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EXECUTIVE SUMMARY

PAYERS, PLANS, AND MANAGED CARE PRACTICE GROUP

The OIG 2013 Work Plan: Compliance Priorities for Sponsors of Part C and Part D Plans

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Introduction

On October 2, 2012, the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) released its Work Plan for the Fiscal Year 2013. Because the OIG oversees the effectiveness of the Centers for Medicare & Medicaid Services' (CMS's) oversight of Medicare and Medicaid, knowing the OIG's priorities for the upcoming year provides sponsors of Medicare Advantage (MA) and Part D plans with insight into where CMS may be focusing its attention. This executive summary highlights the elements of the Work Plan related to Medicare Part C and Part D and includes analysis of key provisions. Areas of emphasis in the Work Plan include: (1) program integrity, with a focus on the quality and accuracy of data used to compensate and monitor MA and Part D plan sponsors (plan sponsors); and (2) plan sponsor oversight of key vendors, including pharmacy benefit managers.

Summary of Medicare Part C OIG Priorities

Data Reporting and Payment-Related Issues

- **Encounter Data Accuracy and Integrity** – The OIG will work to identify problems with risk adjustment data reporting by MA organizations and will review MA encounter data for completeness, consistency, and accuracy. The OIG has identified this as a new audit priority for 2013.

- **Cost and Data Reporting: Accuracy of Expenditures Claimed by Health Care Prepayment Plans (HCPPs)** – The OIG will scrutinize expenditures listed on cost reports submitted by HCPPs to determine whether they were reasonable and allowable for reimbursement.
- **Cost and Data Reporting: CMS Quality Oversight of MA Organization Reporting** – The OIG will evaluate CMS's efforts in ensuring compliance with Part C reporting requirements and improving the quality of reporting data. The OIG will further assess how CMS has used such data to improve, monitor, and assess performance of MA organizations.
- **Risk Adjusted Data and Payments: Sufficiency of Documentation Supporting Diagnoses** – The OIG will determine whether the diagnoses underlying CMS's risk-score calculations were: i) in compliance with Federal requirements; and ii) supported by adequate documentation.
- **Risk Adjusted Data and Payments: Accuracy of Payment Adjustments** – The OIG will evaluate whether payments to MA plans were properly adjusted following data validation reviews.
- **Risk Adjusted Data and Payments: Accuracy and Validity of Diagnosis Codes** – The OIG will review underlying data for beneficiary diagnosis codes provided by Medicare Advantage-Prescription Drug (MA-PD) plans for accuracy and validity. The OIG will use the results of this review to determine the accuracy of calculated risk scores and risk-adjusted monthly payments to MA-PD plans.
- **Duplicate Capitation and Fee-For-Service (FFS) Payments** – The OIG seeks to identify duplicate payments to certain cost-based HMOs under capitation and FFS arrangements.

General Oversight of MA Organizations, CMS, and Contractors

- **Enrollment Practices of Special-Needs Plans** – The OIG will review CMS's oversight of the enrollment practices of special-needs plans to ensure that only beneficiaries with chronic or disabling conditions are being enrolled.

- **Oversight of Contractors Providing Enrollee Benefits** – The OIG will evaluate MA organizations' oversight of contractors (first tier, downstream, and related entities) that provide enrollee benefits (*e.g.* prescription drug and mental health services), including how well the MA organizations oversee and monitor contractor compliance and whether contracts contain required provisions.
- **Data Quality and Accuracy in CMS Bid Review** – The OIG will examine CMS's use of bid reviews to ensure that MA bids were accurate. Specifically, the OIG intends to review the work of CMS's Office of the Actuary and its contracted actuary analysts to ensure compliance of bids with Medicare policies and resolution of bid issues prior to approval.
- **Beneficiary Requests for Reconsideration of Denied Services/Payments** – The OIG intends to review notices of denial sent by MA organizations to beneficiaries to determine the extent to which the notices provided a clear explanation of the beneficiaries' right to request redeterminations and appeals. The OIG will also compare denial of services/payment notices from cases that were appealed against those from cases that were not. The Work Plan identified this item as a new oversight priority for 2013.
- **Benefit Integrity Activities by CMS Contractors -** The OIG will evaluate the benefit integrity activities of the National Benefit Integrity program's Medicare Drug Integrity Contractors (MEDICs). The OIG seeks to determine whether they performed their benefit integrity activities and evaluate any obstacles encountered by the MEDICs in fulfilling their duties. This is a new oversight initiative for 2013.

