redesigned care processes for high quality and efficient service delivery. (ACA, § 3022.) OEI; 00-00-00000; expected issue date: FY 2016

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 under contract with 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. (MMA.) Part D is a voluntary benefit available to Medicare beneficiaries.

Acronyms and Abbreviations for Selected Terms:

ACA—Affordable Care Act
CDC—Centers for Disease Control and Prevention
CMS—Centers for Medicare & Medicaid Services
DIR—direct and indirect remuneration
MA—Medicare Advantage
PDE—prescription drug event
P&T—Pharmacy & Therapeutics

Part C – 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.

Efforts for FY 2015 and beyond may include additional work examining the soundness of rates and risk and payment adjustments in the MA Program.

MA Organizations' Compliance With Part C Requirements

➢ Use of Medicare Advantage encounter data – CMS oversight of data integrity

We will review CMS's oversight and coordination of MA encounter data validation and assess the extent to which CMS's Integrated Data Repository contains valid and complete MA encounter data. In 2012, CMS began requiring MA organizations to submit a more comprehensive set of encounter data reflecting the items and services provided to MA plan enrollees. Prior CMS and OIG audits have indicated vulnerabilities in the accuracy of data reporting by MA organizations. (OEI; 03-15-00060; expected issue date: FY 2016).

➢ Risk adjustment data—Sufficiency of documentation supporting diagnoses

We will review the medical record documentation to ensure that it supports the diagnoses MA organizations submitted to CMS for use in CMS's risk-score calculations and determine whether the diagnoses submitted complied with Federal requirements. Prior OIG reviews have shown that

medical record documentation does not always support the diagnoses submitted to CMS by MA organizations. MA organizations are required to submit risk adjustment data to CMS in accordance with CMS instructions. (42 CFR § 422.310(b).) Payments to MA organizations are adjusted on the basis of the health status of each beneficiary, so inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. (Social Security Act, §§ 1853(a)(1)(C) and (a)(3).) (OAS; W-00-14-35078; W-00-15-35078; various reviews; expected issue date: FY 2015)

Part D – Prescription Drug Program

Part D administration depends upon extensive coordination and information sharing between 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, made on the basis of bids, risk adjustments, and reconciliations, add to the complexities and challenges of the benefit.

CMS provides prescription drug coverage for over 37 million Medicare beneficiaries through Part D. In 2012, Medicare Part D expenditures totaled almost $67 billion. Ensuring the appropriate use of prescription drugs in Medicare is vital for financial reasons as well as patient safety and quality of care. Future OIG work planning efforts for FY 2015 and beyond will consider prescribing policies and practices and the efficacy of safeguards intended to protect beneficiaries and the programs from drug overutilization and improper payments.

Medicare, Sponsor, and Manufacturer Policies and Practices

➢ Savings potential of adjusting risk corridors

We will analyze risk-sharing payments between Medicare 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. CMS has the authority to retain existing risk corridor thresholds or widen them for plan year 2012 and beyond. Risk corridors determine the amount of unexpected profits or losses that Medicare and sponsors share. (Social Security Act, § 1860D-15.) (OEI; 02-14-00320; expected issue date: FY 2016)

➢ **NEW** Part D oversight portfolio

We will summarize OIG audits, evaluations, legal opinions, and investigative work on Medicare Part D and provide progress information on recommendations to improve CMS, Plan Sponsors, and MEDIC oversight of the Part D program. Since the inception of Part D, numerous OIG reports have identified weaknesses in the oversight of the program, including oversight by Part D plan sponsors, MEDICs, and CMS. (OEI; 03-15-00180; expected issue date: FY 2015).

