RxInformer

Emerging issues that will impact workers' comp

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Spring 2012

Healthesystems™

In today's workers' compensation world, change occurs at a dizzying pace. From compliance to treatment strategies, opioid use to potent new drugs that can drive costs sky high ... absorbing all that change may seem like an impossible mission for payers.

Mission: Possible

An effective PBM partner should help identify and educate payers, patients and providers about ongoing trends, emerging issues and concerns by, among other things, analyzing data, delivering clinical insight, and effectively using evidence-based guidelines.

As a medical cost containment provider focused on providing the most proactive PBM services and solutions, we publish the *Rx Informer* to help workers' compensation professionals gain greater insight into the new and evolving industry challenges as opposed to solely reacting to the trends of the past. Each of the following pieces touch on current and potential future trends that in the end can have a serious impact on payers. The idea is to be prepared, know what is happening, and proactively develop the best strategies to meet those ever-changing challenges.

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A Changing Scenario: New Opioids Requiring Close Scrutiny in Workers' Compensation

In the world of prescription drugs, the evolving market is bringing new opioid formulations likely to have a significant impact on the workers' compensation industry. Several new opioids have recently been approved by the FDA and soon will be released to the marketplace, while a few others are currently in development. Given the rampant use of opioids in the workers' compensation population and their effect on long-term claim costs, the potential impact of these products warrants a closer look.

Zohydro

The most interesting of these products is Zohydro, an extended-release hydrocodone product currently in Phase 3 clinical trials from manufacturer Zogenix. Hydrocodone is currently available as an immediate-release opioid, but only in combination with other medications such as acetaminophen (e.g., Norco®, Lortab®, Vicodin® are the most popular combination products). Unlike these currently available hydrocodone products, Zohydro will not be in combination with acetaminophen or ibuprofen; it will also be an extended-release opioid. Unlike the newly marketed abuse-resistant formulation of OxyContin, Zohydro will likely not be crush-resistant, leading to concerns about its abuse potential.

Apart from Zogenix, three additional pharmaceutical companies are currently working to produce a new "pure" formulation of hydrocodone. Zohydro will likely be first to market, with a launch slated for late 2012 or early 2013. It is expected to be a strong competitor to OxyContin for a share of the long-acting opioid market. Like OxyContin, Zohydro should be designated as a Schedule II controlled substance. Zohydro will likely become a highly prescribed medication in the workers' compensation population due to prescribers' familiarity with hydrocodone, the most prescribed medication in the U.S. As a new brand drug, the cost of this medication is expected to be higher than the currently available hydrocodone/acetaminophen products, so widespread use in workers' comp could have a significant impact on drug spend.

Oxecta

In June 2011, the FDA approved Oxecta, a new immediate-release (IR) oxycodone formulation that is now available in pharmacies. Oxecta is indicated for the treatment of moderate-to-severe acute and chronic pain. Unlike other IR oxycodone products, Oxecta is specifically designed to be abuse-deterrent, with properties meant to discourage the injection of dissolved tablets or snorting of crushed tablets. Marketing of Oxecta is likely a response to the growing abuse of immediate-release oxycodone. Prescribers seeking to discourage opioid abuse may turn to Oxecta as an alternative to other immediate-release formulations. Oxecta should be used only for patients who require an abuse deterrent product (i.e., a history of substance abuse or abuse potential has been identified). Oxecta is significantly more expensive than the generic oxycodone IR products. Payers should be modifying drug formularies appropriately, and ensuring only patients meeting the defined criteria are being treated with this drug.

Product Comparisons	Approximate Wholesale Price* per unit
Oxecta (5mg, 7.5mg)	$3.20 - 5mg $3.20 - 7.5mg
Oxycodone IR (various brands)	Approximate pricing (based on Mylan brand generic) $0.48 - 5mg $1.20 - 15mg

** The Average Wholesale Price (AWP) is an approximate value as of April 2012 and is solely provided for illustrative purposes. NOTE: AWP may be higher than retail pricing; however, it is a means of comparing relative costs regardless of drug plan, pharmacy pricing or other factors that may impact actual retail pricing.*

Table 1

Rapid-release Opioid Formulations: Abstral, Onsolis, Lazanda, Subsys

Other opioid formulations that continue to deserve attention are the rapid-release fentanyl (RRF) formulations – Abstral, Onsolis, Lazanda and Subsys. Seeking to capitalize on the marketing success of Actiq and Fentora – with 2006-2010 sales estimated to be in excess of $1.5 billion – these newer RRF products use unique delivery systems to provide the ultra-potent opioid fentanyl to the user. It is well-documented that an opioid's abuse potential is directly linked to how fast the drug reaches the blood stream and the brain. Therefore, the abuse potential of RRFs, where the fentanyl is delivered either sublingually (Abstral), as a nasal spray (Lazanda), or by being absorbed by the mucosa in the cheek (Onsolis) is concerningly high. This has led the FDA to require manufacturer-sponsored programs, known as Risk Evaluation and Mitigation Strategy (REMS) programs to restrict the use of these medications. Onsolis, for example, is available only to patients, physicians and pharmacies that register with the manufacturer, and requires secure, direct-to-patient mailing. Under their REMS requirement, Lazanda and Abstral require prescribers and pharmacies to register with the manufacturer before dispensing.

These and other RFFs could continue to impact the opioid landscape in the United States, as additional formulations continue to be developed. With the U.S. market for RFFs currently valued at over $500 million annually, all estimates project the use of these "novel" opioids to continue rising.

