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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).) Part D is a voluntary benefit available to Medicare beneficiaries.

Acronyms and Abbreviations for Selected Terms Used in Work Plan Part II:

HCPP—Health Care Prepayment Plan
HMO—health maintenance organization
MA—Medicare Advantage

MEDIC—Medicare Drug Integrity Contractor
QIO—Quality Improvement Organization

Program Integrity Oversight of Part C and Part D

Benefit Integrity Activities by CMS Contractors in Medicare Part C and Part D (New)

We will determine the extent to which the National Benefit Integrity (NBI) program Medicare Drug Integrity Contractors (MEDIC) performed Medicare Parts C and D benefit integrity activities. We will also describe barriers that the NBI MEDICs encountered in performing their benefit integrity activities. In FY 2010, the Centers for Medicare & Medicaid Services (CMS) awarded contracts to two national MEDICs, one designated as the NBI MEDIC and the other as the Compliance and Enforcement MEDIC. The NBI MEDIC assumed responsibility for detecting and preventing Medicare Parts C and D fraud, waste, and abuse nationwide. *(OEI; 03-11-00310; expected issue date: FY 2013; work in progress)*

Part C – Medicare Advantage

Medicare Advantage (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 are often 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.

Special-Needs Plans—CMS Oversight of Enrollment and Special-Needs Plans

We will review CMS's oversight of plans' enrollment practices and determine whether Special-Needs Plans' for beneficiaries with chronic or disabling conditions comply with enrollment requirements.

Medicare restricts Special-Needs Plans to beneficiaries with 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 (MIPPA), § 164.) The Affordable Care Act extended Special-Needs Plans through 2013. (Affordable Care Act, § 3205.) (OEI; 07-12-00170; expected issue date: FY 2013; work in progress; Affordable Care Act)

Provision of Services—Compliance With Medicare Requirements

We will review MA organizations' oversight of contractors that provide enrollee 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 they use to ensure that contractors fulfill their obligations. MA organizations are accountable for the performance of the entities with which they contract. MA organizations that delegate responsibilities under their contracts with CMS to other entities must specify in their contracts with those entities provisions 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 2014, new start)

Beneficiary Appeals—Beneficiary Requests for Reconsideration of Denied Services or Payments (New)

We will review notices of denied requests for services or payments that MA organizations sent to beneficiaries to determine whether the notices clearly explained beneficiaries' right to request reconsiderations and to appeal the ensuing determinations. We will also examine differences between denials of services and payments for which beneficiaries did and did not choose to appeal. MA organizations are required to explain beneficiaries' right to request reconsideration when their requests for medical services or payments for services are denied. (Social Security Act, § 1852(g)(2)(A).) A prior OIG report found that fewer than 1 in 10 beneficiaries requested reconsiderations when their MA organizations denied their requests for medical services. (OEI; 00-00-00000; expected issue date: FY 2014, new start)

MA Organization Bid Proposals—CMS Oversight of Data Quality and Accuracy

We will assess the extent to which CMS uses bid reviews to ensure that MA bids are accurate. 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-00-13-35555; various reviews; expected issue date: FY 2014; new start)

Duplicate Payments—Cost-Based Health Maintenance Organization Plans Paid 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 a cost plan's 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-00-13-35553; various reviews; expected issue date: FY 2013; new start)

Encounter Data—CMS Oversight of Data Integrity (New)

We will review the extent to which MA encounter data reflecting the items and services provided to MA plan enrollees are complete, consistent, and verified for accuracy by CMS. In 2012, MA encounter data reporting requirements will expand from an abbreviated set of primarily diagnosis data to a more comprehensive set of data. (One Time Notification, Pub. 100-20, CR 7562.) Prior CMS and OIG audits have indicated vulnerabilities in the accuracy of risk adjustment data reporting by MA organizations. (OEI; 00-00-00000; expected issue date: FY 2014, new start)

Risk Adjustment Data—Sufficiency of Documentation Supporting Diagnoses

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 on the basis of the health status of each beneficiary. (Social Security Act, §§ 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; various reviews; expected issue date: FY 2013; work in progress)

Risk Adjustment Data—Accuracy of Payment Adjustments

We will determine whether CMS properly adjusted payments to MA plans on the basis of the results of its 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 (QIO) 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 2013; work in progress)

