Understand Trends in False Claims and Anti-Kickback Matters to Mitigate Risk

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Agenda

- Trends in healthcare enforcement activity
- Review of recent cases
- Upcoming legislation that may impact PBMs
Overview of False Claims Act and Anti-Kickback Statute

• What is the False Claims Act?
  – Federal FCA enacted in 1863 to punish fraud against the government
  – Amended significantly in 1986, 2009 & 2010
  – Significant use in healthcare industry
  – 30 states with FCA laws

• What is the Anti-Kickback Statute?
  – Federal AKS enacted in 1972. Criminal penalties for those who knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed by government programs.
  – 36 states with AKS laws
Federal Judgments and Settlements
(in billions)

Notable PBM False Claim Settlements

- United States ex rel. DiMattia et al. v. AstraZeneca LP et al. [2015] [$15.8M]
- United States ex rel. Kester v. Novartis Pharmaceuticals Corp. et al., [Accredo, 2014] [$60]
- United States ex rel. Vieux v. AdvancePCS, Inc. [2005] [$137.5M]
- United States ex rel. Ramadoss v. CVS Caremark Inc. [2010] [$4.25M]
- United States, et al. v. CareMed Pharmaceutical Services [$10M]
- United States ex rel. Well v. CVS Caremark, Inc. [$6M]
Retail Prescription Drug Expenditures

Federal Prescription Drug Reimbursement

Growth of Federal Healthcare Programs

**Medicaid**
- Fastest growth rate of all national healthcare expenditures
- Increased number of lives managed by PBM
  - New enrollees from Medicaid eligibility expansion under ACA
  - Continued shift from Fee-for-Service to Managed Medicaid
    - 75% of Medicaid beneficiaries will be covered by managed care organizations in 2015, up 63% from 2012

**Medicare**
- Continued growth as U.S. population ages
- Concentration of lives across fewer PDPs
- Shift towards MA-PD plans away from standalone PDPs
- Growth in employer-only PDPs

*Shift towards specialty drugs means increased dollars under Medicaid and Medicare plans.*
Sources of Enforcement Activity

• Whistle blowers (qui tam)
• Health Care Fraud Prevention and Enforcement Action Team (HEAT)
• Healthcare Fraud Prevention Partnership (HFPP)
• Medicare Fraud Strike Force
• Medicaid Fraud Control Units (MFCU)
• State Attorneys General
• Defense Criminal Investigative Services (DCIS)
### Areas Under Scrutiny for FCA/AKS

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FCA/AKS Risk Areas for PBMs

- Certification of data submissions to Government
- Intermediary roles
  - FWA monitoring of pharmacies
  - Data provided to PDPs and MA-PDs as the basis for their reporting to CMS for risk adjustment
  - TrOOP calculations and data reporting
  - Rebate negotiations, sharing and DIR reporting
- Evaluation of credit balances and timely refund of overpayments
- Specialty pharmacy operations
Spay v. CVS

Issue and Allegations

• Qui tam filed by plan-sponsor’s auditor (Spay).
• Allegations that CVS submitted false claims during 2006-2007 PDP administration:
  • Billed for drugs with expired NDCs and “dummy” prescriber identifiers.
  • DUR process failed to stop drugs dispensed with gender contraindications.
  • Failed to apply correct MAC pricing.
  • Dispensed drugs that failed formulary rules re: prior authorization and quantity limits.

Current Status

• Summary judgment granted in September 2015; 100% of claims against CVS were dismissed.

Key Takeaway

• PDP processes should reflect most up to date guidance from CMS.
• Proactively perform internal review and monitoring of PDE processes and FWA controls.
• Maintain documentation re adjudication processes, controls and systems.
**US ex rel. v. AstraZeneca / Medco**

**Issue and Allegations**

- Qui tam filed by former employees.
- Allegations:
  - Rebates and discounts on AZ drugs were kickbacks paid in exchange for formulary placement of Nexium and increased utilization.
  - Bundled discounts were used to avoid a lower Best Price on blockbuster drug.

