



GLOBAL LIFE SCIENCES: US-HEALTHCARE UPDATE

OIG Work Plan Initiatives for Pharmaceutical Manufacturers and Biotech Companies for Fiscal Year 2012

The Office of the Inspector General of the U.S. Department of Health and Human Services (“OIG”) released its annual Work Plan for Fiscal Year 2012 on October 5, 2011. The Work Plan provides valuable insight into the program areas that the OIG will target for audits and investigations. This year’s Work Plan describes several audit items of particular relevance to pharmaceutical manufacturers and biotech companies, which are outlined in this update.

A. Medicare Part B Reimbursement for Prescription Drugs

Average Sales Price Comparisons

The OIG will perform its periodic review of Medicare Part B drug prices by comparing the average sales price (“ASP”) of select drugs to the average manufacturer price (“AMP”) for those same drugs to identify those drugs that have an ASP that exceeds the AMP by a designated threshold, currently 5 percent.

Additionally, the OIG will perform its periodic review of widely available market prices (“WAMP”) for certain Part B drugs to determine if the ASP for those drugs exceeds the WAMP by a threshold of 5 percent. If the OIG determines that the ASP of a Part B drug exceeds the 5 percent threshold, Centers for Medicare and Medicaid Services (“CMS”) will base payment for that drug on the lesser of the WAMP or 103 percent of the AMP.

Billing for Off-Label Use of Immunosuppressive Drugs

The OIG will review Medicare Part B immunosuppressive drug claims to determine whether: (1) immunosuppressive drugs were billed according to their Food and Drug Administration (“FDA”)-approved labels and (2) Medicare paid for immunosuppressive drugs that should not have been used in combination with other immunosuppressive drugs.

Payments for Off-Label Anticancer Pharmaceuticals and Biologicals

The OIG will continue to review Medicare payments for drugs and biologicals used on an off-label basis in anticancer chemotherapeutic regimens. In particular, the OIG will focus its review on whether patients with particular indications were prescribed anticancer drugs approved by FDA for such indications before resorting to anticancer drugs not approved for those indications, and if so, whether there were improvements in the patient’s medical condition before

the switch was made to the off-label drug(s). If a patient's medical condition improved before the switch, the OIG will determine how much Medicare could have saved had the patient remained on the drug used within its approved label.

Off-Label and Off-Compendia Use of Medications in Government Drug Programs

In 2012, the OIG will review the extent to which Medicare- and Medicaid-funded prescription drugs are prescribed for off-label and off-compendia uses, and the extent to which specified compendia provide support for coverage. Also, the OIG will determine CMS oversight mechanisms related to off-label use of drugs.

Comparison of Medicare Part B and Medicaid Reimbursement Amounts

The OIG will determine whether changes in the reimbursement methodologies for the Part B drug program would result in significant savings on commonly used physician-administered drugs and biologicals by comparing Medicare payments with payments under Medicaid, which provides States with more flexibility in determining reimbursement amounts and the ability to collect rebates from manufacturers.

Coding for Outpatient Drugs and Administration

The OIG, through previous audits, has identified particular drugs, such as chemotherapy drugs, that are vulnerable to incorrect coding. Accordingly, the OIG plans to review Medicare outpatient payments to providers for certain drugs and the administration of those drugs (e.g., chemotherapy) to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units.

Use and Payment of Lucentis and Avastin for Wet Age-Related Macular Degeneration

Due to physicians' off-label use of Avastin, which is approved for colorectal cancer, to treat wet age-related macular degeneration ("wet AMD") over Lucentis, which is specifically approved for wet AMD, the OIG will review how physicians' acquisition costs compare to Medicare Part B reimbursements for Avastin and Lucentis. Since Avastin must be prepared through compounding when used to treat wet AMD, the OIG will also examine the cost associated with such compounding. Furthermore, the OIG will review national claims history data for the use of Avastin and Lucentis to examine whether savings can be realized if one drug or the other is used more to treat wet AMD. Notably, in addition to these reviews, the National Institutes of Health ("NIH") is conducting a two-year study comparing the safety and efficacy of the two drugs to treat wet AMD. In May 2011, the NIH reported that the first year results of the study support that Avastin is as effective as Lucentis in treating wet AMD.

B. Medicare Part D

Increase in Prices for Part D Brand Name Drugs

The OIG plans to determine whether Part D prices (including rebates) are rising faster than inflation and how price increases for brand-name drugs affect the prices Medicare Part D plan sponsors pay for such drugs by reviewing annual changes in prices for brand-name prescription drugs used by Medicare Part D beneficiaries.

