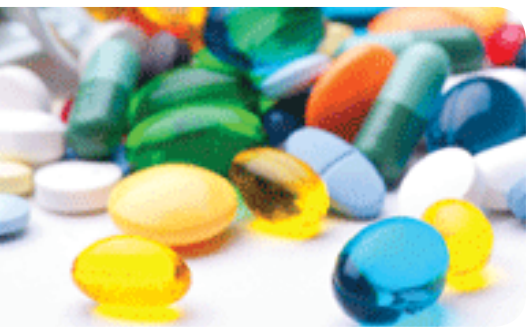
RxInformer

Emerging issues that will impact workers' comp

Drug Pipeline | Abuse-deterrent Opioids | Polypharmacy | Compounds | Fraud Prevention >>



Fall 2012

Healthesystems™

Introduction

Complex issues require strategic and well planned solutions. The workers' compensation industry is wrought with complexities from new medications and shifts in the drug market, to ongoing legislation, fraud and abuse of narcotics, and prescribing trends.

The *Rx Informer* is written by industry professionals – pharmacists, clinicians, data analysts and workers' comp experts – in order to provide insight into emerging challenges and presents forward-thinking strategies about how to prepare for what lies ahead.

In order to predict future trends, we must first examine what has been occurring in the market within the past year. The successful management of opioid therapy has been, and continues to remain, a major issue for workers' comp payers. The strategy Healthesystems has developed for managing the opioid epidemic is a multi-tiered solution focused on the prevention, detection and early intervention of these complex cases, while incorporating evidence-based medicine and clinical expertise to ensure patient-centered treatments are being provided. Much of the information provided within this issue of the *Rx Informer* focuses on data, strategies and tools that claims professionals can use for managing this complex issue.

Other issues such as physician dispensing, repackaged drugs and compound drugs continue to increase in scope and complexity. Healthesystems continues to modify cost containment measures to stay ahead of these issues, as regulations and rules – such as the implementation of the D.0 data standard and other key state laws which were put in place this year – change. By continually focusing on the future-state, we are able to better position our customers for success and deliver cost savings and optimal outcomes.

What does the future of workers' comp hold in store for payers in 2013 and the years ahead? Read this issue of the *Rx Informer* to find out. From uncovering shifts in prescribing trends due to abuse-deterrent opioids to discovering another costly emerging trend in "branded" compounds, this issue of *Rx Informer* delivers valuable and actionable information.

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Medication Management

Regulations

2013-2014 Drug Pipeline

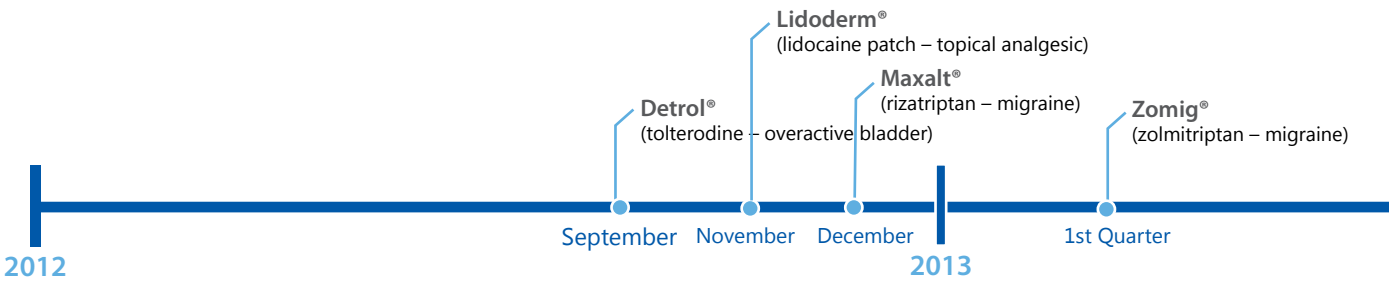
In the 2013-2014 new drug pipeline, there are a few standouts which may have an effect on the workers' compensation industry. Some, like Ampligen®, are back for yet another attempt at approval. Below is a list of some of the drugs which may warrant closer attention by payers and PBMs in the coming year:

