HALL RENDER
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POTENTIAL PRESCRIPTION DRUG AUDIT AREAS HIGHLIGHTED IN THE OIG'S FISCAL YEAR 2013 WORK PLAN

EXECUTIVE SUMMARY

On October 2, 2012, the Department of Health and Human Services Office of Inspector General ("OIG") released its Work Plan for Fiscal Year 2013 ("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, click here.

MEDICARE PART D - PRESCRIPTION DRUG PROGRAM

The following topics were added to the "Medicare Part D" section of the 2013 Plan:

- Beneficiary Use of Manufacturer Copayment Coupons. The OIG plans to review the safeguards that pharmaceutical manufacturers have in place to prevent Medicare Part D beneficiaries ("Beneficiaries") from using copayment coupons to obtain prescription drugs covered by Medicare Part D. Because coupons may entice Beneficiaries to request brand-name drugs instead of less costly generic drugs, the OIG states that the use of coupons can implicate the Anti-Kickback Statute when used to obtain prescriptions under federal health programs, such as Medicare Part D.
- Voluntary Reporting of Fraud, Waste and Abuse by Plan Sponsors. The OIG plans to review the level of voluntary reporting by Sponsors of potential Medicare Part D fraud and abuse. The OIG will use Sponsors' data to determine the number and types of incidents discovered, identify Sponsors' fraud and abuse referral sources and review Sponsors' corrective action for identified fraud and abuse.
- Medicare Part D Sponsors' Oversight of Pharmacy Benefit Managers' Administration of Plan Benefits. The OIG will review Sponsors' ability to oversee pharmacy benefit managers ("PBMs") as they carry out the Sponsors' responsibility to administer formularies and manage prescription drug use. It is the responsibility of the Sponsor to ensure that the PBM correctly follows the same guidance and regulations that the Sponsor must follow with regard to which drugs and therapeutic classes must be covered by the formulary application of utilization management rules and which drugs are excluded from Medicare Part D.
- Specialty Tier Formularies and Related Cost Sharing. The OIG will analyze and compare Sponsors' specialty tier formularies. Typically, drugs placed on specialty tier formularies are expensive and are used to treat uncommon chronic conditions. If the specialty tier cost threshold is set too low, or if Sponsors misclassify a drug, Beneficiaries' plan choice, drug adherence and drug choices may be affected.

The following topics are repeated in the 2013 Plan, indicating that the OIG will continue to audit and review these areas:

- Patient safety and quality of care - Part D drugs approved and registered by FDA
- Characteristics associated with atypically high billing
- Medicare Part D claims duplicated in Medicare Part A or B
- Questionable Medicare Part D claims for HIV drugs
- 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
- Accuracy of Sponsors tracking Beneficiaries' true out-of-pocket costs
- Claims submitted on behalf of incarcerated individuals

- 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
- Reopening Sponsors' final payment determinations
- Savings potential from adjusting CMS's and Sponsors' risk corridors
- Review the supporting systems available to new small-sized and medium-sized Sponsors

PRESCRIPTION DRUGS

The following are the more relevant topics added to the "Prescription Drugs" section of the 2013 Plan:

- Drug Shortages Reported by Physicians and Hospitals. The OIG plans to evaluate experiences that physicians and hospitals have with drug shortages. During a shortage, providers may be forced to ration the supply of the drug, postpone the treatment of patients, substitute the desired drug with other drugs that may be less desirable and/or resort to acquiring drugs from untrustworthy sources. The OIG will ask these providers to describe their conduct during drug shortages. The OIG will also monitor any effects shortages may have on drug pricing, quality of patient care and drug availability.
- Potential Savings from Manufacturer Rebates for Part B Drugs. The OIG plans to analyze the potential Medicare Part B savings associated with requiring drug manufacturers to pay rebates to the Medicare program. This rebate plan would likely be structured similarly to the plan that allows federal and state governments to receive rebates from drug manufacturers for prescriptions billed to the Medicaid program.
- Payments for Immunosuppressive Drug Claims with KX Modifiers. The OIG plans to review compliance with the Medicare Part B requirement that payments for immunosuppressive drugs billed with a "KX" modifier meet the necessary documentation required by Medicare. Immunosuppressive drugs are used when a Beneficiary receives an organ transplant. The OIG will review Part B claims submitted with the KX modifier to ensure the documentation reflects that the Beneficiary's transplant date preceded the date on which the drug was furnished.
- Payments for Drugs Infused Through Medical Equipment Compared to Provider Acquisition Costs. The OIG plans to review provider acquisition costs for Part B covered drugs infused through medical equipment and determine the potential savings if these payments were on the drug's Average Sales Price ("ASP"). Currently, Part B drugs infused through medical equipment are paid based on average wholesale prices ("AWPs"). The OIG states that AWPs for Part B covered drugs often greatly exceed the actual cost of the drugs.

The following topics are repeated in the 2013 Plan indicating that the OIG will continue to audit and review these areas:

- Off-Label Use of Medicare Part B Drugs
- Comparison of ASP to Average Manufacturer Prices for Medicare Part B drugs
- Comparison of ASP to Widely Available Market Prices for Selected Prescription Drugs Covered by Part B
- Medicare Payments for Multiuse Vials of Herceptin
- Medicare Payments for Outpatient Drugs and Administration of the Drugs
- Comparison of Medicare and Medicaid Payments for Physician-Administered Drugs and Biologicals

CONCLUSION AND PRACTICAL TAKEAWAYS

The Plan is a great resource providers can use to enhance their compliance programs annually. Based upon the Plan, pharmacies and Sponsors should consider updating their annual internal audit plans 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.