many Part D sponsors had profits large enough to trigger risk sharing. We will analyze risk-sharing payments between the Government and Part D sponsors for plan years 2006 to 2009. We will also determine whether

there is potential for cost savings if the existing risk corridor thresholds are retained. *(OEI; 00-00-00000; expected issue date: FY 2012; new start)*

Investment Income Earned by Part D Plans

We will review the appropriateness of Part D sponsors' documentation supporting investment income included in their annual bid proposals to CMS. Pursuant to Federal regulations at 42 CFR § 423.265(c)(1), Part D sponsors are required to submit bids for the costs of providing prescription drug coverage, including returns on investment and profits. Sponsors' bids are the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. *(OAS; W-00-11-35507; various reviews; expected issue date: FY 2011; new start)*

Part D Pharmaceutical Manufacturer Rebates

We will review contracted pharmaceutical manufacturer rebates collected by Part D sponsors and PBMs. Regulations at 42 CFR pt. 423, subpart G, calculate Part D reinsurance and risk-corridor payments on the basis of amounts actually paid by the Part D sponsors, net of direct or indirect remunerations (DIR). DIR includes all rebates, subsidies, and other price concessions from sources (including but not limited to manufacturers and pharmacies) that serve to decrease the costs incurred by Part D sponsors for Part D drugs. The term "risk corridor" relates to triggers that are set to protect prescription drug plans from unexpected losses and that allow the Government to share in unexpected gains. In its guidance on reporting requirements, CMS requires that Part D sponsors submit DIR reports for use in the Part D payment reconciliation process. We will identify rebate amounts negotiated between Part D sponsors/PBMs and pharmaceutical manufacturers, compare them with the actual rebates paid, and analyze any discrepancies.
(OAS; W-00-09-35508; W-00-10-35508; various reviews; expected issue date: FY 2011; work in progress)

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

We will review drug costs for specific Part D-covered drugs on PDE records to determine whether contracted prices between pharmacies and Part D sponsors were accurately reflected. Sponsors contract with pharmacies to dispense drugs to eligible Medicare beneficiaries and pay negotiated rates for drugs dispensed to these beneficiaries. The Social Security Act, § 1860D-4(b), says that "A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan." We will also review contracts between sponsors and pharmacies and PDE records to determine the extent to which sponsors and the Federal Government have benefited from retail discount generic programs.
(OAS; W-00-10-35510; W-00-11-35510; various reviews; expected issue date: FY 2011; work in progress)

Part D and Medicaid Prescription Drug Prices

We will review prices paid by Medicare Part D plans and State Medicaid agencies for 200 high-volume prescription drugs. The Patient Protection and Affordable Care Act

of 2010 (Affordable Care Act), § 3313, requires that OIG conduct such a review by October 1, 2011. With the creation of Part D, dual-eligible beneficiaries had their drug coverage transitioned from Medicaid to Part D. We will compare prices paid under the programs (including discounts and rebates) and assess the impact of any price discrepancies on the Federal Government and beneficiaries.
(OEI; 03-10-00320; expected issue date: FY 2011; work in progress)

340B Drug Pricing in the Medicare Part D Program

We will review whether Part D sponsors are including in the remuneration information that they provide to CMS any savings received because their network pharmacies are part of the 340B Drug Pricing Program (340B). Federal regulations at 42 CFR § 423.265 say that a prescription drug plan (PDP) sponsor's bid must include the costs for which the plan is responsible in providing basic and supplemental benefits. Section 340B limits the cost of covered outpatient drugs to certain Federal grantees, federally qualified health center look-alikes, and qualified disproportionate share hospitals (DSH). We will determine whether any applicable savings related to the 340B program received by Part D sponsors are shared with the Federal Government.
(OAS; W-00-11-35562; various reviews; expected issue date: FY 2011; new start)

