

MEDICARE PART D FRAUD AND SPECIALTY DRUGS HIGHLIGHTED IN OIG'S 2016 WORK PLAN

EXECUTIVE SUMMARY

Recently, the Department of Health and Human Services Office of Inspector General ("OIG") released its Work Plan for Fiscal Year 2016 ("Plan"). The Plan provides insight into OIG's potential audit and enforcement activities for the next fiscal year. While the Plan addresses several different provider types, this article addresses the Plan's initiatives related only to pharmacies and Medicare Part D plan sponsors ("Sponsors"). For the Plan's guidance applicable to hospitals, generally, please review Hall Render's article [here](#). For a copy of the complete Plan, see the following [link](#).

MEDICARE PART D - PRESCRIPTION DRUG PROGRAM

The following topics were added to the "Part D - Prescription Drug Program" section of the 2016 Plan:

Medicare Part D Beneficiaries' Exposure to Inappropriate Drug Pairs. OIG plans to review prescriptions of drugs that should not be combined with other drugs, including those that have a severe interaction when combined and those that should not be co-prescribed with component drugs.

Medicare Part D Eligibility Verification Transactions. OIG will review Medicare Eligibility Verification transactions, also known as E1 transactions, submitted by pharmacies to a true out-of-pocket ("TrOOP") facilitator to determine a beneficiary's Part D eligibility and insurance coverage information. OIG plans to review these transactions to assess the validity of the data.

Part D Pharmacy Enrollment. OIG plans to review CMS's Part D pharmacy oversight ability. Additionally, OIG plans to determine the number of the pharmacies that bill for high risk drugs and are enrolled in Medicare. Previous OIG reports have raised concerns about Part D fraud and oversight. In June 2015, OIG was involved in the largest health care fraud takedown in history that mostly concerned prescription drugs and pharmacies.

Increase in Prices for Brand Name Drugs Under Part D. OIG plans to evaluate pharmacy reimbursement for Part D brand name drugs that have changed in price from 2010 to 2014 against the rate of inflation, as many brand name drug prices have risen substantially more than the inflation rate since 2002.

The following topics are repeated in the 2016 Plan, indicating that OIG will continue to audit and review these areas:

- Risk-sharing payments between Medicare and Part D sponsors and whether, if the existing risk corridor thresholds remained at 2006 and 2007 levels, cost savings could have been realized.
- The number and nature of financial interests reported to CMS under the Open Payments Program and the extent to which CMS oversees manufacturers and group purchasing organizations' data reporting compliance pursuant to § 6002 of the Affordable Care Act.
- Part D sponsors' compliance with Medicare requirements for reporting direct and indirect remunerations, including all rebates, subsidies and other price concessions from sources serving to reduce Part D sponsors' costs for drugs.
- Dual-eligible beneficiaries' access to commonly used Part D drugs.
- CMS's steps taken to improve oversight of Part D sponsors' Pharmacy and Therapeutics committee conflict of interest procedures, as required by federal law and regulations.
- Retail pharmacies, previously identified as having questionable Part D billing, and whether they adequately submitted Medicare Part D records in compliance with applicable requirements.
- Quality of Sponsor data used in calculating Medicare Part D coverage gap discounts.

PRESCRIPTION DRUGS

No new topics were added to the 2016 Plan under the "Prescription Drugs" section; however, the following topics were revised in this section:

Part B Payments for Drugs Purchased Under the 340B Program. OIG plans to consider the financial impact of shared savings arrangements on 340B covered entities, the Medicare program and Medicaid beneficiaries. Specifically, OIG anticipates reviewing ways that would allow Medicare recipients to participate in the 340B program.

Covered Uses for Medicare Part B Drugs. OIG plans to review CMS's and its claims processing contractors' oversight actions for Part B drug payments and the challenges those contractors face. OIG is concerned with a lack of oversight mechanisms that could lead to payment for uses that are not medically accepted, commonly referred to off-label use.

The following topics are repeated in the 2016 Plan, indicating that OIG will continue to audit and review these areas:

- Comparison of average sales price to average manufacturer prices for Medicare Part B drugs.
- Payments for immunosuppressive drug claims with KX modifiers.

PRACTICAL TAKEAWAY

The Plan is a valuable resource that providers can use to enhance their compliance programs annually. Based upon the Plan, pharmacies and Sponsors should consider updating their annual internal audit plan to include the applicable OIG focus areas discussed above.

If you have any questions or would like additional information about this topic, please contact Nicholas A. Gonzales at (414) 721-0486 or ngonzales@hallrender.com or your regular Hall Render attorney.

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