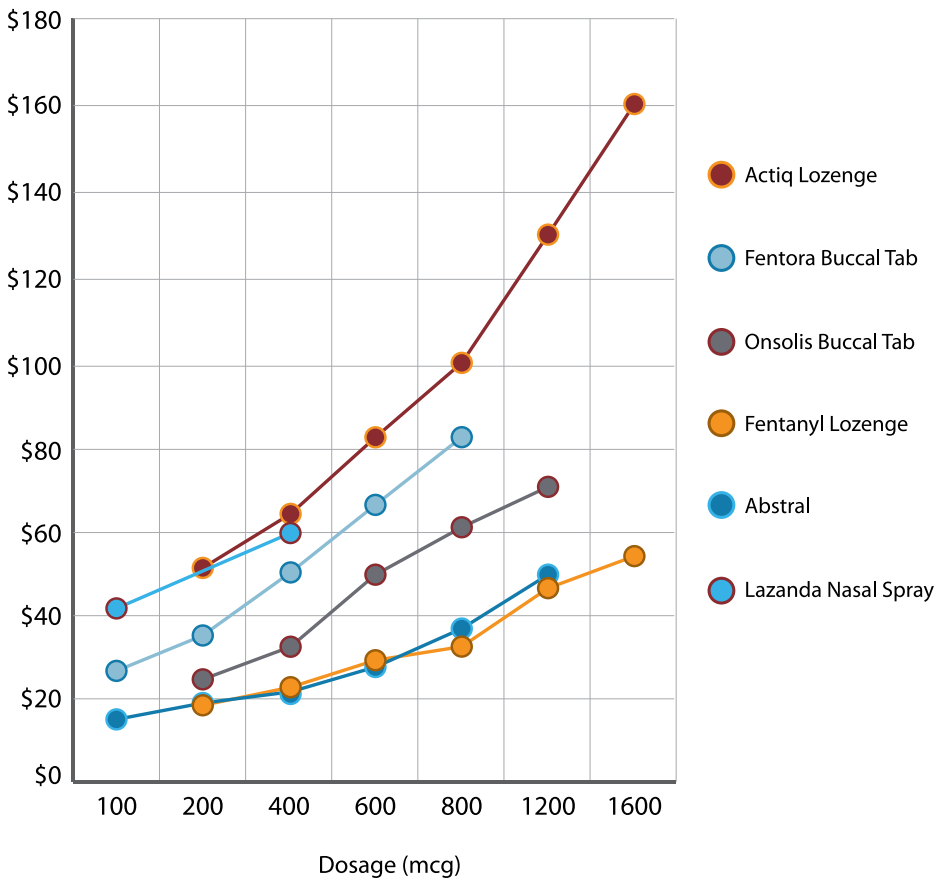


Chart 1

Knowing When to Stop

The Perspective of Ralph Kendall, PharmD, Vice President of Clinical Services, Healthesystems

Dr. Ralph Kendall

While reading a commentary article in a recent issue of the *Journal of Managed Care Pharmacy*, I was struck by a very simple, yet powerful statement, "Stopping prescriptions for medicines that patients no longer need is an important part of good prescribing practice," the author wrote.

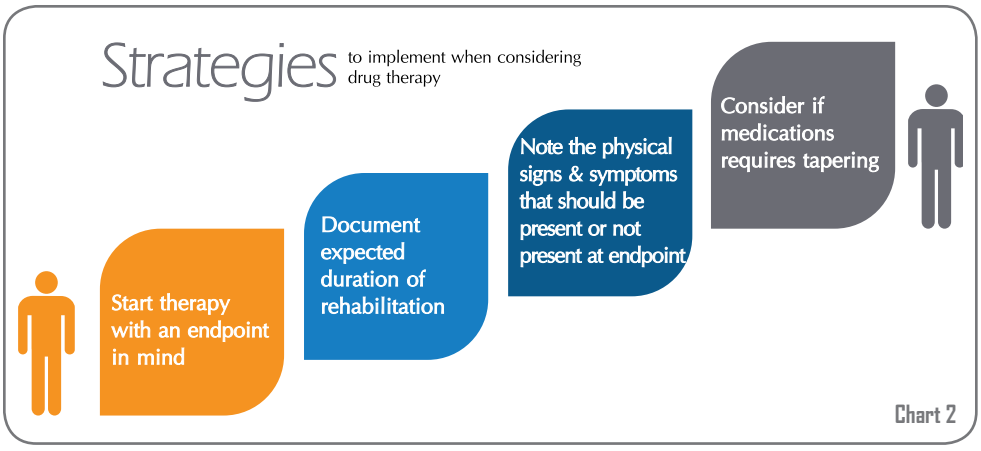
This seems fairly obvious, but it's still not happening across the board.

In fact, it seems we teach the biological processes of disease and injury, proper diagnostic techniques, and how to triage the problems encountered with patients. Yet, medically speaking, what do we do when the complaint is no longer relevant? In many cases, we fall far short of doing the right thing.

In our case history reviews at Healthesystems for example, we've seen countless patients who remain on therapies well past the expected recovery time. We see it across almost all therapeutic classes in workers' compensation injuries. Of course, it doesn't have to be that way.

As healing and rehabilitation progress, we simply must learn to ask if the pain is still as severe? Or if the muscle group is still in spasm? Or is the injured tissue still inflamed? Each of these questions, depending on the answers, can represent having reached the point when specific medications should be discontinued.

Yet, more often than not, we still see the medications used to treat the acute phase of an injury continued for months and even years. Of course, patients who fear the return of pain may contribute to this unfortunate trend. Other factors include the transfer of care from a specialist to a primary care physician (without complete directions as to the intended duration of therapy); patients may like the way medications make them feel; or even worse, workers' compensation patients may be motivated to "extend" their injury status by continuing to use medication. In short, continued use of medication validates the injured worker's suffering and need for treatment. Continuing medications beyond the intended or expected treatment duration, of course, can lead to medication misadventure, including falls, additional medications to treat side effects, expression of toxicity, dependency, diversion, stockpiling and more.



There are solutions. Perhaps the best strategy to begin answering the question of when to stop starts by documenting in the patient record the expected duration of rehabilitation. Providers should be sure to note what physical signs and symptoms will be present or not present when this end-point is reached. Or ask if some medications require tapering.

Most of all, the most effective approach is to begin with the end in mind. Success is almost always sure to follow.

Opioid Use + Multiple Prescribers = A Powder Keg of Potential Misuse, Abuse, Diversion and Increased Pharmacy Costs

The Problem

It may come as a surprise, but injured workers receiving multiple prescriptions from multiple prescribers is not all that uncommon. Naturally, this is a dangerous situation, with serious potential for things to go wrong for both payer and patient.

While these cases may be thought of as extreme and even rare, injured workers using opioids and seeing multiple prescribers is a relatively frequent phenomenon. For example, during several recent new client implementations converting payers to our pharmacy program, Healthesystems identified situations where more than 25% of claimants who were receiving prescriptions on more than one occasion, and were prescribed opioid medications, also saw three or more prescribers during the same period.

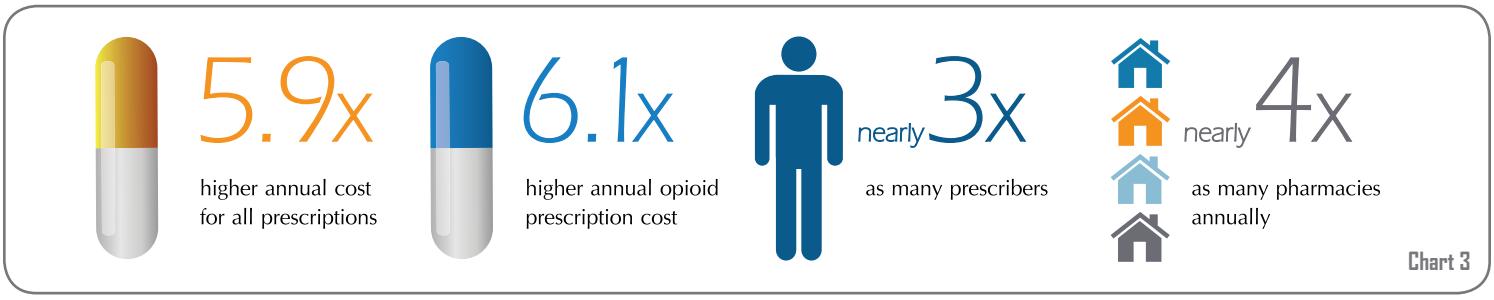
When multiple prescribers are involved, there is a much greater probability for patient confusion and misadventure, including drug interactions, therapeutic duplication, additive adverse side effects, and possible abuse, misuse or diversion. Not only does this practice place claimants at risk for medication-related issues, their monthly prescription costs were 24% higher when compared to claimants who saw a single provider.