Sponsor Compliance With Part D Requirements

➢ Documentation of administrative costs in sponsors' bid proposals

We will review the sufficiency of Part D sponsors' documentation supporting the administrative costs they 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).) Medicare's subsidy payments to Part D plans and beneficiary premiums are calculated on the basis of the sponsors' bids. (OAS; W-00-14-35506; various reviews; expected issue date: FY 2015)

➢ Reconciliation of payments—Sponsor reporting of direct and indirect remuneration

We will determine whether Part D sponsors complied with Medicare requirements for reporting direct and indirect remunerations (DIR). Medicare calculates certain payments to sponsors on the basis of amounts actually paid by the Part D sponsors, net of 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-00-13-35508; W-00-14-35508; various reviews; expected issue date: FY 2015)

➢ Reconciliation of payments—Reopening final payment determinations

We will review CMS policies, procedures, instructions, and processes for reopening final payment determinations and determine the adequacy of Part D sponsor compliance and sponsor-submitted data. 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).) In April 2013, CMS announced that it planned to reopen 2007 and 2008 reconciliations during the 2013 calendar year and would assess at a later time whether it is necessary to reopen 2009, 2010, and 2011 reconciliations. CMS allowed sponsors to request reopening and to submit additional prescription drug event (PDE) data and DIR data. (OAS; W-00-14-35621; W-00-15-35621; various reviews; expected issue date: FY 2015)

➢ Ensuring dual eligibles' access to drugs under Part D

We will review the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries, as required. Dual-eligible beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as Part D plans meet certain limitations outlined in 42 CFR § 423.120, they have discretion to include different Part D drugs and drug utilization tools in their formularies. The ACA, § 3313, requires OIG to conduct this review annually. (OEI; 05-15-00120; expected issue date: FY 2015; ACA)

➢ Recommendation followup – Oversight of conflicts of interest in Medicare prescription drug decisions

We will determine what steps CMS has taken to improve its oversight of Part D sponsors' Pharmacy and Therapeutics (P&T) committee conflict-of-interest procedures. Federal law and regulations require Medicare Part D P&T committees to make prescription drug coverage decisions on the basis

of scientific evidence and standards of practice. To comply with the law, Part D sponsors' P&T committees must prevent conflicts of interest from influencing members to give preference to certain drugs. The OIG report *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions* (OEI-05-10-00450) found that CMS does not adequately oversee Part D sponsors' P&T committee compliance with Federal conflict-of-interest requirements. (OEI; 00-00-00000; expected issue date: FY 2015)

Part D Billing and Payments

➢ Documentation of pharmacies' prescription drug event data

We will conduct additional reviews of selected retail pharmacies identified in a prior OIG report as having questionable Part D billing. We will determine whether Medicare Part D PDE records submitted by the selected pharmacies were adequately supported and complied with applicable Federal requirements. Drug plan sponsors must submit the information necessary for the Secretary to determine payments to the plans. (Social Security Act, § 1860D-15(f)(1).) (OAS; W-00-13-35411; various reviews; expected issue date: FY 2015)

➢ Quality of sponsor data used in calculating coverage-gap discounts

We will review data submitted by Part D sponsors for use in calculating the coverage gap discount to assess the accuracy of the data and determine whether beneficiary payments are correct and amounts paid to sponsors are supported. The ACA required the Secretary to establish a Medicare coverage-gap discount program to provide relief to beneficiaries who are responsible for paying all drug costs during their coverage gaps. (Social Security Act, § 1860D-14A, as amended by the ACA, § 3301.) Sponsors track beneficiary payment information and the drug cost data necessary to calculate eligibility for the program. (OAS; W-00-14-35611; various reviews; expected issue date: FY 2015; ACA)

➢ **NEW** Billing trends for Part D drugs and commonly abused opioids

We will describe trends in Part D billing from 2006 to 2014, including changes in billing for commonly used opioid drugs. We will also describe billing trends associated with pharmacies in 2014. Drug diversion and prescription drug abuse are growing problems. CDC considers prescription drug abuse to be an epidemic, and deaths from drug overdose are now one of the leading causes of accidental death. OIG is also seeing a significant increase in Part D fraud and has a wide portfolio of work involving pharmaceutical matters, including prescription drug diversion. (OEI; 02-15-00190; expected issue date: FY 2015).