WHITE PAPER: FIVE STEPS TO LOWER COSTS FROM DRUG ADVERSE EVENTS

Challenges Facing Payers

The introduction of the Affordable Care Act is forcing Payers to offer low cost solutions in a market where drug prices continue to rapidly increase. Engaging Providers to take an active role in helping to reduce those costs, while maintaining the doctor-patient relationship is an extremely difficult balancing act. Data-driven solutions are being presented, but having the time and resources to analyze, understand, and implement those solutions is scarce. As a result, costs continue to rise, Providers are shunning plan participation, patient outcomes suffer and the Payer industry’s reputation continues to take a beating in the public forum.

Drug Adverse Events are Driving Up Costs

Adverse events (side effects) from commonly prescribed medications are directly impacting Payers’ bottom lines. An independent study conducted by AdverseEvents, Inc., a healthcare informatics company focused on improving outcomes, showed that hospital admissions due to drug adverse events cost the industry $10.64 billion in 2011.

The two main reasons:

1. When making safety related prescribing decisions, Healthcare Providers currently rely almost exclusively on side effect information listed in FDA-approved drug labels and FDA’s occasional post-marketing alerts. This reliance is flawed. Labels are submitted to the FDA during the drug approval process and are based on relatively small clinical trials with homogeneous patient populations. No one would argue that the tested patients accurately represent real world populations. Post marketing surveillance and alerts generated by the FDA are limited by poor data resources and delayed analysis. By the time FDA identifies an adverse event trend and issues an alert, it is already too late and has cost Payers millions, if not billions, of dollars in side effect related costs. As an example, look at the well-known case of Avandia. The AdverseEvents, Inc. study found that in 2010 Avandia was causing adverse events leading to hospital admission at a rate nearly 30 times higher than normal (an admission rate of 0.1397% vs. an industry average admission rate of .005%). The FDA did not take action until November 2012 when it severely restricted Avandia’s use in the U.S. market. Leading up to FDA action, 10,470 hospitalizations were reported as an outcome of an Avandia side-effect. Using an average
hospital stay cost of $15,734\(^1\), it can be estimated that Avandia cost the system $164.7 million. Faster action would have generated millions of dollars in savings, and more importantly a drastic improvement in patient outcomes.

II. Payers are not taking proper adverse event related costs into consideration when constructing, and optimizing, their formularies. By not fully accounting for the cost of side effects, events such as **Formulary Inversion™** can occur (a situation where a drug classified as Tier 1 causes higher admissions rates than Tier 2 or Tier 3 equivalents), **Formulary Omission™**, or cases where drugs covered in formulary are causing admissions at a higher rate than other comparable drugs in the same pharmacologic class that are not covered at all, also arise.

AdverseEvents, Inc. utilized a publicly available formulary from United Heath Group to determine if any of these cases could be uncovered. AEI found 77 instances of **formulary inversion™**. Looking at one of these cases in the anticonvulsants class, it was found that Klonopin, which is in Tier 1, had an admission rate six times higher than a similar drug, Keppra XR which was designated to Tier 2. If all Klonopin prescriptions were changed to Keppra XR, the admissions savings alone would be $7.7 million. Further data points are required to come to a true total cost conclusion and more analysis is clearly warranted.

**Taking on Adverse Events: A Five Step Plan**

Patient outcomes and system costs are negatively affected by drug adverse events. In order to begin to reduce costs from these side effects, all levels of the healthcare ecosystem need to play a role. Patients, Providers, and Payers all need to be accountable.

The Payer is ultimately responsible for the costs and often helps determine what drugs are prescribed. As such, Payers need to take a leadership position and facilitate accountability.

Payers must take actionable steps to reduce costs due to drug adverse events.

**Step 1: Inform**

**INFORM PATIENTS OF THEIR DRUG CHOICES.** Studies show that 75% of patients do research on-line for health information, signaling that as consumers, they want to have an active role in their healthcare. This includes participating in the decision on drug prescriptions.