Audits of Medicare Prescription Drug Plan Sponsors

We will review the extent to which CMS completed seven types of audits of stand-alone prescription drug plans from January 2006 through December 2009 and the types and numbers of problems identified through the audits. The seven audit types are auto-enrollment readiness, benefit integrity, bid, compliance plan, long-term-care pharmacy contract, pharmacy access, and program. CMS conducts these audits as part of its oversight of the Part D program. The Social Security Act, § 1860D-12(b)(3)(C), governs audit authority for Part D. We will also determine what actions CMS took to follow up with PDP sponsors about problems identified.
(OEI; 03-09-00330; expected issue date: FY 2011; work in progress)

Audits of Part D Sponsors' Financial Records

We will review CMS's audits of Part D sponsors' financial records to determine whether they were conducted in accordance with Federal regulations. The Social Security Act, § 1860D-12(b)(3)(c), and Federal regulations at 42 CFR § 423.504(d)(1) require that CMS annually audit financial records (including but not limited to data relating to Medicare utilization and costs, including allowable reinsurance and risk-corridor costs, low-income subsidies, and other costs of at least one-third of Part D sponsors offering plans). We will determine whether CMS has met Federal regulations in conducting Part D audits. We will also examine CMS's audit guide, the timeliness of its audits, and actions taken to address audit findings. This review is part of a series of OIG reviews examining CMS performance of required Part D program, bid, financial, and compliance audits.
(OAS; W-00-10-35511; various reviews; expected issue date: FY 2011; work in progress)

Medicare Part D Sponsors' Internal Controls for Fraud, Waste, and Abuse

We will review the reliability of Medicare Part D sponsors' internal controls to guard against fraud, waste, and abuse. The MMA added a requirement in the Social Security Act, § 1864D-4(c), that Part D sponsors have programs to control fraud, waste, and abuse. Federal regulations at 42 CFR § 423.504(b)(4)(vi)(H) require Part D sponsors to have in place compliance plans that include comprehensive methods to detect, correct, and prevent fraud, waste, and abuse. CMS issued additional guidance to Part D sponsors in its *Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, that provides interpretive rules and guidelines for Part D sponsors for implementing the requirements at 42 CFR § 423.504(b)(4)(vi)(H).
(OAS; W-00-11-35512; various reviews; expected issue date: FY 2011; new start)

Medicare Prescription Drug Sponsors' Training on Fraud, Waste, and Abuse

We will review the extent to which Part D sponsors developed and provided Part D fraud, waste, and abuse training for their network pharmacies in 2009. As a condition for contracting with CMS to offer Part D benefits, plan sponsors must have compliance plans that meet specific elements outlined in regulations at 42 CFR §423.504(b)(4). We will determine the extent to which the training's content reflected CMS guidance and the way in which sponsors and network pharmacies measure the effectiveness of the training in preventing, detecting, and responding to potential fraud, waste, and abuse.
(OEI; 01-10-00060; expected issue date: FY 2011; work in progress)

Medicare Drug Integrity Contractors' Performance Evaluation Reports

We will review the evaluation reports that CMS produces to assess the performance of Medicare Drug Integrity Contractors (MEDIC). CMS contracts with MEDICs to support CMS's audit, oversight, and antifraud and abuse efforts associated with Part D. Regulations at 48 CFR § 42.1502(a) require that CMS conduct an annual performance evaluation of each MEDIC and use the evaluations to make decisions about task order renewal. We will describe the type and extent of information provided in performance evaluation reports and determine whether the performance evaluation reports were issued on time.
(OEI; 00-00-00000; expected issue date: FY 2011; new start)

Pharmacy and Therapeutics Committee Conflicts of Interest

We will review the number and nature of Part D Pharmacy and Therapeutics (P&T) committees' disclosed potential conflicts of interest. Pursuant to 42 CFR § 423.120(b)(1), sponsors using formularies must have P&T committees that select the drugs on sponsors' formularies and determine cost sharing, prior authorization, quantity limits, generic substitution, and other issues affecting drug access. The P&T committee must have at least one physician and one pharmacist who are free of conflicts of interest. We will also describe the extent to which CMS oversees P&T committees' conflicts of interest.
(OEI; 05-10-00450; expected issue date: FY 2011; work in progress)

Medicare Part D Formulary Discrepancies

We will review the extent to which Part D sponsors' formularies listed on their Web sites reflect their most current, approved formularies. Pursuant to Federal regulations at 42 CFR § 423.128, sponsors must provide to their enrollees a list of drugs included on their formularies at the time of enrollment and at least annually thereafter. The regulations also require that a sponsor's Web site be updated at least monthly to reflect the most current formularies. We will describe the nature of any formulary discrepancies.