The Analysis

To analyze this risk-laden scenario further, Healthesystems reviewed the prior PBM programs' historical data to further study cases in which claimants:

- Received prescriptions from three or more prescribers,
- Received prescriptions from three or more pharmacies, and
- Concurrently received multiple opioids

Opioid spend alone for these claimants averaged nearly $5,000 annually. When compared to all claims with opioid use, these claims averaged (see Chart 3 below):



A Solution

Payers and their PBM partners must continually develop and improve fraud, waste and abuse programs that target claims with identified risks. For example, the Healthesystems VigilantRx clinical program proactively identifies patients with multiple prescribers, high-dose opioid prescriptions, high pharmacy costs and inappropriate medications, as these risks occur. This allows payers to address the situation immediately and mitigate the risk quickly. Consistent communication by clinical experts with the prescribers — discussing the importance of patients having a lead prescriber and a single pharmacy or pharmacy system (e.g., a national drug chain) – is critical.

Communication between prescribers also is essential for ensuring patient safety and optimal clinical outcomes in regards to recovery and return-to-work. In every case where multiple prescribers must be involved, and especially when opioids are prescribed, it is important to establish a lead prescriber. This provider should coordinate not only the care plan but also the drug therapy, including discussing the patient's choice of pharmacy, to prevent possible miscommunication and overlap in therapy.

The need to identify claimants upon initiation of opioids, especially those seeing multiple prescribers is clear. This specific type of case and any potential issues should be discussed with both the injured worker and prescribers, and tightly managed through the rehabilitation process. Finally, claims professionals must be empowered to ask physicians to coordinate care with other prescribers and document the expectations and outcomes of opioid use and medication therapy.

This potential for abuse in these cases can be detected fairly easily with the right tools, but any solution lies in a tightly integrated communications effort among the PBM, payer, prescriber and patient.

Medical Marijuana and Drug Interactions in Workers' Comp: Potentially Problematic

As "medical marijuana" or cannabis gains more mainstream traction and publicity about being used for medical purposes, it also is becoming an issue for workers' compensation payers. Clinically, the most important issue to address is which problems might arise if medical marijuana is combined with the most commonly used drugs in workers' comp?

The National Institute of Drug Abuse reports that over 16.7 million Americans reported using marijuana at least once in the prior month, making the studies of the potential effects, adverse effects, and interactions with marijuana a concern.[1] Most of the recently reported data has focused on potential medicinal benefits, while little has been published regarding the potential interactions and adverse events associated with the use of marijuana and other related medications.

Studies have been conducted with Marinol and Cesamet® (nabilone), the two FDA-approved orally administered synthetic cannabinoids, and moderate interactions with opioids were noted. Orally ingested marijuana interacts with many drugs commonly used in the workers' comp population by interfering with drug metabolism. Smoked marijuana induces an additional enzyme frequently involved with drug metabolism, raising additional concern with drug interactions compared to orally taken synthetic cannabinoids.[2] Current studies that discuss oral cannabinoids do not necessarily apply to the inhaled forms of cannabis, adding an additional layer of unknown reactions.

Evidence shows that opioid and cannabinoid receptors may enhance or inhibit one another, though data has not been consistent across species. In rodents and monkeys, opioid consumption such as morphine increased desire for cannabis use. One study found that use of naltrexone, an agent that blocks the effects of opioids in humans, increased the patient's perceived level of marijuana intoxication.[3,4] These patients also experienced increased cardiovascular effects. This demonstrates that marijuana does not work at all of the receptor sites where opioids work, and as such may cause unexpected adverse effects. Medications that contain naltrexone include Embeda® (morphine-naltrexone) and ReVia® (naltrexone).

Both marijuana and opioid medications are CNS depressants and may have additive effects and cause over-sedation. Caution should be used when combining CNS depressants with marijuana, as this may worsen the adverse effects from opioids. While it would seem that the over sedation seen with opioid and marijuana use would be related to increased blood levels of opioids, a recent study did not support this theory. Results reported significantly decreased opioid maximum concentrations and a delay in time to reach maximum concentration levels.[5] This information further reinforces the idea that interactions with marijuana are unpredictable.

In addition to the increased CNS adverse effects with opioids, other drug interactions have been reported. While some are simply case based, consideration of potential interactions is warranted and ongoing research needed. Other examples of interactions include:

- A reported increase of warfarin, a blood thinner, leading to an increased number of bleeding events.
- Decreases in the effects of theophylline, a medication used for respiratory diseases such as COPD and asthma, when used with inhaled marijuana.

There have also been reports of adverse reactions such as toxicity when drugs that are metabolized via the same pathway are used in conjunction with cannabis. Examples of these medications include tricyclic antidepressants and selective serotonin reuptake inhibitors (SSRIs). Other adverse CNS effects exist with the use of benzodiazepines, alcohol, barbiturates and antihistamines.[6]

Data from the National Survey on Drug Use and Health (NSDUH) indicates an association between cannabis use and nonmedical use of opioids. Likewise, an association was found between use of cannabis and medical use of opioids (data was limited to states without medical marijuana laws).[7] This implies a greater risk of drug misuse when cannabis and opioids used together. Prescribers should be cautious when combining medications and look for signs of abuse, addiction and diversion.