Patients must fully understand the benefits and risks involved in their medication, and understand their choices. This begins with the patient doing their own research and continues by encouraging them to have transparent conversations with their Provider.

It is very important that the patient is getting the RIGHT information. Uncontrolled, anecdotal information found in online chat rooms, forums, and other unverified sites often does more harm than good.

Payers have the organizational ability to encourage their end-consumers to use trusted source information - “Payer approved,” either provided by them or more importantly through their Provider. Verifying the source of information provides a level of confidence to both the Provider and patient that the information being accessed is complete, unbiased and accurate.

**Step 2: Empower**

**EMPOWER PROVIDERS TO MAKE BETTER DRUG SAFETY CHOICES.** At the Provider level there are numerous factors that influence prescribing behavior. Persuasive pitches by pharmaceutical sales reps, anecdotal information from peers, data from clinical trials, and of course, the patient’s unique condition, all contribute to what drug a Provider prescribes. These factors contribute to conflicting and incomplete data points, which ultimately leads to ill-informed prescription decisions.

In addition, it is common practice to rely solely on FDA guidance for drug safety, even though most researchers and Providers readily admit that the FDA data is faulty and incomplete. In no other aspect of American society does an entire profession rely almost entirely on a government organization without independent oversight and analysis.

This process is flawed.

Much of FDA’s data are derived from clinical trials. From a safety perspective, these data are not reliable because pharmaceutical developers, in order to increase the likelihood that drug efficacy signals can be detected, purposefully enroll homogenous groups of clinical trial subjects. Such methods are widespread in the industry and leave open the possibility that drugs will have various and unexpected side effects after their approval.

Accordingly, the full adverse event profile of a drug is almost never known until it is marketed to a large population. The FDA does monitor post-marketing case reports via the FDA Adverse Event Reporting Systems (FAERS) and when the side effect profile reaches a critical mass, they may take action via black box warnings, “Dear Dr.” letters, and in severe cases, removing the drug from the market. Unfortunately, this often happens after thousands of patients have been affected and millions of dollars worth of insurance claims have been filed.

In order for Payers to ultimately lower treatment costs they must utilize tools that will allow for easy and quick monitoring of post-marketing adverse event reports themselves, while then being able to transfer this information in laymen terms to patients. By ensuring that the entire adverse event profile is taken into account, Providers can make a more informed decision that is in the best interest of their patients.

**Step 3: Recruit**

**RECRUIT PROVIDERS TO THE NETWORK WITH A VALUE PROPOSITION BEYOND JUST COST.** Due to cost analysis decisions by the Payer tight restrictions on what medications can be prescribed are causing Providers to readily opt out of Payer plans. They feel a loss of control over their patients’ care.

In order to attract Providers, Payers must offer value-added services that foster the doctor-patient relationship, rather than limiting it. Committing to drug safety by giving Provider networks the tools they need to make better prescribing decisions is a win-win. It accomplishes the Payers goal of reducing costs, the Provider goal of delivering the highest quality healthcare, and the patient goal of being well.

**Step 4: Analyze**

**ANALYZE FORMULARIES ON A TRUE COST BASIS.** The full adverse events picture is not currently being taken into account when constructing formularies. Payers need easy access to the FAERS dataset in
order to analyze side effect incidence and outcomes (such as hospital admissions and readmissions) in order to fully understand the true costs of drugs on their formulary.

By uncovering instances of Formulary Inversion™ and Formulary Omission™ steps can be taken to properly adjust formulary tiers and covered drugs.

Step 5: Monitor

**MONITOR POST-MARKET SAFETY SIGNALS TO MAKE PREEMPTIVE DECISIONS THAT SAVE MONEY AND LIVES.** FDA drug warnings and drug withdrawals can take years - risking lives, as well as millions of dollars in hospitalization costs, and unnecessary patient visits and tests. Payers actively participating in post market surveillance enables better understanding of drug and class specific trends that help inform making potential life- and cost-saving decisions prior to formal FDA action.

