ROETZEL
FOCUSED ON WHAT MATTERS TO YOU

CORPORATE COMPLIANCE ALERT

4/8/14

Pharmacy Trends with Medicare Part D Sponsors & Pharmacy Benefit Managers

Medicare Part D Sponsor Files Another False Claims Complaint

In a lawsuit unsealed in late March, Fox Rx Inc. (Fox), the parent company of a Medicare Part D sponsor, alleges in a 36-page Complaint that CVS Pharmacy Inc. (CVS) knowingly submitted claims for prescription coverage of Schedule II and other controlled substances without valid prescriptions. Fox filed the action for violations of the False Claims Act (FCA) on behalf of itself, the United States, 18 states and the cities of Chicago, New York and Washington, D.C. Should the false claims allegations of the whistleblower prove true, CVS stands to suffer hundreds of millions of dollars in damages and civil penalties for its violations. Fox has filed similar lawsuits against Omnicare and Walgreens.

The CVS Fox suit alleges that between January 1, 2008 and March 2010, approximately 20% - nearly one out of every five – of the controlled substances claims submitted by CVS to the Fox plan were illegal for lack of a valid prescriber's Drug Enforcement Administration registration number (DEA number). By comparison, only 7.24% of claims for controlled substances submitted to Fox by other retail chain pharmacies during the same time period were submitted without a valid DEA number. Fox, its pharmacy benefit managers (PBMs) and other "downstream" entities relied on the claim information in determining whether to pay CVS's claims and in reporting the claim information to the Centers for Medicare & Medicaid Services (CMS). The omission of DEA numbers on CVS's claims are alleged to have caused Fox and its PBMs to submit false claims to CMS, thus leading Fox to invoke the FCA and its whistleblower provisions in the filing of the Complaint.

Pharmacy Benefits Managers Terminating Provider Agreements with Pharmacies

Throughout the country pharmacies are receiving termination notices pursuant to their respective Provider Agreements (PA) from various PBMs either for cause, based upon an alleged risk, or pursuant to a not-for-cause termination notice. Commonly, the not-for-cause termination allows the PBM to terminate the PA. When this occurs, there are limited remedies available in law, but depending upon the circumstances, several remedies under equity can be asserted against the PBM. If the termination is for cause, it has been successful to demonstrate the provider pharmacy has an effective compliance program that either has or will address the "risk concern" expressed by the PBM. Many of the risks asserted by the PBMs for cause termination derive from co-pay waivers, HIPAA and lack of proper Business Associate Agreements, mail orders, diabetic supply cold calls, compounding, pharmacies, marketing sales forces and non-compliance with the PA.

The PBMs are terminating the majority providers based upon competitive interests of the PBMs and not due to any wrongdoing by the provider pharmacy. It is imperative for provider pharmacies to react immediately after receiving the termination notice. The combination of attacking the PBM for bias and harm to patient care, while demonstrating proper compliance with state and federal Medicare laws and if necessary, filing a Complaint and pursuing Restraining Orders have provided positive results for provider pharmacies.

Given that a whistleblower's "share" of any settlement or damage award in an FCA matter may be significant, the incentives are great for Medicare Part D sponsors and their PBMs to closely scrutinize all prescription drug claims for compliance with state and federal laws as well as the PAs. With this climate, all pharmacies would be well advised to review all PAs and understand the importance of proper documentation and recordkeeping in their dispensing of prescription drugs. Roetzel's Corporate Compliance attorneys are experienced in both the regulatory issues of the pharmacy industry and the FCA. For further information, or a review of your current compliance procedures and manuals, please contact the following Roetzel attorneys:

Brian E. Dickerson
202.570.0248 | bdickerson@ralaw.com

Ned Milenkovich
312.582.1676 | nmilenkovich@ralaw.com