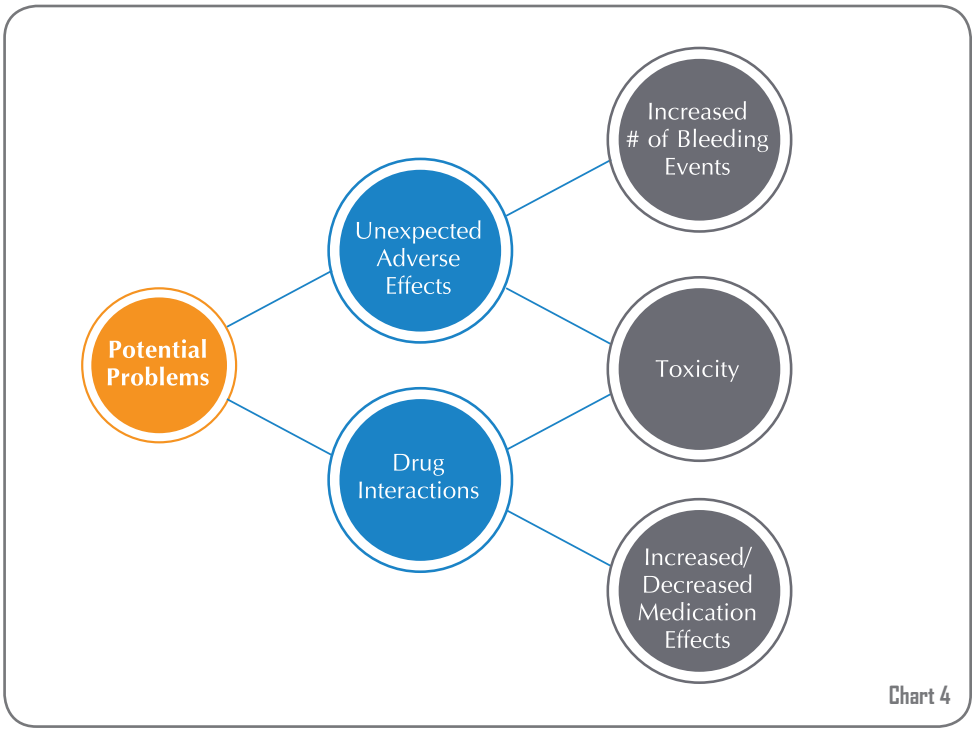


Chart 4

Patient interviews and drug screens are potential ways to assess marijuana use. This information is important when providing patient care to identify both potential addictive behaviors, as well as medication interactions. Marijuana interactions should be evaluated with all concurrent prescription medications.

Marijuana interactions should be evaluated with all concurrent prescription medications.

Clearly, there are concerns and possible contraindications for medical marijuana use in the workers' compensation population. Though a number of states have removed state-level criminal charges for marijuana possession and use by patients with certain medical conditions, the FDA has deemed marijuana as a Category I agent due to its high abuse potential. There is currently no accepted medical use in therapy in the United States, and there is a lack of accepted safety data.[8]

Healthesystems is closely tracking this issue, ensuring clients are aware of the potential for medical marijuana's impact on other prescription drugs. We believe that working with clients to find ways to limit this type of risk is a critical part of the workers' compensation care continuum.

Reformulated Opioids: Are Abuse Deterrents Losing Their Promise?

No one can argue that opioid abuse — the focus of countless articles, debates and discussions — is not a concern in workers' compensation.

For starters, estimates for this very specific patient population indicate that potent and highly addictive opioids account for approximately 25% of a payer's total prescription costs. More specifically, oxycodone-based products, primarily OxyContin®, account for a large percentage of the total opioid spend for many workers' compensation payers.

When considering that approximately one-third of all claimants who begin using an opioid for three or more consecutive months will continue using the drug for longer than one year, the situation gets even more worrisome. Also, research shows that continued opioid therapy is often associated with delays in returning to work and settling claims.

Taken together, those factors clearly pointed to the notion that something needed to be done to slow the growing opioid abuse trend, especially in workers' compensation. One such effort occurred in August of 2010, when OxyContin OP, a crush-resistant and abuse-deterrent reformulation of OxyContin (oxycodone extended-release), entered the market, ostensibly to replace OxyContin OC, the original and highly abused formulation.

Unfortunately, the promise of abuse-deterrent forms of OxyContin may be more wishful thinking than reality. Certain segments of Healthesystems data shows that as time has passed, and after an initial spike in use of OxyContin OP, there have been many instances where physicians have shifted prescribing away from the OP formulation to other non-abuse deterrent opioid preparations, primarily Oxycodone IR and Opana ER (oxymorphone).

Opioid Products Analyzed
Fentanyl Patches (Duragesic)
Hydromorphone HCl ER (Exalgo)
Morphine Sulfate (Kadian)
Morphine Sulfate ER (MS Contin)
Morphine Sulfate Beads (Avinza)
Morphine-Naltrexone (Embeda)
Oxycodone HCl IR
Oxycodone HCl ER (OxyContin®)
Opana IR (Oxymorphone HCl IR)
Opana ER (Oxymorphone HCl ER)
Butrans (buprenorphine patch)
Subutex (buprenorphine HCl)
Suboxone (buprenorphine-naloxone)

Table 2

When analyzing the shifts in opioid utilization after the release of the abuse-deterrent OxyContin 18 months ago, Healthesystems reviewed prescription activity data for thirteen different opioids (see Table 2).

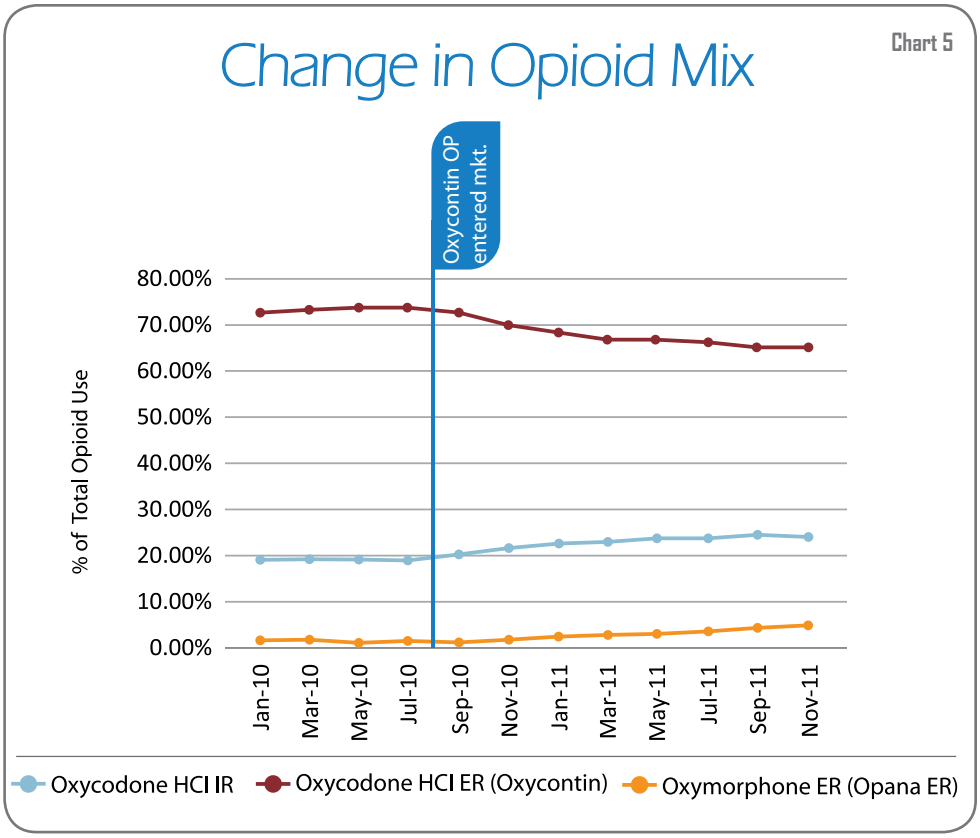
Of the opioids Healthesystems reviewed, the use of oxycodone immediate-release (IR) and OxyContin accounted for approximately 89% of the total opioids prescribed in 2011. Interestingly, in the months after the release of OxyContin OP, there was an almost 9% decrease in all types of OxyContin prescriptions (See Chart 5). Conversely, over the same time period, there was over a 5.3% increase in oxycodone IR prescriptions and a 2.1% increase in Opana ER (oxymorphone).