New Drugs

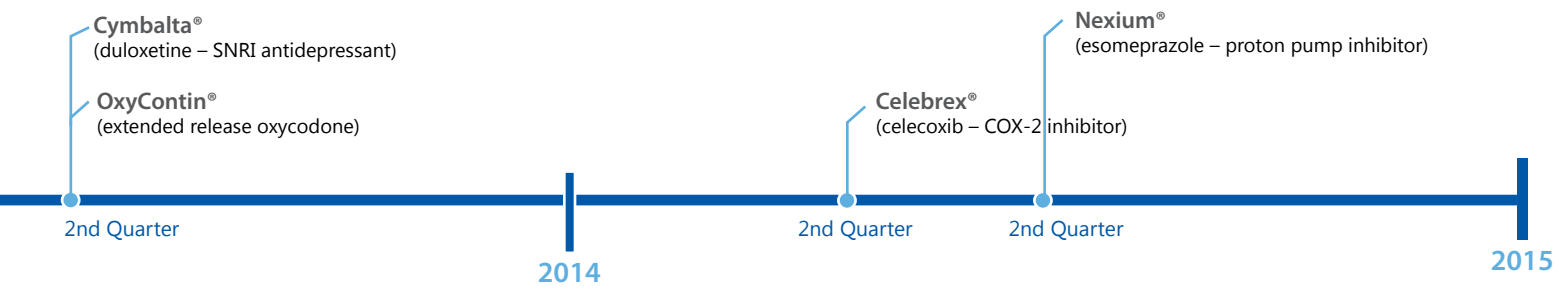
Drug name	Description	Uses	Advantages	Disadvantages	Status
Ampligen®[1] (rintatolimod) Mfg: Hemispherx Biopharma	Anti-viral and immune modulator	Treatment of chronic fatigue syndrome	Could become first-ever treatment for chronic fatigue syndrome	Controversial history spanning three decades Multiple, unsuccessful attempts for FDA approval	Approval decision: Feb. 2013
Naloxegol[2] (naloxone analog) Mfg: AstraZeneca, Nektar Therapeutics	Oral opioid receptor antagonist	Treats opioid-induced constipation	Counteracts constipation side effects PEGylated form (polyethylene glycol) prevents penetration of CNS– won't counteract pain reduction qualities of opioids	Expected to be more expensive than currently approved therapies for constipation	Approval decision: 2014
Suvorexant[3] Mfg: Merck & Co.	Sleep medication	Treatment of insomnia	Blocks orexins, which promote wakefulness No withdrawal or rebound symptoms Decreased time to sleep by approx. 30 minutes Increased sleep time by an hour	Expected to be higher in cost than currently available generic medications for insomnia	Filed NDA: 2012 Approval decision: 2013

First Time Generics

Below is a list of drugs that are new generics or will be released within the next two years as generics:



Drug name	Description	Uses	Advantages	Disadvantages	Status
Zohydro™ [4] (hydrocodone) Mfg: Zogenix	Extended-release formulation of single-entity hydrocodone	Around-the-clock management of moderate-to-severe chronic pain	Less frequent dosing Lower risk of acetaminophen-induced liver toxicity	Not expected to be abuse-deterrent formulation – abuse potential is present Expected to be highly prescribed in workers' comp settings Higher cost due to brand name Expected to be a DEA Schedule II drug, thus stricter prescribing/dispensing regulations	Approval decision: March 1, 2013
Zelrix[5] (sumatriptan) Mfg: NuPathe, Inc.	Transdermal patch form of common migraine medication	Treatment for migraine	Believed to bypass GI tract – good for migraine sufferers with vomiting/nausea symptoms	Other formulations already available, including generic subcutaneous injection & intranasal sprays Expensive brand-name option going against strong generic alternatives Market already saturated Second attempt at FDA approval – first attempt was denied due to safety, manufacturing, and drug chemistry concerns	Approval decision: Jan. 2013



Abuse-deterrent Opioids: Are Intended Results Being Achieved?

In 1997, the Centers for Disease Control (CDC) cited a National Vital Statistics System report showing that drug companies were producing an estimated 96 mg of opioids per person. Fast forward to 2007; that number has risen to 698 mg per person, a 627 percent increase in manufacturing. The CDC article goes on to state that the 698 mg per person amount is enough to medicate every person in the United States with a typical prescription of Vicodin® every 4 hours for 3 weeks.

As is well documented in the workers' compensation industry and in the general media as a whole, the sizable increase in opioid manufacturing has also resulted in a significant growth in the abuse of these powerful drugs. According to the CDC, there were 2 million people in 2010 reporting using prescription painkillers for non-medical purposes. The complexity of this dilemma can become even greater since certain opioids, when used appropriately, can be effective tools for treating pain. But as the evidence from many studies has shown, the drugs are frequently being misused or diverted. That creates a dilemma for prescribers. How can prescribers adequately treat a patient's pain while also preventing drug abuse, misuse and diversion? It's a question that has no easy answer.

Drug manufacturers have tried to address the abuse issue by creating abuse-deterrent, crush-resistant formulations designed to prevent people from tampering with the drugs. However, the reformulation of the drugs solves just a small portion of a much larger medication therapy issue while also introducing an added cost component, since they primarily are new brand drugs with patents. While these newly designed abuse deterrent features help mitigate certain methods of misuse (snorting, smoking, etc.), patients can still overmedicate, and those truly seeking to abuse opioids will simply move to a different drug.