Risk-Adjusted Payments—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-00-13-35540; various reviews; expected issue date: FY 2013; new start)

Cost Reports—Accuracy of Expenditures Claimed by Health Care Prepayment Plans

We will review expenditures claimed on cost reports by selected Health Care Prepayment Plans (HCPP). HCPPs are organization, union, or employer-sponsored plans that provide or arrange for some or all of Part B Medicare benefits on a prepayment basis. Payment for Part A services is made on a fee-for-service basis. 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-00-12-35563; various reviews; expected issue date: FY 2013; work in progress)

Reporting Requirements—CMS Quality Oversight of MA Organization Reporting

We will review CMS's efforts to ensure MA organizations' compliance with CMS's Part C Reporting Requirements and improve the quality of the Part C Reporting Requirements data. We will also review how CMS has used the Reporting Requirements data to monitor, assess, and improve MA organizations' performance. The Part C Reporting Requirements are a group of measures that CMS established. CMS requires MA organizations to develop, compile, evaluate, and report these data to CMS and others (42 CFR 422.516(a)). The information is intended to serve as a resource for CMS to conduct the oversight, monitoring, compliance, and auditing activities that are necessary to ensure the quality of benefits provided by MA organizations. (OEI; 03-11-00720; expected issue date: FY 2012; work in progress)

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.

Acronyms and Abbreviations for Selected Terms Used in This Section:

HIV—human immunodeficiency virus

PDP—prescription drug plan

PBM—pharmacy benefit manager

TrOOP—true out-of-pocket [costs]

PDE—prescription drug event

Program Integrity—Beneficiary Use of Manufacturer Copayment Coupons (New)

We will identify safeguards pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D. The use of copay coupons in Federal health programs implicates the anti-kickback statute. Coupons may create an incentive for beneficiaries to choose more expensive brand-name drugs over lower-cost generic drugs. A recent survey suggests that beneficiaries are using copay coupons to obtain specific brand-name prescription drugs, causing Medicare to pay more than necessary when less costly versions of the same drugs are available. (OEI; 05-12-00460; expected issue date: FY 2014; work in progress)

Program Integrity—Voluntary Reporting of Fraud, Waste, and Abuse by Plan Sponsors (New)

We will review the extent to which plan sponsors offering Part D prescription drug coverage have voluntarily reported Part D antifraud activity data to CMS since 2010. Although the Part D program represents a significant portion of Medicare costs and beneficiary enrollment, little is known about the potential fraud and abuse identified by Part D plan sponsors. Beginning in 2010, sponsors may voluntarily report to CMS aggregate data about their anti-fraud, waste, and abuse activities related to Part D. The data will measure the types of incidents, the sources by which incidents are identified to Part D plan sponsors, as well as the activities taken by sponsors to respond to the incidents. (42 CFR § 423.504(b)(4)(vi)(G).) (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Pharmacy Benefit Managers—Part D Sponsors' Oversight of Pharmacy Benefit Managers' Administration of Plan Benefits (New)

We will assess Part D sponsors' abilities to oversee the ways in which pharmacy benefit managers (PBM) carry out their responsibilities to administer their formularies and manage prescription drug use. Formularies are listings of brand name and generic medications that are preferred by an insurance plan. Sponsors can delegate the administration of Part D plan benefits, including formularies and utilization management rules, to PBMs. PBMs are required to follow the same guidance and regulations as

sponsors concerning which drugs and therapeutic classes must be covered by the formulary, how the utilization management rules are applied, and which drugs are excluded under Part D. The sponsors remain responsible for the formularies and must ensure that the PBMs are in compliance with all Federal regulations and CMS guidance. (42 CFR § 423.505(i).) (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Patient Safety and Quality of Care—Part D Drugs Approved and Registered by FDA

We will determine whether the drugs used in the Part D program were previously found to be safe and effective by the Food and Drug Administration (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-00-13-35561; various reviews; expected issue date: FY 2013; new start)

Drug Payments—Specialty Tier Formularies and Related Cost Sharing (New)

