Health Law @ MINTZ LEVIN
Mintz Levin Cohn Ferris Glovsky and Popeo PC

Health Law Advisory

OCTOBER 9, 2012

Fiscal Year 2013 Work Plan Highlights OIG's Medicare Parts C and D Priorities

BY THERESA C. CARNEGIE, TARA E. SWENSON, AND ROY M. ALBERT

Last week, the OIG published its FY 2013 Work Plan. The Work Plan summarizes new and ongoing reviews and activities that the OIG plans to pursue with respect to HHS programs and operations during FY 2013 and beyond.

The Work Plan includes several initiatives related to Medicare Advantage and Medicare Part D that will be of interest to Medicare Advantage Organizations, Part D plan sponsors, pharmaceutical manufacturers, PBMs, and pharmacies. Many of the areas identified will result in the OIG reviewing the conduct of and oversight by Medicare Advantage Organizations (MAOs), plan sponsors, and CMS.

Medicare Advantage

Through the Work Plan, the OIG identified twelve areas in the Medicare Advantage program that it will begin, or continue to, investigate in FY 2013. Some of these areas will result in the OIG taking a closer look at oversight in the Medicare Advantage program, various practices relating to risk-adjustment, and beneficiary denials and appeals.

MAO and CMS Oversight

The OIG will investigate: (a) the extent to which MAOs monitor and oversee whether their various contractors (first tier, downstream, and related entities) comply with federal regulations and the processes they use; (b) CMS' oversight of enrollment in special needs plans (SNPs), and (c) how often CMS reviews MAOs' bid proposals for accuracy and whether issues identified during the reviews are remedied prior to CMS approving an MAO's bid.

Risk-Adjustment Payments

MAOs should expect to field additional questions regarding their practices relating to risk-adjustment payments. The OIG will take actions to answer various questions regarding risk adjustment, including:

- Are MAOs submitting complete and consistent encounter data? Is CMS verifying the accuracy of encounter data?
- Are the diagnoses that MAOs report (that affect the risk-adjusted payments they receive) supported by medical records?
- Has CMS properly adjusted payments to MAOs resulting from CMS' risk adjustment data validation reviews?
- Have MAOs that offer Medicare Advantage plans that include the Medicare Part D prescription drug benefit (MA-PDs) submitted accurate data and valid diagnosis codes? Has

that data resulted in accurate risk scores and risk-adjusted payments?

Denial Notices and Appeal Trends

An area new to the OIG's Work Plan relates to appeals by Medicare Advantage beneficiaries when the MAO denies their requests and/or payments for medical services. The OIG will review denial notices sent to beneficiaries to determine whether the notices properly explained the beneficiaries' appeal rights. The OIG will also investigate what differences exist between denials of services and payments that resulted in beneficiaries appealing when compared to instances when beneficiaries did not appeal. It is unclear whether the OIG will focus only on differences in the denial notices themselves, or whether it will also consider the value and the type of services at issue in the notices.

Click here for a complete list of the Medicare Advantage areas included in the Work Plan.

Medicare Part D

The Work Plan indicates that the OIG is very interested in Part D issues and lists almost twenty Part D areas that will be investigated in FY 2013, many of which are new. Many of the areas relate to general Part D issues such as risk corridors, coverage gap discounts, and prescription drug event data. The OIG will also focus on the use of coupons by Part D beneficiaries and plan sponsor oversight of PBMs and pharmacies.

Pharmaceutical Manufacturer Coupons

The OIG plans to analyze federal health care program beneficiary use of manufacturer copayment coupons. Although HHS/OIG has never prosecuted anyone for use of co-pay coupons in connection with federal health care programs, it is generally accepted that such coupons would be considered an illegal inducement under the Federal Anti-Kickback Statute. Despite the fact that co-pay assistance programs exclude federal health care program beneficiaries, there is evidence that this exclusion may not be monitored or enforced.

In the Work Plan, the OIG points to a recent survey of 1,000 seniors enrolled in the Part D program commissioned by the National Coalition on Health Care. The survey found that 6% of Medicare beneficiaries had used co-pay coupons despite the ban and that such coupons had induced 4% of these beneficiaries to switch from a generic to a brand-name drug.

The OIG plans to identify safeguards implemented by manufacturers to ensure that Part D program beneficiaries do not use copayment coupons. The OIG notes that, where a co-pay coupon is used and the beneficiary chooses a brand drug over a less costly version of the same drug (e.g., generic), the Medicare program pays more than necessary.

Pharmaceutical manufacturers, coupon administrators, PBMs, plans, and pharmacies should all take note of the OIG's interest in co-pay coupons.

Manufacturers typically contract with third-party vendors to administer and process claims under their co-pay assistance programs. Manufacturers should review their arrangements with coupon processing vendors to ensure that vendors have implemented adequate safeguards to prevent use of co-pay coupons by federal health care program beneficiaries. Manufacturers will also want to ramp up their auditing and monitoring of such vendors to ensure compliance with the federal restrictions.

PBMs and plans should also consider addressing the use of co-pay coupons in their pharmacy network agreements and should identify protections that they expect their network pharmacies to implement with respect to coupons and federal health care program beneficiaries.