Over the past two years these new drugs may not necessarily be achieving the results for which they are intended. In fact, based upon analysis Healthesystems has performed on opioid prescribing patterns – specifically claimants that have modified their opioid drug therapy after the introduction of the abuse deterrent formulations – the subsequent shifts in therapy has raised several significant concerns.

One critical question is whether these drugs are actually deterring abuse. To date, it is still too early to tell, and there isn't any evidence to suggest whether the drugs are achieving success. The drugs are relatively new and it isn't clear whether drug abusers have been able to circumvent the abuse-deterrent technologies. In addition, a Healthesystems' review of prescription activity from September 2010 through August 2012 shows that the demand for opioids does not necessarily decrease – instead it frequently shifts from one drug product to another.

This last point is troubling. After the release of the abuse-deterrent OxyContin® OP in August 2010, data analysis uncovered an increase in the number of opioid prescriptions for non-abuse deterrent formulations. The apparent shift moved towards an increased use of both immediate and extended release oxymorphone (Opana® IR and Opana® ER, respectively), both of which increased after the release of OxyContin OP. Simultaneously, use of the new abuse-deterrent OxyContin OP formulation continued to decrease sharply over the following year, which may represent users seeking out a new source.

A similar trend seems to be playing out with the new crush-resistant formulation of Opana ER which was released earlier this year, in 2012. As the old formulation has left the market, trends are showing some shifts in prescribing patterns towards the utilization of drugs such as Oxycodone® IR. While the data appears to illustrate some clear patterns occurring with Opana ER, it is still too early to identify the full impact of the new crush-resistant

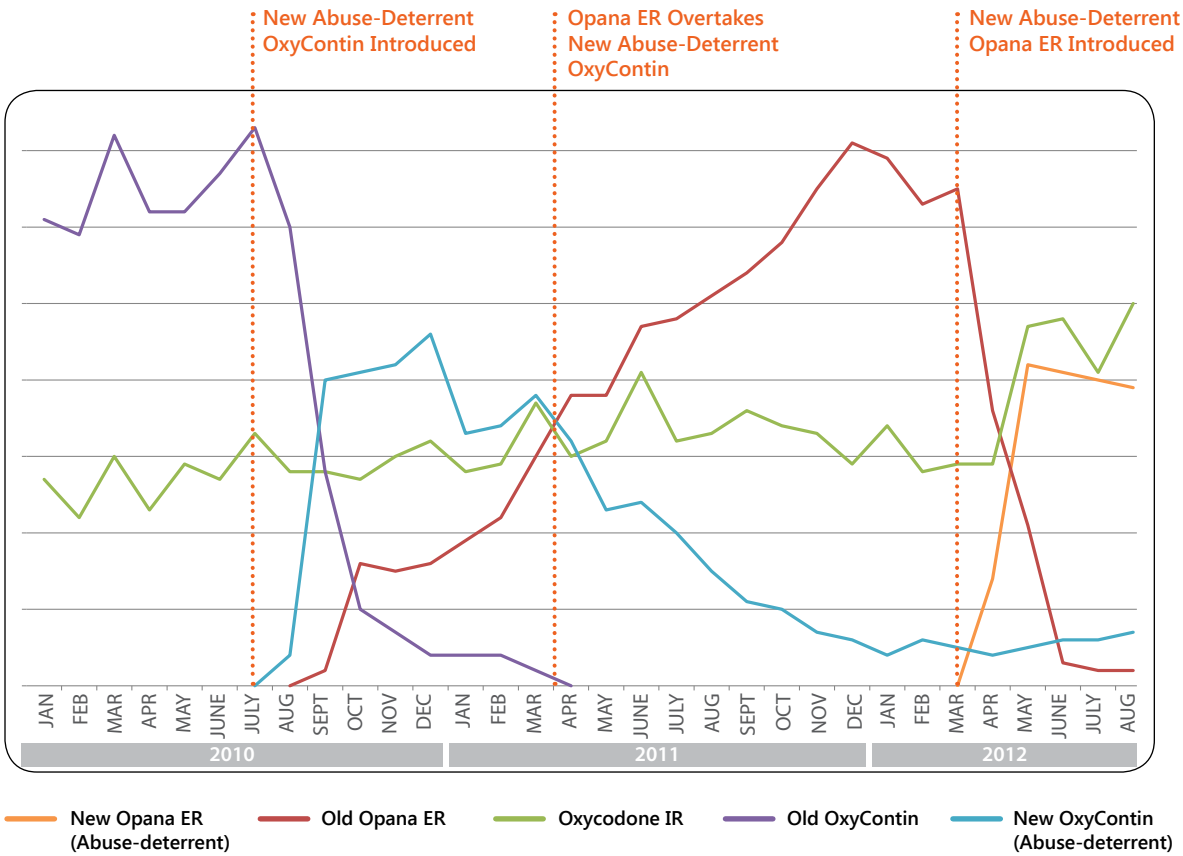
formulation; however, it is this type of close monitoring and early intervention that is crucial to be sure payers are staying ahead of the next potential curve.