While this unfortunate trend was happening, much debate and discussion focused on OxyContin OP, questioning its effectiveness compared to the more abuse-prone version. Also, widely published information on the internet from illegitimate users have described OxyContin OP's unfavorable characteristics and identified the obstacles that exist in trying to extract the active ingredient to get the same "high" experienced with the original formulation.

Clearly, something was driving this unexpected shift in prescribing away from the abuse-deterrent OxyContin OP. And while there may be a number of valid reasons, the trend from OxyContin OP to other, non-abuse deterrent opioid products points to a potential motivation driven by those who abuse opioids in workers' compensation. For example, could the possibility exist that complaints by abusers to their medical prescriber influenced the prescription to move from OxyContin OP to another non-deterrent alternative?

Currently, with the impending release of the crush-resistant Opana ER, approved in December 2011 and expected to be available this spring, there is another potential opportunity for monitoring similar shifts in prescribing. Will there be an early spike and then decline in Opana ER prescriptions, similar to what happened with OxyContin OP? It remains to be seen, but should be monitored. With the development of abuse-deterrent formulations there was hope that a decrease in opioid abuse among workers' comp claimants would follow. But so far, according to Healthesystems' analysis, there seems to be a shift — even if unintended — toward more easily abused formulations.

Chart 5



One strategy for payers to employ is ensuring that injured workers using opioids participate in a pain management agreement with their prescriber and be subject to random urine drug screens. Also, PBMs and payers should initiate programs that encourage following up with prescribers in regards to an opioid exit plans is also recommended.

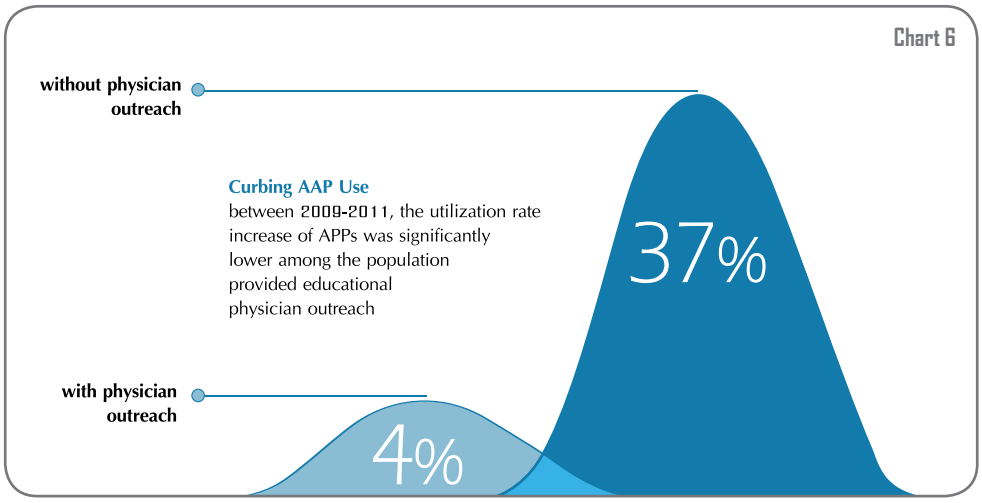
Whether abuse-deterrent opioid products end up having their intended effect is still unknown. For its part, Healthesystems will continue to proactively monitor and analyze prescription data to provide workers' compensation payers with the insight necessary to stay ahead of the prescription drug curve, especially in this case where so much is at stake – for both payers and patients.

Antipsychotic Use Moves into Uncharted, Unexpected Treatment Territory

In the past three years, the off-label use of atypical antipsychotic (AAP) medications in the U.S. has risen to alarming levels. In 2010 alone, more than 50,000,000 prescriptions were written for these products, mostly by non-psychiatric physicians.[9,10] Largely a result of aggressive direct-to-consumer and physician marketing, this group – including agents such as Risperdal® (risperidone), Zyprexa® (olanzapine), Geodon® (ziprasidone), Invega® (paliperidone), and Seroquel® (quetiapine) – is now the "best-selling" medication class in America.

Once reserved for serious psychiatric conditions such as schizophrenia and bipolar disorder, AAPs have found their way into the treatment of conditions such as low back pain, anxiety, elderly "agitation" and sedation.

Driving this unfortunate trend is how these products are marketed: as safer, more efficacious alternatives to the "typical" members of the drug class (e.g., Haldol, Thorazine). Older drugs, such as Haldol, have well-documented use risks, including permanent abnormal movement disorders and neuroleptic malignant syndrome, a rare but potentially fatal side effect of antipsychotic use. AAPs were promoted to the psychiatric community as a better, safer choice. Unfortunately, post-marketing studies of the newer AAPs have found otherwise. In fact, AAPs have been shown to be no more effective than their older counterparts. Plus, their safety profile offers no pronounced benefit and can even be interpreted as less effective than the older meds. Antipsychotics are implicated in tens of thousands of ER admissions yearly. Seroquel, for example, is ranked eighth in the Drug Abuse Warning Network's list of the top 10 medications causing lethal and non-lethal poisonings.[11] The FDA also has mandated that all AAPs carry a warning to alert prescribers to the risk of suicide, diabetes and significant weight gain in patients using these meds chronically.