Summary of Medicare Part D OIG Priorities

Part D Program Integrity and Administration

- **Part D Sponsors' Oversight of Pharmacy Benefit Managers (PMBs) –** The OIG will evaluate Part D sponsors' capacity to monitor the ways in which PBMs administer formularies and manage prescription drug utilization. The Work Plan identified this issue as a new oversight priority for 2013.

- **FDA Approval and Registration for Part D Drugs –** The OIG intends to confirm that covered and dispensed Part D drugs were previously found to be safe and effective by the Food and Drug Administration (FDA).
- **Program Integrity: Benefit Integrity Activities by CMS Contractors** – The OIG will review the efforts of MEDICs in detecting fraud and waste in the Part D program as well as in Part C. This is a new oversight initiative for 2013.
- **Program Integrity: Beneficiary Use of Manufacturer Copayment Coupons** – The OIG seeks to identify the procedures pharmaceutical manufacturers have in place to prevent beneficiaries from using copayment coupons to obtain covered Part D prescription drugs. In response to a recent survey suggesting that beneficiaries are using copay coupons to obtain brand-name prescription drugs, the Work Plan identified this issue as a new oversight priority for 2013.
- **Program Integrity: Voluntary Reporting of Fraud, Waste, and Abuse by Plan Sponsors** – The OIG will examine Plan D sponsors' record of voluntary reporting of antifraud activity to CMS since 2010. The OIG will pay particular attention to data on the types of incidents, the sources or means by which the incidents were identified, and the actions taken by sponsors in response. This is a new oversight initiative for 2013.
- **Sponsor Bid Proposals: Documentation of Administrative Costs** – The OIG will scrutinize the documentation of administrative costs submitted by Part D sponsors, including yearly bid proposals to CMS.
- **Sponsor Bid Proposals: Investment Income Documentation** – The OIG will review the appropriateness of documentation of investment income in Part D sponsors' annual bid proposals.
- **Information Systems that Support Small and Medium-Sized Plans** – The OIG will examine the implementation of support systems for Part D drug benefit plans and the expansion of beneficiary options at MA plans, small and medium-sized Part D sponsors, and other Part D sponsors with limited or no participation in the Medicare program.

Drug Pricing and Payment-Related Issues

- **Drug Payments: Specialty Tier Formularies and Related Cost Sharing Requirements** - The OIG seeks to study and compare differences in prescription drug plans' specialty tier formularies and their respective cost sharing requirements. The Work Plan introduced this issue as a new oversight priority for 2013.
- **Drug Payments: Characteristics Associated with Atypically High Billing** – The OIG will examine Part D drugs billed in 2009 to single out beneficiaries and prescribers associated with high billings and to identify commonalities among them.
- **Drug Payments: Part D Payment Claims in Part A and Part B** – The OIG will examine Part D claims to uncover duplicate payments in Part A or Part B. Throughout this process, the OIG intends to verify that the sampled Part D claims were correct and supported.
- **Drug Payments: Questionable HIV Drug Claims** – The OIG seeks to analyze billing practices for HIV drugs and identify prescribers, pharmacies, and beneficiaries responsible for questionable billing practices.
- **Drug Payments: Drugs Dispensed By Retail Pharmacies with Discount Generic Programs** – The OIG will examine whether the Part D program is receiving discounted drug prices offered at certain retail pharmacies. This analysis will determine the number and share of Part D claims that were paid above discount prices and the amounts associated with these claims.
- **Coverage Gap: Sponsor Data Quality for Calculating Coverage Gap Discounts** – The OIG will analyze the accuracy of Plan D sponsor data to determine whether beneficiary payments are correct and adequately supported.
- **Coverage Gap: Accuracy of Sponsors' Tracking of True Out-of-Pocket (TrOOP) Costs** – The OIG will evaluate the accuracy of sponsors' tracking of TrOOP costs with particular emphasis on adjustments to pharmacy claims.

- **Prescription Drug Event (PDE) Data for Incarcerated Individuals** – The OIG will examine PDE data for drugs improperly dispensed to incarcerated individuals.
- **Reconciliation of Payments to Sponsors: Discrepancies between Actual and Negotiated Rebates** – The OIG will compare the rebates negotiated by Part D sponsors and pharmaceutical manufacturers against the rebates actually paid. The OIG will pay particular attention to Direct and Indirect Remuneration Reports submitted by Part D sponsors in the reconciliation process.
- **Reconciliation of Payments to Sponsors: Reopening Final Payment Determinations** – The OIG will examine CMS's procedures for reopening final payment determinations, as well as the data it received in previous years.
- **Risk Sharing and Risk Corridors** – The OIG will examine risk sharing payments between the government and Part D sponsors to identify potential cost savings by maintaining existing risk corridor thresholds at 2006 and 2007 levels. CMS has the authority to maintain or widen the risk corridors.