It's important to note that the trends do not necessarily always mean abuse. Some patients claim that the reformulated product does not work as well, or patients experience increased side effects to the new product. Still, data does suggest that the prescribing of other opioids is rising markedly while the use of the abuse-deterrent drugs continues to decline.

It is vital for payers to have a PBM that monitors these types of opioid treatment changes, in addition to identifying increased utilization (increases in quantities or MED, etc.), and encourage providers to use pain management agreements/contracts with their patients. By analyzing data as these drugs come to market, PBMs can identify and monitor those claimants who have already switched from an abuse-deterrent drug to another narcotic.

Finding the balance between treating patients seeking legitimate pain relief and those who are drug-seeking abusers is a constant challenge for physicians and payers alike. PBMs can help maintain that balance by closely monitoring claimant drug utilization behavior, and by proactively communicating with prescribing physicians. The result: better pain management and reduced opportunity for abuse.

Change in Opioid Mix



Polypharmacy: Red Flags in Pharmacy Management

Opioids are often prescribed to a workers' compensation claimant to manage pain which is inherent in many workplace injuries. Yet this class of popular drugs often comes with unwelcome side effects – such as sleepiness. In turn, physicians may then prescribe another drug, a CNS stimulant such as Provigil®, or an amphetamine, to help the patient stay alert. However, this may create a further adverse reaction – and now the patient can't get to sleep. A common reaction in these situations is, incredibly, to prescribe a third medication such as Ambien® to treat the sleep disturbance. This, unfortunately, is an all-too-common situation in workers' comp, one called "polypharmacy."

Polypharmacy occurs when patients are prescribed multiple drugs; very often, more drugs than are medically necessary for treatment of the original condition. These additional drugs are often prescribed to counter the side effects of another drug, and in some cases can interact with each other and reduce the effectiveness of the medications.

Polypharmacy scenarios occurring at the group health benefit level is not as prevalent as it is in the workers' compensation environment. There are several factors that likely contribute to this. In workers' compensation, patients are less inclined to refuse an additional medication due to the lack of out-of-pocket costs required from them. In addition, prescribers treating workers' compensation claimants may have fewer restrictions on drug choice, which may cause more liberal prescribing practices. Regardless of the reason, the financial and long term therapeutic challenges resulting from these types of situations usually drive the majority of most payers total pharmacy costs in addition to requiring the most amount of expertise and time associated with managing claims.

In order to reduce pharmacy costs and protect patients from the potential dangers associated with polypharmacy, claims professionals need to be keenly aware of the more common red flags pointing to polypharmacy.

Therapeutic duplication.

Claims professionals should question situations where a workers' comp patient is being prescribed both an oral and a topical formulation of non-steroidal anti-inflammatories (naproxen, ibuprofen, etc.), for example. Oftentimes patients are receiving such duplications, which can create safety hazards and drive up costs.

Multiple providers.

It's quite common for workers' compensation patients to see more than one health care provider. Prescriptions, therefore, can overlap. For example, patients could be receiving opioids from two different providers, doubling up on a powerful drug.

Polypharmacy occurrs when patients are prescribed multiple drugs; very often, more drugs than are medically necessary for treatment of the original condition.

POLYPHARMACY IN ACTION

- Medications in **DARK BLUE** represent Therapeutic Duplications
- ALL medications listed may have possible Drug Interactions

The illustration above represents an example of a dangerous polypharmacy scenario. This workers' compensation patient was prescribed all of the medications listed above in January 2012 as a result of a motor vehicle accident and several different medical conditions including: chronic pain syndrome, displacement of thoracic or lumbar intervertabral disc without myelopathy and lumbago, among others. Among the medications being taken, several represent therapeutic duplications in which the patient could be taking an increased and dangerous dose of drugs. In addition, four medications are not related to the injury and all could potentially have drug-drug interactions.

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Physician-dispensed medications.
Beyond the challenges typically seen resulting from physician dispensed drugs such as excessive cost (frequently over 200% more expensive than drugs dispensed through retail pharmacy), the larger issue is the lack of visibility about the therapy being applied. Physician dispensed drugs frequently bypass the drug formulary and clinical edits that would normally occur from drugs being provided from a retail pharmacy. As a result, when adjudicated, the prescriptions can go unchecked against the patient's existing drug regimen history unless the PBM and payer have the tools in place to process these out of network/paper bills the same way a retail transaction would occur. This is especially dangerous when the physician dispensed drug includes opioids and other powerful drug agents. Frequently, opioids can comprise as much as one third of all physician dispensed and/or repackaged drugs.

