New Drugs Trigger Safety Concerns and Higher Medical Expenses for Healthcare Payers

Healthcare Recovery Solutions LLC (HRS) reviewed a study conducted at Yale University, which found that new safety concerns develop in nearly one third of all FDA-approved drugs after they have been released onto the market. With the FDA under pressure to expedite drug approval, the prevalence of drugs with post-market safety concerns could increase, having significant implications for healthcare payers and consumers.

Post-Market Safety Events Run High

Researchers at Yale University analyzed all drugs approved by the FDA from the start of 2001 to the end of 2010, and followed them through February 2017. A "post-market safety event" happened when the FDA withdrew the drug from the market due to safety concerns, issued a black box warning, or issued a safety communication to let physicians and patients know that new safety information has been determined. It was found that 32%, or 123 approved drugs incurred post-market safety events. Moreover, biologics, psychiatric drugs, and drugs approved through the FDA's accelerated approval pathway were associated with higher rates of safety events.

FDA Approval Process Can't Detect All Dangers

The FDA's assessment of new drugs is based largely on premarket clinical trials, most of which study less than 1,000 patients over a period of 6 months or less. With this relatively short process, many safety issues that would normally be observed if more patients use the drug over a longer time period go undetected.

Healthcare Payers Carrying the Cost

The leading researcher in Yale's study states that these findings "show that there is the potential for compromising patient safety when drug evaluation is persistently sped up." One third of drugs that come to market have adverse health impacts and patients taking these drugs may require medical attention to treat their negative effects. These treatments translate to greater financial burdens on healthcare payers.

Healthcare payers can shift the financial burden associated with harmful pharmaceuticals back to the product manufacturer. The key is the ability to proactively identify these cases within your member population. Taking affirmative action gives payers the opportunity to recover these expenses. Healthcare Recovery Solutions is the industry expert in identifying difficult-to-detect claims for healthcare payers, and has the tools necessary to pursue the recoveries.