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CLIENT ALERT

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OIG Work Plan Midyear Update Adds Activities Related to Medicare Part D and Medicaid Rebates

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THE UPDATE TO THE FISCAL YEAR 2015 ANNUAL WORK PLAN INCLUDES NEW INITIATIVES THAT MAY AFFECT PHARMACEUTICAL COMPANIES AND MEDICARE PART D PAYORS AND PHARMACIES.

Annually, the Department of Health and Human Services Office of the Inspector General (OIG) issues a Work Plan describing its current and planned legal and investigative activities. On May 28, the OIG issued a midyear update to its Fiscal Year 2015 Annual Work Plan, which adds 22 new reviews and activities to the 171 items already underway for 2015 and beyond. Several of the new items target the pharmaceutical industry, including two pertaining to Medicare Part D payors and pharmacies and two that analyze aspects of the effects of generic drug pricing on the Medicaid rebates paid by pharmaceutical manufacturers.

New Initiatives Targeting Medicare Part D

According to the Work Plan, more than 37 million Medicare beneficiaries obtain prescription drugs through Part D, at a cost of almost $67 billion in 2012. The OIG's efforts in this area are dual-pronged, focusing on both patient safety and improper payments.

In that vein, the OIG intends to analyze Medicare Part D insurance plan billing trends from 2006 to 2014 and billing trends by pharmacies in 2014. The purpose of these reviews is to address drug diversion and prescription drug abuse, which the Centers for Disease Control and Prevention consider to be at "epidemic" levels, as well as the "significant increase in Part D fraud" identified by the OIG. The OIG plans to address this increase with a "wide portfolio of work involving pharmaceutical matters," but it has not provided specifics regarding what this "portfolio of work" will entail. The OIG anticipates issuing the results of its analyses later this year.

In addition, noting that numerous OIG reports have identified weaknesses in Medicare Part D oversight, the OIG plans to (1) summarize its prior audits, evaluations, legal opinions and investigative work related to Medicare Part D and (2) provide an update on progress made with respect to recommendations to improve oversight of the Medicare Part D program.

As a result of these new initiatives, Part D payors and pharmacies may see an uptick in OIG audits, evaluations, inspections, investigations and enforcement actions. The outcome of these initiatives also may serve as useful resource materials for Part D payors and pharmacies.

New Initiatives Targeting Medicaid Rebates Paid by Pharmaceutical Manufacturers

As part of the Medicaid drug rebate program, pharmaceutical manufacturers must periodically report the average manufacturer prices (AMPs). Sales of authorized generics may only be included in AMP calculations when the pharmaceutical company is selling the authorized generics to a wholesaler, not when they are being sold to a secondary manufacturer. The OIG will issue one report that analyzes whether pharmaceutical companies are manipulating AMPs by including sales of authorized generics to secondary manufacturers in their AMP calculations, as doing so would decrease the reported AMPs, resulting in lower rebate amounts being due to the Medicaid program.

Currently, pharmaceutical companies are required to pay a Medicaid rebate when the price of a brand name drug increases more than inflation. No such rebate is required with regard to generic drugs. The OIG also plans to analyze whether generic drug prices have increased more than inflation, as measured by the consumer price index for urban areas. This analysis will be used to determine whether requiring a rebate when the price of a generic drug increases more than inflation would yield potential savings to the Medicaid program.

As a result of these activities, pharmaceutical companies may be subject to increases in Medicaid rebate obligations and new reporting requirements.

The full midyear update is available on the OIG's website at https://oig.hhs.gov/reports-and-publications/archives/workplan/2015/WP-Update-2015.pdf.