The goal of any polypharmacy-reduction process is to ensure optimal patient health and safety.

Depending on the PBM's analytics and real-time prescription regimen monitoring capabilities, the responsibility of identifying the red flags and notifying the claims professional typically should be with the PBM. Subsequently, there are a few ways for claims professionals and the PBM to work together to address polypharmacy situations and reduce the instances of over-prescribed medications. They include:

Education at all levels.
Pharmacy benefit managers should have all the available clinical and evidence based medicine resources necessary to take charge of education. PBMs should target communications to the claimant's prescribing physicians, while ensuring claims professionals are armed with all the appropriate tools to be aware of the red flags and make better informed drug authorization decisions.

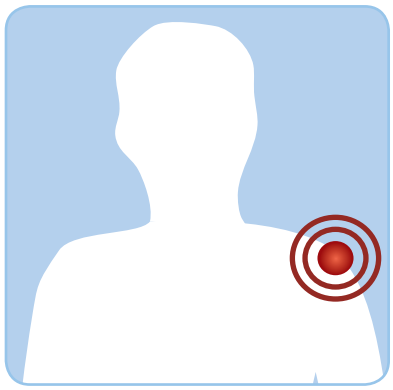
Communication with the physician community.
Claims professionals can alert physicians to instances of potential polypharmacy simply by asking the question: is this medication treatment being used to address the side effect of another medication? Is there a simpler regimen? One study published recently by the American Heart Association cited the complexity of therapy as one of the main causes for patient noncompliance - the more medications patients are taking, the less likely they are to adhere to therapy.[6] Claims professionals should ask physicians how medication use is being monitored. They should start the conversation with the physician, state the case, and be persistent.

The goal of any polypharmacy-reduction process is to ensure optimal patient health and safety. PBMs can start by opening up the dialogue with the medical community. By building that relationship, PBMs can drive a safer, more cost-effective claims process.

Polypharmacy: Red Flags in Action

The below three scenarios represent workers' compensation situations in which a polypharmacy issue may be present. These scenarios should raise red flags for claims professionals and warrant close attention.

Scenario 1

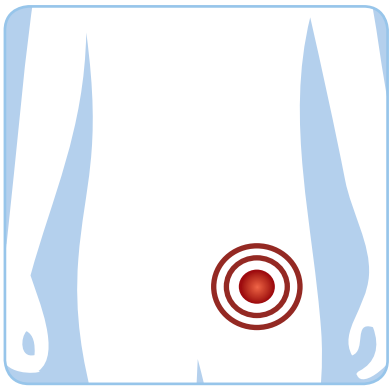


Too Much or Too Little?

Chris was a claims professional managing a recent workers' compensation claim involving a patient who had suffered a shoulder injury in the workplace, prohibiting him from working even a computer. The patient was given a prescription for dextroamphetamine as well as Ambien®. The PBM alerted Chris about a potential polypharmacy issue between these two medications. What should Chris do?

He should contact the prescribing physician(s) immediately. In cases where a sedative (Ambien®) and CNS stimulant (dextroamphetamine) are being used together, there's a strong chance of one drug being prescribed to offset the effects of another.

Scenario 2

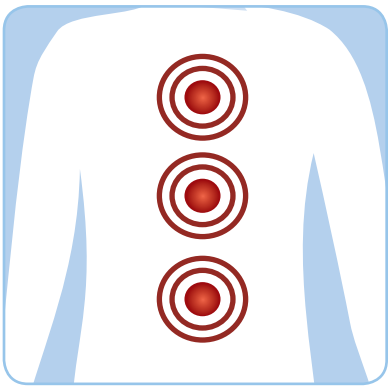


On Track or Overkill?

Melinda's family physician prescribed an oral NSAID for her hip pain. When she asked if she should continue the topical NSAID cream the workers' compensation physician had prescribed, he said yes. Yet when the claim came in to the claim handler, both drugs were flagged and the claim was held up in review. Why?

The duplication in NSAID use could have caused serious harm to Melinda. Also, one form would have been sufficient. If Melinda's physician felt she needed a more potent drug, he could have instructed her to stop using the cream and stick with the oral form of the drug.

Scenario 3



More Doctors, More Confusion

When injured on the job, Travis received a prescription for duloxetine (Cymbalta® a SNRI), prescribed by the workers' comp physician to handle his pain. In dealing with the pain and reduction in mobility, Travis began experiencing signs of depression. His family physician prescribed escitalopram (Lexapro™ a SSRI). Is this a drug duplication?

