POTENTIAL PRESCRIPTION DRUG AUDIT AREAS HIGHLIGHTED IN THE OIG'S FISCAL YEAR 2014 WORK PLAN

EXECUTIVE SUMMARY

On January 31, 2014, the Department of Health and Human Services Office of Inspector General ("OIG") released its Work Plan for Fiscal Year 2014 ("Plan"). The Plan provides insight into the 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 2014 Plan:

Comparison of Medicare Part D and Medicaid Pharmacy Reimbursement and Rebates. The OIG plans to compare pharmacy reimbursement and rebate amounts for a sample of brand-name drugs paid for by Medicare Part D and Medicaid. A previous review by the OIG concluded that Medicare Part D and state Medicaid programs paid roughly the same amount for brand-name drugs, despite the fact that Medicaid rebate amounts substantially exceeded Part D rebate amounts.

Review of Pharmacies' Prescription Drug Event Data. The OIG plans to review pharmacies identified in the OIG report "Retail Pharmacies with Questionable Part D Billing" (see Hall Render's previous article on this topic here). The OIG will evaluate whether the prescription drug event records at issue were supported and complied with federal law.

The following topics are repeated in the 2014 Plan, indicating that the OIG will continue to audit and review these areas:

- Medicare Part D claims duplicated in Medicare Part A or B and the extent to which sample Part D claims are supported.
- Questionable Medicare Part D claims for HIV drugs. The OIG will describe beneficiaries with questionable utilization patterns and prescribers and pharmacies affiliated with them.
- Drugs dispensed from a retail pharmacy that has, in effect, a discount generic drug program (for example, $4 for a 30-day supply of certain medications).
- Quality of Sponsor data used in calculating Medicare Part D coverage-gap discounts.
- Sponsors' documentation of their administrative costs and investment income when submitting annual bid proposals to the Centers for Medicare & Medicaid Services ("CMS").
- Sponsors' discrepancies between negotiated and actual rebates received from pharmaceutical manufacturers.
- Re-opening Sponsors' final payment determinations.
- Savings potential from adjusting CMS and Sponsors' risk corridors.
- Manufacturer safeguards to prevent beneficiaries from using manufacturer copayment coupons to obtain prescription drugs covered by Medicare Part D.
- The extent to which Sponsors' drug formularies include drugs commonly used by dual-eligible beneficiaries.

PRESCRIPTION DRUGS

The following are the more relevant topics added to the "Prescription Drugs" section of the 2014 Plan:

Part B Payments for Drugs Purchased Under the 340B Program. The OIG plans to consider how much spending could be decreased under

Medicare Part B if Medicare were able to share in the savings for drugs purchased under the 340B program.

Covered Uses for Medicare Part B Drugs. The OIG plans to evaluate whether CMS's and its claims processing contractors' oversight was appropriate in determining whether payment for Part B drugs met coverage criteria. As part of this review, the OIG will analyze the challenges contractors encounter when making coverage decisions for drugs. The OIG's concern is that the government or its contractors pay for drugs that lack clinical evidence demonstrating such drugs are safe and effective.

Payment for Compounded Drugs Under Medicare Part B. The OIG plans to analyze each Medicare Administrative Contractor's ("MAC's") policies and procedures to prevent a MAC from processing inappropriate Part B claims for compounded medications. In certain circumstances, Medicare will pay for compounded drugs as long as such drugs are compounded in accordance with the Federal Food, Drug and Cosmetic Act.

The following topics are repeated in the 2014 Plan, indicating that the 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; and
- Medicare payments for outpatient drugs and administration of the drugs.

CONCLUSION AND PRACTICAL TAKEAWAYS

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 Susan D. Bizzell at (317) 977-1453 or sbizzell@hallrender.com, Nicholas A. Gonzales at (414) 721-0486 or ngonzales@hallrender.com or your regular Hall Render attorney.

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