Additionally, pharmaceutical manufacturers' marketing practices have been an issue with the Department of Justice (DOJ). In 2010, the DOJ levied fines of more than a half-billion dollars against Astra-Zeneca for the company's off-label Seroquel promotion. In 2009, Eli Lilly received a $1.4 billion fine – one of the largest sanctions of its kind in U.S. history — for illegally marketing the off-label use of their blockbuster drug, Zyprexa.[12] Worst of all, physicians may be unaware of the risks AAP meds bring, in addition to them not having any added benefit. To combat that trend, Healthesystems began an educational effort in 2009 to alert prescribers within the patient population to the dangers of inappropriate AAP use. In a recent analysis (accounting for the rise in Average Wholesale Price), an interesting trend has emerged — among certain populations in which Healthesystems made educational efforts, the average rate of AAP use increase was 4% between 2009-2011 (this increase was largely due to the doubling, from three to seven, of available agents in this class). However, in a similar physician population without educational efforts, the utilization rate increase was 37%.[13]

With cumulative annual sales exceeding $14 billion, it is likely that the number of heavily marketed AAPs will continue to grow.

In the interest of patient safety and cost savings, Healthesystems will continue to engage in proactive education efforts targeted towards prescribers. As illustrated by the results, our efforts have achieved positive outcomes, for all stakeholders.

State of the States: Trends in Compliance & Regulatory Affairs

Alabama Fee Schedule: The Alabama Department of Industrial Relations (DIR) increased the dispensing fee for both brand name and generic drugs. Additionally, DIR increased the rates for durable medical equipment and home health services in conjunction with the increase in the medical consumer price increase. Finally, the new fee schedule increased the rates for most non-emergency and ground transportation services, as well as the rates for air ambulance services. The aforementioned changes were effective as of January 1, 2012.

California: The Division of Workers' Compensation has adjusted the ambulance services section of the official medical fee schedule (OMFS) to conform to changes in the Medicare payment system, as required by Labor Code section 5307.1. The effective date of the changes was March 1, 2012 for ambulance services. The adjustment incorporates the 2.4% ambulance inflation factor for 2012 as adopted by Medicare.

Maine: Maine's fee schedule was updated and made effective on December 11, 2011. Notable changes include a more specific definition of durable medical equipment, as well as a change in the reimbursement methodology for DME. DME items are now reimbursed at the lesser of the providers' cost plus 20% or $500. Providers will now be required to submit an invoice or proof of their cost for any DME item or supply greater than $100.

Nevada: Beginning February 1, 2012, Nevada's Workers' Compensation Section has increased the pharmacy dispense fee, as well as rates for home health and other fee schedule services in conjunction with an overall 3% increase in all reimbursement rates. The adjustment to all fee schedule rates is tied to the medical consumer price index, as in prior years.

Ohio: The Bureau of Workers' Compensation has published new guidance for self insurers, effective as of January 1, 2012. These changes relate to reimbursement rules for repackaged drugs, which are now payable based upon the average wholesale price (AWP) of the original labeler. The BWC also implemented two new dispensing fees for compound drugs – one dispensing fee for sterile compound drugs and one dispensing fee for non-sterile compound drugs.

Oklahoma Fee Schedule: Oklahoma's 2012 fee schedule became effective on January 1, 2012. There is new reimbursement language which addresses how repackaged and compounded medications are paid. Overall, medical reimbursement for DME products was reduced across the board, and is now payable based upon the lesser of the provider's usual and customary charges or 90% of Medicare's rate.

New York: New York's Attorney General is pushing for expansion and enhancement of the state's prescription drug monitoring program. I-STOP, which stands for Internet System for Tracking Over-Prescribing, would improve the current prescription drug monitoring program by creating an online, real-time reporting system that would require reporting by prescribers at the time the prescription is issued and by dispensers at the time the medication is dispensed. Furthermore, I-STOP would require health care practitioners to review a patient's prescription history prior to issuing a prescription and would require pharmacists to review the system to ensure that the patient's prescription is legitimate.

Hawaii: A bill introduced during the 2011 legislative session to cap the price of repackaged and compound drugs was carried over to the 2012 legislative session. House Bill 1243 would limit reimbursement for repackaged drugs to the fee schedule rate plus a markup and dispensing fee. For compound medications, HB 1243 would set reimbursement for each ingredient at the underlying drug code.

Arizona: Arizona House Bill 2367 would add the state as an employer eligible for the state's not yet active directed care, medical management pilot program. The pilot program allows employers or the employer's insurance carrier to contract with providers to create a network in which injured workers must obtain care. The pilot program is an opportunity to determine if network contracts can provide for rates lower than the fee schedule rates and result in costs savings. Arizona's legislature is also considering the implementation of medical treatment guidelines. House Bill 2365 would establish the American College of Occupational and Environmental Medicine (ACOEM) Treatment Guidelines as the standard for the treatment of injured workers in Arizona. For instances when the ACOEM guidelines do not address a particular treatment issues, HB 2365 also allows providers to use other national treatment guidelines.

ODG Update: Guidelines Gain Momentum In The Battle To Boost Care, Control Costs

Background

By their nature, injuries sustained on the job often are complex, difficult to assess and, as result, expensive to treat. It requires multiple, reliable information sources to help ensure appropriate diagnoses and treatments, so that injured workers receive the most appropriate care. One such reliable information source gaining traction among various state workers' compensation organizations is the Official Disability Guideline (ODG) and ODG Treatment Guidelines in Workers' Compensation.

ODG Perspective

In fact, a growing number of states have adopted ODG and/or ODG Treatment for Workers' Compensation program management. The acceptance of ODG and ODG Treatment is due in part to their reputation as "evidence-based" approaches. Plus, the Advisory Board for managing these guidelines includes extremely experienced professionals, including physicians, nurses, pharmacists, scientists, insurance professionals and employers in a wide variety of specialties applicable to injured workers' conditions and care.

Today's Concerns

Currently, the ODG Treatment is updated and expanded monthly and so far several areas have been reviewed. See Table 3 above for a listing.

Antibiotic and chronic obstructive pulmonary disease (COPD) therapies are currently in the review development pipeline.

ODG Treatment Areas Reviewed

Anti-anxiety agents (benzodiazepines)	Corticosteroids (oral)
Antidepressants	GI drugs
Antidiabetic medications	Muscle relaxants
Anti-epilepsy drugs	Non-prescription analgesics
Antihypertensive medications	NSAIDs
Cannabinoids	Opioids

Table 3

Managing Change

Adopting ODG/ODG Treatment guidelines requires procedures for handling several changes. One critical consideration for many payers is how to handle "legacy claims," claims with dates of injury prior to the effective date of the ODG/ODG Treatment guidelines implementation. The State of Texas recently went through this process and is a prime example for other states to consider as a prototype for change. Texas revised its Administrative Code to delineate how legacy claims were to be handled. Texas established the date for guideline adoption. Subsequently, the revised code addressed how to handle claims from that date (and forward) until the legacy claim could reasonably be transitioned to the new guideline requirements for medication selections. Texas also has established a deadline of September 1, 2013 for converting legacy claims.