It could be. While Cymbalta® is approved for use in pain management, it may also be effective for treating the underlying depression. Lexapro use is probably unnecessary. Claims managers should contact both prescribing physicians to get a sense of how they've intended the drugs to be used. In this case, use of both medications could result in a very serious interaction. It is wise to ensure the prescribers are aware of all medications being prescribed to their patient.

Evidence-based Medicine: A Personalized Approach for Opioids

Evidence-based medicine (EBM) is a process by which clinicians can use existing studies, clinical trials, and other proven measures to assess the benefits and risks of treatments and the drugs used in those treatments. When prescribing in a workers' comp setting, it's especially helpful in understanding the best use of a particular medication.

Nowhere would EBM be most useful than when evaluating treatments involving opioids. In a perfect world, EBM would show enough supporting data to support the use of opioids at various stages in the treatment cycle.

However, the world is not perfect. Because of any number of patient-specific factors, EBM is limited when applied to opioid regimens. The problem: opioids are being used in an area where there isn't a lot of evidence. There is relatively no evidence on the long-term use, which is critical to the overall health of the patient.

Still, PBMs can create their own evidence-based review of opioid use. The evidence in opioid use is a much more personalized approach that depends on patient-specific factors. Because the underlying issue being treated is pain, it will be specific to every claimant. And pain can be very difficult to measure, manage and treat. Unlike other diseases in which medication effectiveness can be easily measured, opioid use will vary widely from patient to patient.

Nowhere would EBM be most useful than when evaluating treatments involving opioids.

When collaborating with prescribers, PBMs should ask for evidence that:

- The opioid needs to be prescribed to the claimant
- It is working for the claimant
- Claimant use of the opioid is being monitored
- The claimant has improved functioning with this dose
- The claimant needs the prescribed dose
- The claimant has tried or is taking other medications

Because of the risk of diversion or abuse, PBMs must be diligent in ensuring the claimants still have a need for, and are taking the opioids prescribed. But the risks of long-term opioid use go well beyond dependency, abuse, or diversion; there are health consequences that stem from such long-term use. These side effects include potential for hormone abnormalities, hyperalgesia (increased pain sensitivity), tolerance (needing to take more of the opioid to achieve the same level of pain relief), and immunosuppression. That's why PBMs should continue to verify if the need is still present and if so, if the dosage is appropriate.

Much of today's medicine is evidence based, but EBM cannot be easily applied to opioid prescribing. Instead, a more personalized approach that depends on patient-specific factors should be used. The treatment goal should always be to manage pain effectively without adversely affecting the health and safety of the patient.

Applying evidence-based medicine to the opioid class of drugs can prove challenging. Still, baseline parameters can be applied on an individual basis to establish a more personalized approach to EBM. The Official Disability Guidelines (ODG), developed by the Work Loss Data Institute, help to establish evidence-based standards which can be used to assist in determining appropriate prescription drug treatments for workers' comp claimants. PBMs, such as Healthesystems, can incorporate these standards into clinical programs to develop patient-specific treatment guides such as the table below:

Recommendations for Opioid Use	*Based on Official Disability Guidelines (ODG)*
Establish a treatment plan	☐ Have alternatives been tried? ☐ Is the patient likely to improve with opioid therapy? ☐ Screened for addiction risk? ☐ Are "red flags" present?
Steps to take before initiating opioids	☐ Evaluate for neuropathic pain ☐ Trial of non-opioid analgesics ☐ Goal setting with patient ☐ Baseline pain and functional assessment ☐ Informed consent and pain management agreement (optional)
Initiating opioids	☐ Intermittent pain: short-acting opioid ☐ Continuous pain: long-acting opioid ☐ Change one drug at a time ☐ Initiate prophylaxis treatment of constipation
On-going management	☐ Monitor adherence (urinalysis, pill count) ☐ Document improvement in pain and functional assessment ☐ "4 A's" (Analgesia, Activities of daily living, Adverse effects, Aberrant behavior)
When to discontinue opioids	☐ Hyperalgesia ☐ No overall improvement ☐ Decrease in functioning ☐ Resolution of pain ☐ Illegal activity
When to continue opioids	☐ Patient has improved pain and function ☐ Return to work

Source: Official Disability Guidelines (ODG)

Compounds: The Topical, Transdermal and Oral Debate

The use of compound medications continues to require scrutiny by both payers and PBMs, as these questionable formulations continue to be utilized. Compounds – drugs composed of several ingredients compounded in a pharmacy with questionable, if any, quality control measures – can often be prescribed to workers' comp patients. Payers must determine if approving a compound provides real patient benefits, if the compound is therapeutically necessary, or even if it could potentially pose a danger to the patient. A recent fungal meningitis outbreak resulting from an injectable steroid product made by a compounding pharmacy is a prime example of the dangers inherent in this practice.