Demonstrating that the Payer maintains a close watch on the drug safety landscape can ensure a level of confidence in their Provider network, and in turn the Providers’ patients, that emerging safety issues are being thoroughly reviewed and analyzed for their benefit, and that prescription decisions are not based solely on upfront drug costs. This can help foster better prescribing decisions and patient outcomes.

Close monitoring of drug adverse events can also signal cases of Formulary Inversion™. Switching formulary tiers due to an inversion event could save the Payers millions in adverse event related costs, and should be considered best practice.

**Bringing it All Together**

The emergence of health economics and outcome optimization using ‘big data’ has identified numerous issues, and in turn, solutions. However, the solutions are often extremely time, budget, and resource intensive. A solution that can genuinely fit into the existing health ecosystem and encourage change organically will be a solution that gets implemented.

**Introducing AdverseEvents**

Founded in 2010 by healthcare industry veterans, AdverseEvents, Inc. is a California-based informatics company that improves patient safety and reduces systemic healthcare costs. AdverseEvents offers a suite of products based on its proprietary RxFilter™ and RxScore™ technology that is designed to help inform, empower, recruit, analyze and monitor.

**About RxFilter™:**

*RxFilter™ provides complete data optimization of the FAERS dataset through a 17-step algorithmic process to make it completely accessible and searchable.* The RxFilter™ process:

- Corrects for drug name misspellings and incorrect data within the major fields
- Aggregates generic and non-U.S. brand name drugs under a single U.S. brand name
- Removes duplicate cases
- Layers in full MedDRA hierarchy
- Embeds PRR and ROR calculations
- Identifies common adverse event and condition types within the database
• Standardizes approximately 98% of the cases in each quarterly data upload, leaving only 2% of the cases in the hands of analysts to manually review

About RxScore™

RxScore™ is a predictive algorithmic scoring model that provides a drug safety ranking system based predominantly on post-marketing safety signals. Combining 9 multi-weighted factors, it relies upon a patent-pending methodology that is a statistical, interpretable, and comparable measure for drug safety.

Applying AdverseEvents’ RxFilter™ and RxScore™ to the Five Steps

Inform

Inform patients about their choices. RxScore.com is a free-of-charge patient/consumer focused web application utilizing the RxFilter™ technology to serve as a one-stop-shop for all adverse event information, allowing the patient to actively participate in their healthcare. It provides personalized adverse event overviews based on one or multiple drugs, eliminating the need to go to Internet forums and other non-standardized web sites. The patient has the ability to access their RxScore™ directly from the site, request the RxScore™ from their Provider, or find a Provider that has access to the RxScore™ Provider application.

Empower

Empower Provider networks to make better drug safety choices. By putting the RxScore™ in the hands of the Provider, the doctor remains in control of the healthcare conversation. Providers can purchase access to the RxScore™ Provider application individually or through affiliate groups. Payers also have the ability to provide access to their networks via the RxScore™ Payers application.

Recruit

Recruit Providers to your network with a value proposition beyond cost. By implementing the RxScore™ Payers application, Payers are investing in their network by providing access to RxScore™ Provider. Doing so establishes commitment to the doctor-patient relationship and provides tools that allow their network to reduce total cost from drug adverse events, while providing them a value-added service and a further incentive to be an in-network Provider.

Analyze

Analyze your formulary on a true cost basis. Custom consulting with AdverseEvents to answer specific questions surrounding Formulary Inversion™ and Formulary Omission™. Perform practice group risk assessments to understand where the Provider relations group should focus their time, or conduct drug/class specific analyses, including real-time FAERS data extraction via FOIA requests, as well as full analysis by AdverseEvents analysts.

Monitor post-marketing safety signals to make preemptive decisions. Access AdverseEvents Enterprise which includes direct RxFilter searching, custom data exports, and a dedicated AdverseEvents Solutions Consultant. Stay on top of the drug safety landscape through quarterly FAERS data release overview reports, drug specific in-depth analysis prior to FDA actions, and daily Drug Safety Monitor alerts.