Another factor related to the ODG Treatment guidelines is making the monthly drug plan or formulary changes with each updated "Y" and "N" drug list ("Y" identifies all medications that may be compensable without prior or pre-authorization; "N" indicates drugs that are not considered appropriate and require pre-authorization). For states that require plan compliance, quick action is needed to make revisions. Information is posted on the ODG website at the end of each month and the changes are effective the first day of the next month. ODG allows a 30-day grace period to make changes. Depending on the systems that require attention and resources available to make changes in drug plans or formularies, that timeframe can be challenging.

At times, it also takes clarification as to what is intended with a revised listing. For example, Ryzolt®, which was on the "N" list in December 2011, was removed with the January changes. However, it did not appear on the January "Y" list. As a result, a number of inquiries arose from uncertainty as to how the product is now classified. It is reasonable to anticipate other drugs will convert from "N" to "Y" in the future and there may be the need to clarify what the changes actually mean.

What The Future Holds – More Questions

Right now it is premature to determine the full impact of ODG Treatment guidelines. As part of its overall strategy for clients, Healthesystems is currently analyzing data to evaluate the program's initial phase in Texas. Other variables that may affect implementation success for an ODG-based program include:

- Are the ODG Treatment guidelines being followed?
- Have the clinical outcomes and overall patient well-being improved?
- Is there improvement in reducing length of disability?
- What is the cost impact of avoiding "N" drug use?
- Are cost savings realized by following the guidelines for diagnosis and treatment?
- What other additional therapeutic class reviews are coming?

As the utilization of ODG Treatment guidelines increases and therapeutic drug classes are added, Healthesystems will keep a close eye on the outcomes. It is safe to say, however, that the use of a standard set of treatment guidelines — when applied across all jurisdictions — is a welcome step in the right direction. This step should help our industry move toward much needed evidence-based clinical standards of care.

Dr. Ralph Kendall, Vice President of Clinical Services at Healthesystems, is a member of the Work Loss Data Institute's (WLDI) Official Disability Guidelines (ODG) Editorial Advisory Board.

Healthesystems™

At Healthesystems, our goal is to collaborate with our clients, and help solve the complexities of workers' compensation pharmacy and ancillary benefits management programs. The articles in this edition of *Rx Informer* are intended to provide payers with a clear idea of how a collaborative PBM-payer relationship can work to create positive outcomes for payers, patients and providers. The topics in this publication touch on several aspects of the workers' comp cost control continuum. For more information about any of these topics and emerging issues contact one of our representatives at 800.921.1880 or info@healthesystems.com.

Or, sign up for our monthly clinical or compliance focused e-newsletters at www.healthesystems.com/newsletters and stay informed about issues as they unfold.

Rx Informer References:

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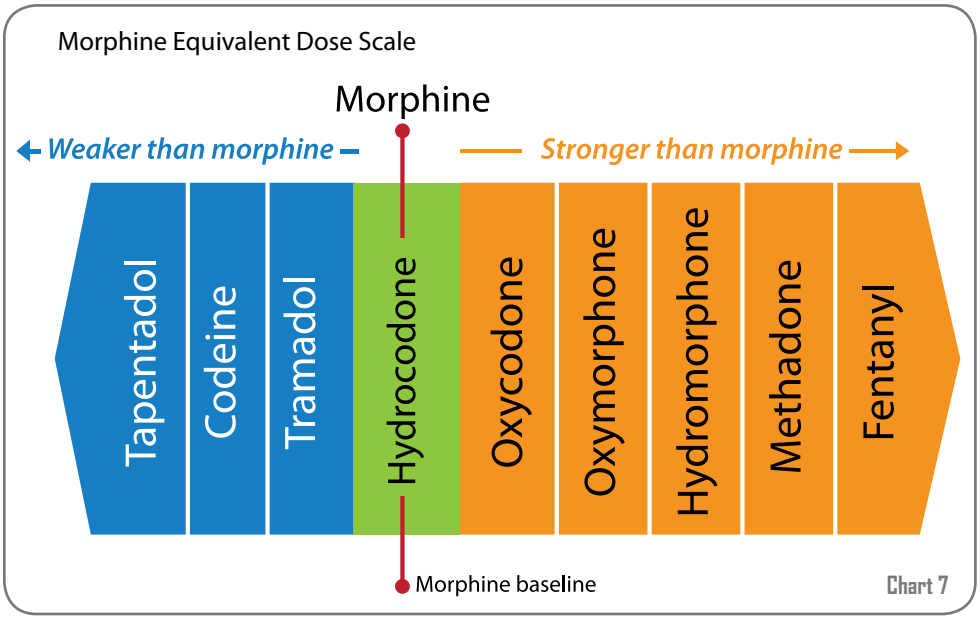
Rx Informer Reference Material & Additional Data

Included on this insert are insightful analytics and useful tools relating to workers' compensation pharmacy benefits management. These graphics are intended to supplement the data provided in this publication and provide added insight into managing workers' compensation drug cost drivers.



Morphine Equivalent Dose, or MED, is a method of comparing the strength of opioids in relation to the drug morphine. The opioid scale illustrates how some of the most commonly prescribed drugs in workers' comp compare in strength using morphine as a baseline.

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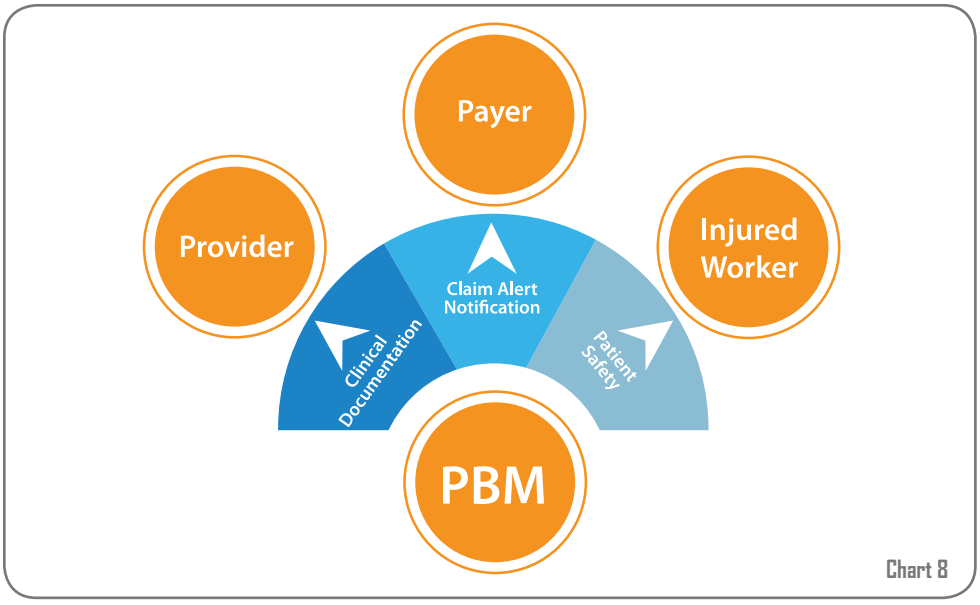

Managing drug utilization and controlling costs requires communication, education and interaction of all stakeholders in the claim process. Chart 8 illustrates the central role in which the PBM plays in managing this critical process.

