Genetic testing and kickbacks: Lessons for pharmacies

by Jeffrey S. Baird, Esq.

Recent enforcement actions against genetic testing labs provide valuable lessons for pharmacies. An Oct. 9, 2019, Department of Justice press release states, in part:

“The Justice Department announced today that UTC Laboratories Inc … has agreed to pay $41.6 million … to resolve allegations that [it] violated the False Claims Act by paying kickbacks in exchange for laboratory referrals for pharmacogenetic testing … The government alleged that between 2013 and 2017, UTC … paid remuneration to physicians to induce the ordering of pharmacogenetic tests, purportedly in return for their participation in a clinical trial … The government also alleged that UTC … paid … sales commissions, to entities and individuals as part of the scheme … The settlement … resolves allegations in six [whistleblower] lawsuits….”

Pharmacies can derive six lessons from this:

• **A kickoff results in a false claim** – If a pharmacy is engaged in a kickoff arrangement, then claims that ultimately arise out of that arrangement are “false claims.”

• **Large claims submissions invite scrutiny** – Third party payers have edits in place that spot claims submissions that are “out of the ordinary.” Examples are:
  – A pharmacy has a history of submitting claims at a historically established dollar level and for particular products. But then the payer notices a spike in the dollar amount of claims submissions for a particular product.
  – A pharmacy submits a noticeably greater number of claims for a particular product category than other pharmacies.

• **Every employee is a potential whistleblower** – If an employee witnesses fraudulent actions by his/her employer, then the employee may be motivated to gather information and hire an attorney who specializes in filing whistleblower lawsuits. The lawsuit will be filed in federal court and will “go under seal.” A civil assistant U.S. attorney, or AUSA, will review the lawsuit and investigate the allegations. If the AUSA concludes that the lawsuit has merit, then the DOJ will take over prosecuting the lawsuit. The lawsuit will be unsealed and served on the employer. The lawsuit is based on violation of the federal False Claims Act. Normally, whistleblower lawsuits are settled, with the whistleblower receiving 15-20 percent of the settlement proceeds. If the facts are egregious, then the lawsuit may lead to a criminal prosecution.

• **Avoid sham clinical trials** – A legitimate clinical trial is one that is connected to a hospital or medical school, and/or overseen by an institutional review board. A sham clinical trial is one that is a subterfuge designed to funnel money to referring physicians.

• **1099 independent contractor marketing reps** – The federal anti-kickback statute, or AKS, prohibits a pharmacy from giving anything of value to persons/entities in exchange for referring (or arranging for the referral of) patients covered by a federal health care program, or FHCP, if a pharmacy pays commissions to 1099 independent contractor marketing reps for generating FHCP patients. If so, then the AKS is likely violated.

• **Products and services that are not medically necessary** – If a pharmacy submits a large number of claims for products that were not used very much in the past, then the pharmacy will find itself in the government’s crosshairs.

Jeffrey S. Baird, Esq. is chairman of the Health Care Group at Brown & Fortunato, P.C., a law firm based in Amarillo, Texas. He represents pharmacies, infusion companies, home medical equipment companies, and other health care providers throughout the United States. Baird is board certified in health law by the Texas Board of Legal Specialization. He can be reached at 806-345-6320, or at jbaird@bf-law.com.