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

Part D Formulary Coverage Determinations and Appeals Process

We will review the coverage determination and appeals processes Part D sponsors established pursuant to regulations at 42 CFR pt. 423, subpart M. Section 423.566(b) permits enrollees to appeal, among other things, a determination not to cover a drug because it is not included in the formulary. We will determine whether these processes comply with Federal regulations and CMS's guidelines. In accordance with 42 CFR pt. 423 subpart M, each Part D sponsor and Part D plan that it offers must establish and maintain procedures for standard and expedited coverage determinations and appeals. We will also determine the number of beneficiaries requesting and appealing coverage determinations.

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

Dual Eligibles' Access to Drugs Under Medicare Part D

We will review the extent to which Part D drug formularies developed by sponsors in accordance with 42 CFR § 423.120, include drugs commonly used by dual-eligible beneficiaries. These beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as they meet certain limitations outlined in 42 CFR § 423.120, plans have the discretion to include different Part D drugs and drug utilization tools in their formularies. Section 3313 of the Affordable Care Act requires OIG to conduct this review annually. We will also compare the availability of drugs commonly used by dual-eligible beneficiaries enrolled in plans that have premiums above the national average monthly bid amount to the availability under those plans that have premiums below that amount.

(OEI; 05-10-00390; expected issue date: FY 2011; work in progress)

Medicare Information Systems and Data Security

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

Medicare Annual Reports to Congress on Contractor Information Systems Security Programs

We will review independent evaluations of information systems security programs of Medicare FIs, carriers, and MACs. Section 912 of the MMA requires annual independent evaluations of security programs of FIs, carriers, and MACs and subsequent OIG assessment of these evaluations. OIG is required to annually report the results of its assessments to Congress. Our report to Congress will include our assessment of the scope and sufficiency of the evaluations performed and will summarize the results of independent evaluations.
(OAS; W-00-11-41010; expected issue date: FY 2011; 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. The purpose of this review will be to assess compliance with applicable Federal requirements. Section 911 of the MMA requires the Secretary to submit to Congress a plan outlining a strategy for accomplishing the replacement of FIs and carriers with MACs no later than 2011. The plan that the Secretary submitted to Congress calls for the establishment of 23 new administrative contracts. 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 (CWF) system, and Medicare banking records need to be terminated as soon as the contractors' performance periods end.
(OAS; W-00-11-41011; various reviews; expected issue date: FY 2011; new start)

Medicare Part D Selected Controls for Systems Tracking True Out-of-Pocket Costs

We will review selected Medicare Part D general and application controls at the CMS contractor, known as the TrOOP facilitator, responsible for collecting information on TrOOP from payers that are secondary to Medicare Part D. TrOOP calculations are critical to the Medicare Part D payment process because they affect the proportions of the drug cost for which the beneficiary, the Part D plan, and Medicare are each responsible. With respect to general controls, we will focus on continuity-of-service planning and controls related to software development changes. We will also review application controls, including ensuring the accuracy and completeness of standard transactions generated by the TrOOP facilitator for covered prescriptions and documenting payers that are secondary to Medicare. The transactions are transmitted by the TrOOP facilitator to the plans, which use them to compute beneficiary TrOOP for covered prescription drugs. We will follow up on issues identified in a prior audit of a TrOOP facilitator.
(OAS; W-00-11-41012; expected issue date: FY 2011; new start)

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

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

(OAS; W-00-11-41013; various reviews; expected issue date: FY 2011; 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. Office of Management and Budget (OMB) Memorandum M-06-16, issued June 23, 2006, recommended that all Federal departments and agencies take action to protect sensitive information by following the National Institute of Standards and Technology's Special Publications 800-53 and 800-53A. We will assess and test contractors' and hospitals' policies and procedures for electronic health information protections, access, storage, and transport.

(OAS; W-00-11-41014; various reviews; expected issue date: FY 2011; new start)