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This graphic illustrates the importance of early intervention for controlling opioid drug costs. Over a 15 year period, opioid drug costs per claim increase sharply, especially after the first five years. As illustrated in Chart 9, when analyzing the actual drivers of opioid cost over time, the major contributors are the increases in drug mix (potency) and in dosage amounts, while utilization (i.e., the number of scripts and pills dispensed), by comparison, is relatively small. It's the "incremental" increase in dosage and drug mix that begin manifesting during years 3 to 5 where the dramatic growth in costs per claim occurs.

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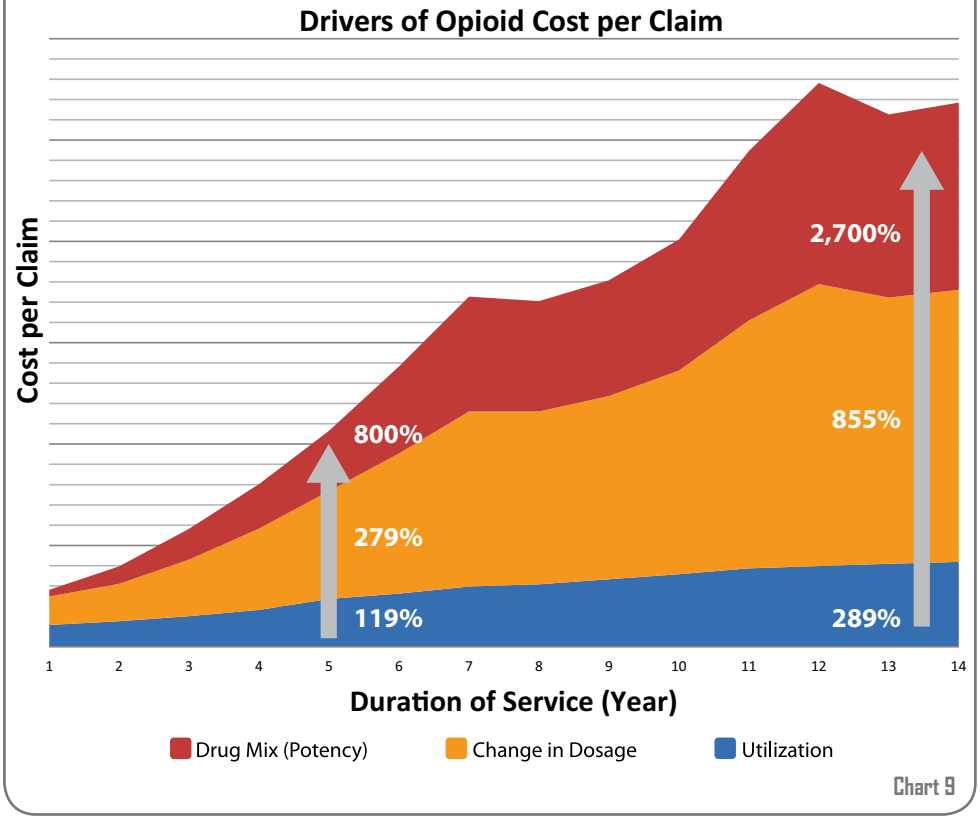

Chart 9

Chart 10 illustrates the comprehensive elements required to support a proactive opioid management strategy. Prescription opioids can comprise anywhere from 25 to 40 percent of a payer's total annual prescription drug cost. Therefore, it is critical to implement a strategic opioid management program capable of quickly identifying at-risk claims. The use of early detection, early intervention tools are proven to alter the costly and often unproductive path treatments may frequently follow.

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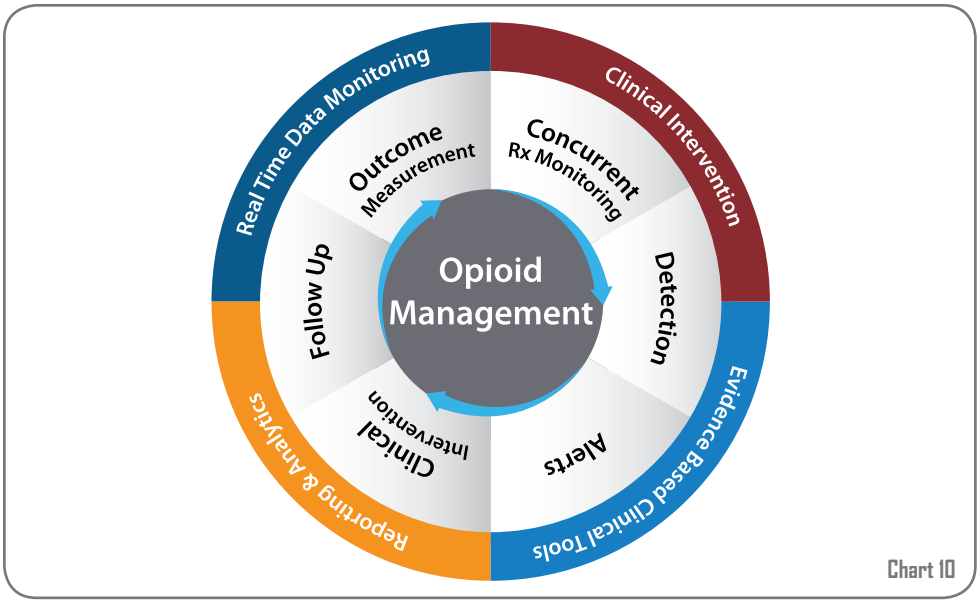

Chart 10

About Healthesystems

Healthesystems is a specialty provider of innovative medical cost management solutions for the workers' compensation industry. Our comprehensive products include a leading Pharmacy Benefit Management Program, expert Clinical Review Services and a revolutionary Ancillary Benefits Management solution for prospectively managing ancillary medical services.

Our Verticē Claims Information Portal delivers real-time pharmacy and ancillary benefits management program information, reports and tools. This intuitive web portal allows claims professionals to access tools for quickly and efficiently processing provider transactions, running reports, retrieving relevant clinical information and many other functions.

By leveraging powerful technology, clinical expertise and enhanced workflow automation tools, we provide clients with flexible programs that reduce the total cost of medical care and manage drug utilization, including the overuse of narcotics and other problematic drugs, all while increasing the quality of care for injured workers.

Data referenced in this document was produced using Healthesystems' proprietary pharmacy database information.

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