OIG Issues 2014 Work Plan Including New and Continuing Reviews of Pharmaceutical Reimbursements

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On January 31, 2014, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released the long-awaited 2014 Work Plan, describing the new studies it will initiate, as well as studies from previous years that it plans to continue or complete this year. As always, the OIG's primary focus is on looking for ways to lower costs, whether by identifying and recovering overpayments, standardizing reimbursements for similar services, or revising requirements for reimbursements. Below are brief summaries of the new and continuing reviews the OIG will be conducting this year.

The OIG plans to initiate the following new audits and reviews related to pharmaceutical reimbursements:

Oversight of pharmaceutical compounding: Citing the recent meningitis outbreak linked to contaminated injections of compounded drugs, the OIG plans to study Medicare's oversight of pharmaceutical compounding in acute care hospitals, and how State agencies and hospital accreditors assess such pharmacy services.

FDA—Inspection of generic drug manufacturers: The OIG plans to review the extent to which FDA conducts inspections of generic drug manufacturers, as well as the results of such inspections and the enforcement actions taken by FDA in response to shortcomings or deficiencies found.

Comparison of Medicare Part D and Medicaid pharmacy reimbursement and rebates: Following previous work in this area, the OIG will compare pharmacy reimbursement and rebate amounts for a sample of brand-name drugs paid by Medicare Part D and by Medicaid.

Documentation of pharmacies' prescription drug event data: A previous OIG study identified selected retail pharmacies with questionable Part D Billing. The OIG now plans to examine whether the Medicare Part D Prescription Drug Event (PDE) records submitted by the selected pharmacies were adequately supported and complied with applicable Federal requirements.

Nebulizer machines and related drugs—Supplier compliance with payment requirements: Having previously found that suppliers were overpaid approximately $46 million for inhalation drugs used with nebulizer machines, the OIG will review Medicare Part B payments to determine whether the claims were for nebulizers and related drugs that were medically necessary, and were supported in accordance with Medicare requirements.

Manufacturer reporting of average sales prices for Part B drugs: Having previously recommended that CMS seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit their average sales prices (ASPs) to CMS, the OIG will determine the potential effect on average sales price reporting if the recommendation were to be implemented.

Part B payments for drugs purchased under the 340B Program: The OIG will determine how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs.

Covered uses for Medicare Part B drugs: The OIG plans to review the oversight actions CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria.

Payment for compounded drugs under Medicare Part B: The OIG will examine MACs' policies and procedures for reviewing and processing Part B claims for compounded drugs and assess the appropriateness of such claims in light of the Federal Food, Drug, and Cosmetic Act.

Comparison of Medicare Part D and Medicaid pharmacy reimbursement and rebates: A previous OIG review revealed that Part D sponsors and State Medicaid agencies paid roughly the same amounts for brand-name drugs. However, statutorily-defined Medicaid unit rebate amounts for brand-name drugs exceeded Part D unit rebate amounts by a substantial margin, resulting in lower drug program costs for Medicaid. This review, which is a follow-up to the previous review, will compare pharmacy reimbursement and rebate amounts for a sample of brand-name drugs paid by Medicare Part D and by Medicaid.

The OIG plans to continue and complete the following audits and reviews begin in earlier years:

End-stage renal disease facilities—Payment system for renal dialysis services and drugs: The OIG is continuing to review Medicare payments and utilization of renal dialysis services and related drugs pursuant to the new bundled end-stage renal disease (ESRD) prospective payment system (PPS), comparing acquisition costs for certain drugs to inflation-adjusted cost estimates and determining how costs for the drugs have changed.

Comparison of average sales prices to average manufacturer prices: Auditors are reviewing Medicare Part B drug prices by comparing ASPs to average manufacturer prices (AMPs) and identifying prices that exceed a designated threshold.

Payments for immunosuppressive drug claims with KX modifiers: The OIG is determining whether Part B payments for immunosuppressive drugs that were billed with a service code modifier "KX" met Medicare documentation requirements.

Ethics—Conflicts of interest involving prescription drug compendia: Citing concerns about conflicts of interest involving the drug compendia, the OIG plans to determine the extent to which publishers of drug compendia recognized by CMS have publicly transparent processes for evaluating anticancer drug therapies, and identifying conflicts of interest related to the therapies included in the compendia. As part of this review, the OIG will also determine the extent to which the publishers have processes for evaluating non-anticancer drug therapies and for identifying related conflicts.

Savings potential of retail pharmacy discount generic drug programs: The OIG is studying whether Part D sponsors receive the discount drug prices available to the general public at certain retail pharmacies, and whether the number and percentage of Part D claims for which the amounts paid were equal to the discount prices.

Program integrity—Manufacturer safeguards to prevent the use of copayment coupons for drugs paid for by Part D: The OIG is examining what 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.

Questionable utilization patterns for HIV drugs: The OIG is studying the extent to which Medicare Part D beneficiaries had questionable utilization patterns for HIV drugs, including identifying the characteristics of beneficiaries with questionable utilization patterns and the associated pharmacies and prescribers.

States' methods for resolving rebate disputes with manufacturers: While federal law requires drug manufacturers to enter into drug rebate agreements as a prerequisite to Medicaid coverage, previous OIG reports have found large amounts in uncollected rebates. The OIG is reviewing the causes and resolutions of Medicaid rebate disputes with manufacturers and the methods States use to resolve them.

Manufacturer compliance with AMP reporting requirements: The OIG will review manufacturer compliance with AMP reporting requirements and determine what percentage of manufacturers complied with the requirements. We will also determine whether stepped-up enforcement actions by CMS and OIG are reflected in increased compliance by manufacturers.

States' collection and reporting of rebates: The OIG will determine whether the increased amount of manufacturer rebates for brand-name and generic drugs were collected by States and reported to the Federal government, as required. We will also determine the amount of supplemental drug rebates that States collected during a selected period.

Rebates for new formulations of existing drugs: The Affordable Care Act increased the additional rebate for drugs that are new formulations of existing drugs under certain conditions. The OIG is reviewing drug manufacturers' compliance with the rebate requirements, as well as whether manufacturers have correctly identified all of their drugs that are subject to the requirements.

Conclusion and AGG Recommendations

Because OIG audits frequently result in subject matter investigations in future years, pharmacies and drug manufacturers should review the 2014 Work Plan proactively, and to conduct their own internal reviews of the same areas that the OIG has singled out for scrutiny. With the government's increased emphasis on enforcement and the recovery of "misspent" healthcare funds, providers should institute strict internal controls and monitor their billings and reimbursements for possible overpayments - before CMS, the OIG, or both do it for them.

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