We will analyze the variation in prescription drug plans' (PDP) specialty tier formularies and beneficiary cost-sharing requirements. Drugs placed on specialty tiers are generally expensive; are used to treat rare, chronic conditions; and require special administration, distribution, and handling. A drug's inclusion on a specialty tier is based solely on its cost and not the patient's condition. If CMS sets the cost threshold too low or if PDP sponsors misclassify a drug as a specialty-tier drug, beneficiaries' plan choices, drug adherence, and drug choices could be affected. CMS's requirement for inclusion on specialty tiers is that the drug's monthly cost exceed a certain threshold (\$600 in 2012). (*Medicare Prescription Drug Benefit Plan Manual*, Pub. 100-18, Ch. 6, § 30.2.4.) (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Drug Payments—Characteristics Associated With Atypically High Billing

We will review Part D drugs billed in 2009 to identify characteristics of associated prescribers and beneficiaries. We will identify the prescribers and beneficiaries associated with atypically high billing and determine what, if any, characteristics they have in common. Part D 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; 02-09-00603; OEI; 02-09-00604; various reviews; expected issue date: FY 2013; work in progress)

Drug Payments—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 were supported. A drug prescribed for a Part D beneficiary will 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 treatment as

hospital inpatients. Drugs covered under Part B include injectable drugs administered by a physician, certain self-administered drugs, drugs used in conjunction with medical equipment, 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 2013; work in progress)

Drug Payments—Questionable Claims for HIV Drugs

We will describe billing for human immunodeficiency virus (HIV) drugs under Medicare Part D and determine the extent to which Part D billing for HIV drugs was questionable in 2010. Part D covers drugs that are prescribed and used for medically accepted indications. We will identify pharmacies, prescribers, and beneficiaries associated with the questionable Part D billing. (OEI; 02-11-00170; expected issue date: FY 2013; work in progress)

Drug Payments—Drugs Dispensed Through Retail Pharmacies With Discount Generic Programs

We will determine whether Part D is receiving the discount drug prices available at certain retail pharmacies. 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. However, some retail pharmacies have restrictions in their discount generic programs that may negate the “usual and customary” requirement and prevent Part D from sharing in these discounted prices. This review will determine the number and percentage of Part D claims that were paid above the discount prices and the dollars associated with these claims. (OEI; 03-11-00460; expected issue date: FY 2013; work in progress)

Coverage Gap—Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts

We will review data submitted by Part D sponsors used in calculating the coverage gap discount. We will 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-00-13-35611; various reviews; expected issue date: FY 2013; new start; Affordable Care Act)

Coverage Gap—Accuracy of Sponsors’ Tracking of True Out-of-Pocket Costs

We will review the accuracy of Part D sponsors’ tracking of beneficiaries’ true out-of-pocket (TrOOP) costs. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. We will determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries’ TrOOP expenses that qualify to be included to meet thresholds for catastrophic coverage. For 2010, for example, once an enrollee had reached \$4,550 in annual TrOOP costs (or \$6,440 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-00-12-35234; various reviews; expected issue date: FY 2013; work in progress)

Prescription Drug Event Data—Data Submitted for Incarcerated Individuals

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-00-12-35577; various reviews; expected issue date: FY 2013; work in progress)

Sponsors' Bid Proposals—Documentation of Administrative Costs

We will review the sufficiency 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-00-13-35506; various reviews; expected issue date: FY 2013; new start)

Sponsors' Bid Proposals—Documentation of Investment Income

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 2013; work in progress)

Reconciliation of Payments to Sponsors—Discrepancies Between Negotiated and Actual Rebates

We will compare the rebate amounts negotiated between Part D sponsors (or PBMs) and pharmaceutical manufacturers with the actual rebates paid and analyze any discrepancies. Medicare calculates certain payments to sponsors 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. CMS requires that Part D sponsors submit DIR reports for use in the payment reconciliation process. (OAS; W-00-11-35508; W-00-12-35508; various reviews; expected issue date: FY 2013; work in progress)

Reconciliation of Payments to Sponsors—Reopening Final Payment Determinations

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 previous years' Part D payment reconciliations. CMS allowed sponsors to request reopening and to submit additional PDE data and DIR data. (OAS; W-00-13-35621; various reviews; expected issue date: FY 2013; new start)

Risk Sharing and Risk Corridors—Savings Potential of Adjusting Risk Corridors

We will analyze risk-sharing payments between the Government and Part D sponsors to determine whether cost savings could have been realized had the existing risk corridor thresholds remained at 2006 and 2007 levels. 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 2014; new start)

Information Systems—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-00-13-41013; various reviews; expected issue date: FY 2013; new start)

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.

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