Analysis

Although the OIG Work Plan reflects a broad range of oversight priorities, the analysis that follows focuses on select topics that deserve particular attention in 2013.

Program Integrity

The oversight priorities set forth in the Work Plan reflect the growing role of contractors in combating Medicare fraud and abuse. In particular, the Work Plan expresses a desire to assess the effectiveness of these contractors' activities and to identify the shortcomings of current fraud detection and prevention efforts.

In addition, the Work Plan's emphasis on data quality relates to the integrity of the MA and Part D programs, as the government needs to ensure the accuracy

of the information it uses to evaluate plan performance. The OIG's data quality initiatives for MA plans address accuracy of MA encounter data, cost reporting, diagnoses used for risk adjustment, and the data underlying plan bids. Part D data quality initiatives include reviewing plan sponsor documentation of administrative costs and investment income, information systems, and the quality of data used to calculate TrOOP and administer the coverage gap discount program.

Oversight of PBMs and other First-Tier, Downstream, or Related Entities (FDRs)

The Work Plan indicates that the relationship between health plans and contracted PBMs will be a major focus area for CMS and the OIG. In a January 2012 memo highlighting the results of its 2011 Program Audit, CMS observed inadequacies in both PBM formulary administration and sponsor oversight.[2] The challenges of formulary administration may be compounded as prescription drug plans begin moving toward four and five-tier models.[3]

Given the existing challenges plans face in formulary administration and a progression toward multi-tiered plans, plan sponsors should seek to measure the extent to which contracted PBMs have systems, policies, and processes in place to ensure the plan's compliance in areas such as transition fills and notification requirements, drug utilization management, and drug tier placement. Since plan sponsors are ultimately responsible for the design, approval, and administration of their formularies, it is critical that they ensure their PBM's compliance with CMS regulations and guidance by implementing the monitoring and oversight measures described in the new compliance program guidelines in Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.[4]

The Work Plan's inclusion of MA organization oversight of contractors providing enrollee benefits is consistent with the recent focus of CMS activities. In the new

compliance program guidelines,[5] which were developed in consultation with the OIG, CMS also stresses the importance FDR oversight by plan sponsors. Among other things, the compliance program guidelines emphasize the importance of inclusion of "appropriate contract provisions in the FDR contract"[6] and recommend a periodic "review of the FDRs' compliance policies and procedures and Standards of Conduct" as a best practice.[7] Additionally, CMS released a model MA contract amendment for FDR contracts in October 2012.[8] Though the use of the contract amendment is voluntary,[9] CMS strongly encourages its use as a means of facilitating the MA contracting process and ensuring compliance with Medicare laws, regulations, and agency instructions.

Conclusion

Sponsors of MA and Part D plans should review the Work Plan when formulating compliance agendas for the coming year, as it reflects the priorities of the organization responsible for overseeing CMS' effectiveness as a regulator. Although there are new priorities outlined in the Work Plan, it emphasizes traditional areas of oversight focus that may be weaknesses for many plan sponsors, such as data quality and FDR oversight.

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[2] Memorandum from the Centers for Medicare & Medicaid Services to All MA and Prescription Drug Plan, 2011 Program Audit Findings and Best Practices 1 (Jan. 20, 2012) *available at* http://www.ncpanet.org/pdf/leg/feb12/2011_program_audit_findings_best_practices.pdf.

[3] Lakshminarasimha Nemani, *Pharmacy Benefit Managers: Role, Emerging Trends & Challenges in Drug Benefit Management*, NATIONAL HEALTHCARE REFORM MAGAZINE, July 1, 2012. *Available at* http://www.healthcarereformmagazine.com/article/pharmacy-benefit-managers-role-emerging-trends-challenges-in-drug-benefit-management.html.

[4] *See* Centers for Medicare and Medicaid Services, Medicare Managed Care Manual, CMS Pub. 100-16, Ch. 21 (Rev. 109, Jul. 27, 2012); Centers for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Manual, CMS Pub. 100-18, Ch. 9 (Rev. 15, Jul. 27, 2012) *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf

[5] *Id.*

[6] *Id.* at 50.1.3.

[7] *Id.*

[8] *See* Memorandum from the Centers for Medicare and Medicaid Services to All MA Organizations, Release of the Medicare Advantage Contract Amendment (Oct. 5, 2012) *available at* http://www.iceforhealth.org/library/documents/2012-1005_Release_of_the_Medicare_Advantage_Contract_Amendment.pdf.

[9] *Id.* at 1.