Duplicate and Improper Payments

The OIG will review Part D drug claims to determine the extent to which such payments improperly duplicated Part A or B payments. In addition, the OIG will review Part D payments to individuals with Part D drug coverage to ensure that Part D drug plans are not paying for drugs that are covered under the Part A hospice benefit.

Part D Pharmaceutical Manufacturer Rebates

Since Part D reinsurance and risk corridor payments are made on the basis of amounts actually paid by the Part D sponsors, net of any remuneration, including rebates, the OIG will review contractual rebates between pharmaceutical manufacturers and Part D sponsors and pharmacy benefit managers (“PBMs”), compare them with the actual rebates paid, and analyze any discrepancies.

Quality of Data Used in Calculating Coverage Gap Discounts

As provided for in the Affordable Care Act (“ACA”), Medicare Part D beneficiaries are afforded discounts on their purchases of Part D drugs while they are in the coverage gap. The OIG will review Part D sponsor data to ensure that beneficiary payments while they are in the coverage gap are correct and that the payments Part D sponsors receive are supported.

C. Medicaid Prescription Drugs

Calculation of Average Manufacturer Prices and Best Prices

The OIG will review selected drug manufacturers’ methodologies for calculating AMP and best price and will determine if those methodologies are consistent with statutes, regulations, manufacturers’ rebate agreements, and CMS Drug Manufacturer Releases. The 2012 Work Plan acknowledges the significant changes to AMP and best price instituted by the Deficit Reduction Act of 2005 (“DRA”) and the impact on the Federal Upper Limit (“FUL”) for drug reimbursement.

Recalculation of Base-Date Average Manufacturer Prices

The OIG will review changes to manufacturers’ base-date AMPs and assess the impact of such changes on their Medicaid rebates, and the OIG will review the manufacturers’ reasoning and documentation justifying these changes.

Update of Manufacturer Compliance With AMP Reporting Requirements

Based on an audit in 2008, the OIG believes that more than half of drug manufacturers that were required to submit quarterly AMPs to CMS failed to comply with reporting requirements in at least one quarter and were even less likely to comply with monthly AMP reporting requirements. The Work Plan notes that after the release of this 2008 report, the OIG and CMS worked to improve manufacturer compliance with AMP reporting requirements. Therefore, in fiscal year 2012, the OIG plans to review manufacturer compliance with AMP reporting requirements and determine what percentage of manufacturers complied with AMP reporting requirements in 2011 in order to assess whether stepped-up enforcement actions by CMS and the OIG are reflected in increased compliance by manufacturers.

Impact of the Deficit Reduction Act of 2005 on Rebates for Authorized Generics

The OIG will examine the extent to which manufacturers are reporting pricing data on, and paying rebates for, authorized generics. The OIG will determine the impact the DRA has had on rebates generally and on the number of new authorized generics released.

Zero-Dollar Unit Rebate Amounts

For manufacturers who have failed to report their Medicaid rebate data, CMS sets the unit rebate amount (“URA”) for those products at \$0 (i.e., zero-dollar URA). In such instances, States are required to work with the manufacturer to

determine the appropriate rebate amounts. The OIG will review whether States are collecting the rebates associated with these zero-dollar URAs.

States' Rebate Disputes with Manufacturers

According to the OIG, previous reports have found large amounts of rebates uncollected by the States. Thus, the OIG plans to examine the States' rebate disputes with the manufacturers by reviewing the cause of, and resolution to, such disputes.

Rebates on Drugs Paid by Medicaid Managed Care Organizations

Since the ACA expanded Medicaid rebates to include drugs dispensed to Medicaid managed care organization ("MCO") enrollees, the OIG will review whether Medicaid MCOs are providing the States with utilization data needed to collect rebates on these drugs. The review will look at whether States have procedures to accurately collect this data, whether States are collecting these rebates from manufacturers, and whether the States have procedures to track the collection of these rebates.

Rebates on New Formulations

The ACA imposed an alternative rebate on new formulations of single source and innovator multiple source drugs that are oral solid dosage forms. The OIG will review drug manufacturers' compliance with Medicaid drug rebate requirements for drugs that are new formulations of existing drugs, and will also determine whether manufacturers have correctly identified all their drugs that are considered "new formulations" under the ACA.

D. Legal and Investigative Activities Related to Medicare and Medicaid

The OIG will continue its legal activities related to health care fraud, including litigation involving program exclusions, imposition of civil monetary penalties, issuance of fraud alerts and advisory opinions, and development of safe harbor regulations under the anti-kickback statute.

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The audits and investigations identified in the 2012 Work Plan provide a road map to the OIG's focus for the coming year. If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work, or one of the following: James C. Stansel (1.202.736.8092, jstansel@sidley.com), Trevor L. Wear (1.312.853.7101, twear@sidley.com), Rina Mady (1.202.736.8209, rmady@sidley.com).

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