PBM and Pharmacy Oversight

The Work Plan identifies several Medicare Part D review areas that may affect the relationships between plan sponsors, PBMs, and their pharmacy networks.

First, OIG plans to assess Part D plan sponsors' ability to oversee PBM administration of formularies and management of prescription drug use. When plan sponsors delegate the administration of Part D benefits to a PBM, the PBM is required to follow the same guidance and regulations as the plan sponsor with respect to drugs and therapeutic classes that must be covered by the formulary, how utilization management rules are applied, and which drugs are excluded under Part D. Because plan sponsors are ultimately responsible for

their formularies, they must ensure that contracted PBMs are in compliance with all federal regulations and CMS guidance.

Second, the Work Plan indicates that the OIG will review the extent to which plan sponsors have voluntarily reported Part D anti-fraud activity data to CMS since 2010. The OIG will consider types of incidents, sources by which incidents are identified, as well as actions taken by plan sponsors to respond to such incidents. Plan sponsors are often dependent upon their PBMs and contracted pharmacy network for fraud detection, monitoring, and reporting.

Third, the OIG plans to compare the rebate amounts negotiated between plan sponsors (or PBMs) and pharmaceutical manufacturers with the actual rebates paid to identify any discrepancies and to determine if plan sponsors have submitted complete and accurate direct and indirect remuneration (DIR) reports. In light of this review, plan sponsors and PBMs will need to continue to closely monitor their data capture and reporting systems with respect to manufacturer rebates.

As a result of these initiatives, PBMs and pharmacies can expect that Part D plan sponsors will continue to aggressively flow-down Medicare Part D compliance requirements in their contractual arrangements. Plan sponsors may also look to enhance and strengthen their oversight and auditing of PBM and pharmacy Part D operations.

General Medicare Part D Program Initiatives

The Work Plan identifies a variety of other areas related to the Medicare Part D program that the OIG intends to review in FY 2013.

- Patient Safety and Quality of Care: The OIG will review the safety and effectiveness of drugs used in the Part D program to ensure that Part D beneficiaries only receive drugs that are properly registered with the FDA.
- Specialty Tier Formularies and Cost-Sharing: Under CMS requirements, a drug's monthly cost must exceed a certain threshold (e.g., $600 in 2012) in order for the drug to be included on a specialty tier. The OIG notes that if CMS sets the cost threshold too low or if plan sponsors misclassify a drug as a specialty drug, beneficiaries' plan choices, drug adherence, and drug choices may be affected. As a result, the OIG intends to analyze the variation in plan specialty tier formularies and beneficiary cost-sharing requirements.
- Drug Payments: The OIG plans to analyze Part D drug claims to identify characteristics of prescribers and beneficiaries with atypically high billing, to determine whether Part D claims have been duplicated in Part A or Part B, and to identify questionable Part D billing for HIV drugs. The OIG also will review drugs dispensed through retail pharmacies with discount generic programs (e.g., $4 for a 30-day supply) to determine whether the Part D program is receiving the benefit of the discounted prices available under these programs.
- Coverage Gap: The integrity of coverage gap discount and TrOOP tracking data will be the focus of OIG reviews. The OIG will review the accuracy of the data submitted by Part D plan sponsors for purposes of calculating the coverage gap discount to ensure that beneficiary payments are correct and amounts paid to plan sponsors are supported. Part D plan sponsors' tracking of TrOOP costs will also be analyzed to determine the appropriateness of adjustments to pharmacy claims on Part D prescriptions and the effect on beneficiaries' TrOOP expenses that qualify for purposes of the catastrophic coverage thresholds.
- Prescription Drug Event Data: The OIG will review PDE data to determine the extent to which plan sponsors submitted data for prescription drugs for incarcerated individuals.
- Plan Sponsors' Bid Proposals: Part D plan sponsors' bids serve as the basis for calculating Medicare's subsidy payments to Part D plans and beneficiary premiums. The OIG plans to review the sufficiency and appropriateness of plan sponsor documentation supporting administrative costs and investment income.
- Reconciliation of Payments to Plan Sponsors: The OIG will review CMS' policies,

procedures, and processes for reopening final payment determinations.

- Risk Sharing and Risk Corridors: Risk corridors determine the amount of unexpected profits or losses that the federal government and plan sponsors share. The OIG will analyze risk-sharing payments to determine whether cost savings could have been realized had the existing risk corridor thresholds remained at 2006 and 2007 levels.
- Information Systems: The OIG will review the Part D supporting systems at small and medium size plans, and plans new to Medicare, to assess compliance with Medicare Part D contractual requirements and CMS regulations.

Upcoming OIG Webcast

On October 24, the OIG will launch an OIG Outlook 2013 webcast, during which OIG top executives will discuss emerging trends in combating fraud, waste, and abuse in federal health care programs, OIG's top priorities for FY 2013, and upcoming projects outlined in the FY 2013 Work Plan. For more information on the webcast, click here.

* * *

View Mintz Levin's Health Law attorneys.

Read and subscribe to *Health Law & Policy Matters* blog.