Until recently, it was difficult for payers and PBMs to even determine the ingredients contained in a compound. In 2012 retail pharmacies implemented NCPDP Data Standard D.0 which provided the necessary tools for being able to record all ingredient level detail of compound drugs. Now there's an opportunity for deeper scrutiny of these ingredients, and the chance to effectively evaluate each ingredient for safety and efficacy. This is helpful when considering whether compounded agents are appropriate for the treatment of chronic pain.

Topical Application

The theory regarding topical agents:

- Oral analgesics can contain intolerable adverse effects that are bypassed with topical administration
- They can be customized specifically to patient's pain management need
- There is a faster onset of action with topically administered products
- The medication can be applied directly to pain source
- There are fewer systemic side effects, drug interactions, and risk of systemic accumulation typically associated with topically administered medications
- Patients can cut down on medication burden by combining agents together
- These compounds can help decrease opioid consumption

The Truth

Concerns regarding these compounded agents include:

- Limited clinical trial evidence; most research conducted for other indications not chronic pain management, many trials conducted only in animal models
- No FDA oversight to prove both safety and efficacy
- Limited data regarding stability of agents combined into a single topical product
- Many ingredients ineffective when administered topically; some require metabolism in the liver to the active drug for effect, and topical application eliminates this step (e.g., tramadol)
- No consensus regarding appropriate bases to mix the active ingredients
- No oversight to assess the accuracy of ingredients in the compounds; no quality control requirements

Topical vs. Transdermal

The difference in topical versus transdermal applications:

- Transdermal is intended to penetrate the dermal layer into systemic circulation with a systemic effect
- Topical is intended to penetrate the epidermis (top layer of the skin) for local action
- Topical products are not intended for systemic absorption therefore, ideally less adverse systemic effects
- Of note, damage or heat can increase the extent and rate of absorption and produce systemic effects in a product intended for topical use only (e.g., the topical fentanyl patches were big in the news a few years back due to overdose if used with a heating pad)

Separating the Theory from the Facts

There is a significant amount of variability in compounded agents. Limited data exists regarding the interactivity/stability of combined ingredients; interaction with the base compounds (which can affect stability and absorption), patient skin integrity, patient climate, and the overall stability of product.

Beyond the issues of stability and patient variability are the ingredients and their appropriateness for use topically or in transdermal compounds. The table on the following page shows some of the more common ingredients found in compounds prescribed for workers' comp patients.

Limited data exists regarding the interactivity/stability of combined ingredients in compounds

The Future

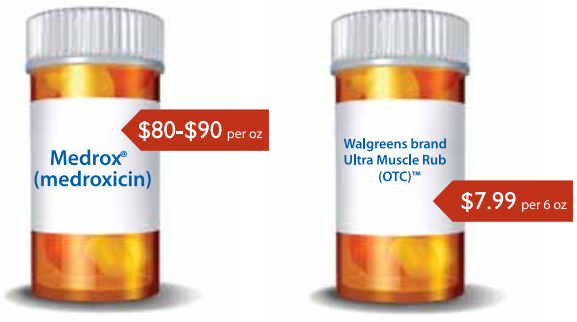
A few topical compounds are currently in clinical trial stage. At the moment, EpiCept NP-1 (4% Amitriptyline/ 2% Ketamine) Topical Cream is currently being studied. Also, baclofen/amitriptyline/ ketamine and ketamine clonidine are being studied.

Even with current clinical trials underway, their applicability to workers' comp and chronic pain management is in question. Current clinical trials are looking at compounded agents for either PHN (post-herpetic neuralgia), DPN (diabetic peripheral neuropathy), or chemo/radiation induced neuropathy. These trials are not studying long-term use for chronic pain related to injury or trauma.

Additionally, branded compounds such as the agents Medrox® (medroxicin), Dendracin® (Neurodendraxin®), and Terocin® (terodoloricin) are all proprietary compounds with their formulated generic name and expensive price tag for ingredients that are available at local pharmacies for pennies on the dollar. These agents are available in a virtually identical formulation such as Ultra Strength Muscle Rub; a combination of menthol, methyl salicylate, camphor, and capsaicin. Compare the cost of Medrox AWP $201.00 for a 6 oz (168g) container with Ultra Strength Muscle Rub at AWP $5.99 per container (114g).

These agents have the look and appeal of a commercially available prescription topical agent. They are combined in concentrations so that they are considered a proprietary blend, thus manufacturers can set their price for these Branded Compounds and circumvent price hits that are in play with the ingredient prices of an individually compounded agent.

While there are trials under way for a few select commercial compounds, currently the supporting data for use of these extemporaneously compounded agents is limited to small populations, poorly conducted studies, or isolated case reports. The pricey container of ingredients may stand out, but the evidence does not.