**Current Status**

- In 2015 AZ and Medco settled for $7.9M each.

**Key Takeaway**

- Proactively review manufacturer agreements for compliance risks.
- Compliance training should be required of sales and contracting teams.
- Rebate and discount arrangements should be a part of regular compliance monitoring.
Well v. CVS Caremark

**Issue and Allegations**

- Qui tam filed by Caremark claims manager (Well) in 2007
- Allegations:
  - Medicaid incurred prescription drug costs for Medicaid eligibles also insured by Caremark-administered private health plans (i.e. pay-and-chase claims).
  - Caremark failed to refund Medicaid the full amount it paid on certain claims by improperly deducting certain co-payment and deductible amounts when calculating repayments to Medicaid.

**Current Status**

- Settled for $6M in 2014.

**Key Takeaway**

- Promptly review claims and eligibility data submitted by Medicaid for completeness and accuracy.
- Coordinate swift resolution of issues identified by Medicaid agencies.
- Clearly document Medicaid refund policies and procedures with plan sponsors.
US ex rel. Kester v. Novartis

Issue and Allegations

• Qui tam filed by Novartis account manager. Suit filed against Novartis and specialty pharmacies (Accredo, BioScrip, Curascript, CVS, etc.)
  • Allegations:
    • Kickbacks in the form of rebates and patient referrals were provided in exchange for increased shipments/sales of drugs.

Current Status

• BioScrip and Accredo have settled for $15 and $60 million, respectively.
• Novartis is scheduled for trial in November where the Government will be seeking $3.3 billion in damages.

Key Takeaway

• Increased focused on specialty drugs by Government investigators.
• Proactively review manufacturer contracts for compliance risks.
• Compliance training should be required of all customer care representatives.
• Customer communications and management processes should be subject to regular compliance monitoring.
Blanding Health Mart Pharmacy

Issue and Allegations

• FCA case initiated by the Florida branch of the Defense Criminal Investigative Service (DCIS).
• Allegations:
  • Compounding pharmacy sought reimbursement for TRICARE prescriptions that were not medically necessary or were written by physicians who did not treat the patient.

Current Status

• Settled with the government for $8.4M in July 2015.

Key Takeaway

• Increased Government scrutiny on the cost and medical necessity of compound drugs.
• The number of false claims investigations in Florida are increasing, especially as related to the TRICARE program.
• PBMs should regularly evaluate and monitor their own and in-network compounding pharmacies for issues of fraud, waste and abuse.
PBM Hurdles in Government Investigations and Litigation

- Cases involve a significant amount of documents and data across a broad array of issues and areas of the business.
- Investigations require information from multiple datasets across different business functions and systems (e.g., client/plan set up, DUR processes, claims adjudication, rebate invoices, warehouse drug purchases, etc.).
- Enterprise growth and M&A activity in the industry often lead to the need for analysis of historical data across legacy and/or decommissioned systems, acquired entities and sub-entities.
- Review and analysis of unstructured data stored in various formats can be complex (hard copy, free form text in data, voice files, etc.).
- Lack of clear and/or complete documentation supporting business decisions and processes complicates defense against certain allegations.
Upcoming Legislation
Legislation of interest to PBMs

• MAC Transparency Act
  – Bill introduced in Congress in January 2015
  – Proposed bill would require PBMs to:
    • Update MAC pricing at least every 7 days to accurately reflect the market
      price,
    • Disclose to pharmacies the sources used for making any pricing updates, and
    • Provide advance notice of pricing updates to all pharmacies in advance of
      using pricing for claims reimbursement.

• Ensuring Seniors Access to Local Pharmacies Act of 2015
  – Bill introduced in Congress in February 2015
  – Proposed bill would require PBMs to accept any independent
    pharmacy to participate in their preferred network if one or more of
    their stores is located in a "medically underserved area".