

Part II:

Medicare
Part C and Part D

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Part II: Medicare Part C and Part D

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

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

Part C (Medicare Advantage)

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

CMS—CENTERS FOR MEDICARE & MEDICAID SERVICES

DME—DURABLE MEDICAL EQUIPMENT

FFS—FEE FOR SERVICE

FMO—FIELD MARKETING ORGANIZATIONS

HCPP—HEALTH CARE PREPAYMENT PLAN

HMO—HEALTH MAINTENANCE ORGANIZATION

MA—MEDICARE ADVANTAGE

QIO—QUALITY IMPROVEMENT ORGANIZATIONS

SNF—SKILLED NURSING FACILITY

SNP—SPECIAL NEEDS PLANS

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

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

Enhanced Payments to Plans for Certain Beneficiary Types

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

Special Needs Plans: Enrollment of Medicare Beneficiaries With Chronic Conditions

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

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

Medicare Advantage Risk Adjustment Data Submissions

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

Medicare Advantage Risk Adjustment Data Validation

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

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

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

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

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

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

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

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

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

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

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

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

Quality of the Part C Bid Review Process

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

Medicare Advantage Organizations' Oversight of Contractors

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

Medicare Advantage Plans Oversight of Durable Medical Equipment Suppliers

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

Medicare Advantage Organizations' Identification of Potential Fraud and Abuse

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

Medicare Advantage Organizations' Reporting Requirements

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

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

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

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

Part D (Prescription Drug Program)

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

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

Part D Drug Pricing and Payment-Related Reviews

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

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

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

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

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

Medicare Part D Claims Duplicated in Part A and Part B

We will review Medicare Part D claims to determine whether they were duplicated in Part A or Part B. We will also determine the extent to which payments for the sampled Part D claims were correct and supported. A drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. (Social Security Act, § 1860D-2(e)(2)(B).) Medicare Part A covers drugs for beneficiaries who are receiving treatments as hospital inpatients. Drugs covered under Medicare Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with DME, and some vaccines. Medicare Part A and Part B do not cover most outpatient prescription drugs that may be covered under Part D. (OAS; W-00-11-35409; various reviews; expected issue date: FY 2012; new start)

Characteristics Associated With Part D Billing in 2009

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

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

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

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

We will determine whether Part D claims were paid at the discounted prices available at certain retail pharmacies, and whether the Plan Finder Website is accurately reporting these prices to beneficiaries. In 2006, several retail chain pharmacies began offering certain generic drugs at discounted prices (e.g., \$4 for a 30-day supply). Typically, sponsors should also pay these discounted prices if their contracts include a "usual and customary" clause, which means they pay the lowest price that is consistently charged at a pharmacy. These prices should also be reflected in CMS's Plan Finder Web site, which helps beneficiaries choose a prescription drug plan based on estimates of costs and coverage. (OEI; 03-11-00460; expected issue date: FY 2012; work in progress)

Duplicate Drug Claims for Hospice Beneficiaries

We will review the appropriateness of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D. We will determine whether payments under Part D are correct, supported, and not duplicated in hospice per diem amounts. We will also determine the extent of any duplication found and identify controls to prevent duplicate drug payments. Medicare Part D drug plans should not pay for drugs that are covered under the Part A hospice benefit. CMS publishes hospice payment rates, which include prescription drugs used for pain relief and symptom control related to the beneficiary's terminal illness. (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 11, § 30.2.) Hospice providers are paid per diem amounts, which include payments for these drugs. A drug prescribed for a Part D beneficiary shall not be considered for payment if the drug was prescribed and dispensed or administered under Part A or Part B. (Social Security Act, § 1860D-2(e)(2)(B).) (OAS; W-00-10-35307; W-00-11-35307; various reviews; expected issue date: FY 2012; work in progress)

Aberrant Part D Claims For Schedule II and Other Drugs

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

Refills of Schedule II Drugs (New)

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

Medicare Part D Expenditures for Revatio (New)

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

Questionable Part D Billing for HIV Drugs (New)

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

Prescription Drug Event Data Submitted for Incarcerated Individuals (New)

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

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

Part D Pharmaceutical Manufacturer Rebates

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

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

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

Off-Formulary Drugs in Part D

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

Part D Formulary Coverage Determinations and Beneficiary Appeals Process

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

Utilization Management Controls in Medicare Part D (New)

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

Medicare Part D Risk Sharing and Risk Corridors

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

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

We will review the implementation of systems that support Part D prescription drug benefit plans and the expansion of beneficiary choices at MA plans, small- to medium-size Part D sponsors, and other Part D sponsors with little or no previous involvement in the Medicare program. We will evaluate the general and application controls that are critical to support these systems' functions. We will also assess the plans' compliance with Medicare Part D contractual requirements; CMS regulations; and CMS instructions for systems supporting key Part D components, such as beneficiary enrollment, coordination of benefits, true out-of-pocket (TrOOP) costs, and PDE operations. This is a followup on issues identified in prior reviews of larger plans. (OAS; W-00-12-41013; various reviews; expected issue date: FY 2012; new start)

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

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

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

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

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

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

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

Part D Administration and Program Integrity

ACRONYMS AND ABBREVIATIONS FOR SELECTED TERMS USED IN THIS SECTION:

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

PBM—PHARMACY BENEFIT MANAGER

Safety and Effectiveness of Part D Drugs

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

Sponsors' Documentation of Administrative Costs Included in Bid Proposals

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

Sponsors' Documentation of Investment Income Included in Bid Proposals

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

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

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

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

Medicare's Audits of Part D Sponsors' Financial Records

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

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

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

Sponsors' Internal Controls for Fraud, Waste, and Abuse

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

Sponsors' Audits of Pharmacies

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

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

Sponsors’ Pharmacy and Therapeutics Committees: Potential Conflicts of Interest

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

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