"Branded" compound product is $500 more expensive

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The table below lists some of the more common ingredients found in compounds prescribed for workers' comp patients and denotes issues that exist with topical application of the agents.

Common Ingredients Found In Topical Compounds

Generic Medication Name	Drug Category	Issues with Topical Application
Amitriptyline	Tricyclic antidepressant	No topical dose yet available Data is gleaned from small, poorly designed clinical trials and case studies Currently being studied for its reaction when combined with ketamine
Baclofen	Oral skeletal muscle relaxant	Centrally acting; has not shown therapeutic effect in topical application
Clonidine	Sympatholytic medication	Blocks apha-2 receptors on skin nerve terminals Found effective in diabetic peripheral neuropathy, but has stability questions when in combination with other ingredients
Cyclobenzaprine	Muscle relaxant	Relieves muscle spasms with no direct action on the muscle involved No evidence of transdermal efficacy
Diclofenac	Nonsteroidal anti-inflammatory (NSAID)	Readily available in topical and transdermal formulations; no rationale for compounding Reports of adverse liver toxicity, including topical applications Safety concerns exist with lower concentrations
Doxepin	Tricyclic antidepressant	Only TCA approved for topical use in itching secondary to eczema Not indicated for pain management
Gabapentin	Seizure treatment drug	Binds proteins confined to brain and spinal cord without altering skeletal muscle tissue[7] Topical use not supported by literature or clinical justification

Generic Medication Name	Drug Category	Issues with Topical Application
Ketamine	Dissociative anesthetic	Used as general anesthetic and can be used intravenously for severe, refractory pain Studies concluded no significant difference between treatment groups, including placebos
Ketoprofen	Nonsteroidal anti-inflammatory (NSAID)	Remains popular despite failed topical NSAID trials over last decade[8] Drug delivery system critical to clinical effectiveness of topical anti-inflammatory therapy[9] Topical dosing yielded inconsistent concentrations in muscle tissue[10] Topical use has been associated with high number of adverse events[11] No FDA-approved topical products marketed
Lidocaine	Local anesthetic and antiarrhythmic drug	Commercially available as topical cream, ointment, jelly Lidoderm (lidocaine patch) available as topical analgesic. FDA-approved for post-herpectic neuralgia; also used off-label for various neuropathic pain conditions Not effective nor recommended for non-neuropathic pain[12]
Nifedipine	Dihydropyridine calcium channel blocker	Studied for treatment of thrombosed hemorrhoids; however no data to support topical use in pain treatment, and 2011 review did not support topical use[13]
Tramadol	Centrally acting synthetic analgesic	Required hepatic metabolism to be effective[14]; as such, topical use bypasses hepatic circulation and is not expected to be effective topically

ODG and Upcoming Legacy

In 2007, Texas opted for change. That's when the Texas Department of Insurance (TDI) Division of Workers' Comp (DWC) adopted the Work Loss Data Institute's *Official Disability Guidelines – Treatment in Workers' Comp* (ODG Treatment) as their state's new standard for medical care administered for workers' compensation claims.[15] The hope then was to improve outcomes for injured workers and to best utilize available medical services.

More recently, Texas has adopted the ODG Workers' Compensation Drug Formulary. Effective September 2011, prescribers must seek preauthorization when prescribing any drug excluded from the TDI-DWC closed formulary for those injuries dating after September 1, 2011 – herein referred to as "new claims."

According to recent evidence, the changes are working, especially in terms of lowering drug costs. A 2011 study conducted by the Texas Department of Insurance, *Pharmaceutical Utilization and Costs, 2006-2010*, reveals that even in the three years post-ODG adoption, recent claims have a lower-than-average pharmacy cost when compared with legacy claims for injury years 1991-2005. The study also showed that injured employees within a benefits network receive drugs earlier and take them for a shorter period of time at a lower cost than injured workers outside the network.

That's a promising sign given Texas' history. In fact, in 2011, out of 17 states studied, Texas had one of the highest workers' comp prescription drug costs per claim. Still, evidence suggests that the trend, at least in Texas, is reversing thanks to implementation of ODG.

It's a trend Healthesystems has been watching closely, especially since the time is getting closer for when "legacy claims" – claims with dates of injury prior to the September 1, 2011 – will be required to follow the ODG formulary. Probably the most telling findings of a preliminary study Healthesystems has performed on the impact of the Texas closed formulary, were the number of prescriptions written for the different drug classes. With new claims, the Healthesystems analysis shows 95% of prescriptions were included in the newly adopted ODG formulary as required by regulation, leaving only 5% of medications being identified as "N" drugs, whereby they were not covered or required pre-authorization by the carrier/payer.

Tables 1 and 2 illustrate the top in-formulary medications based on script volume for *legacy claims* compared to the top in-formulary drugs being prescribed for *new claims*. Keep in mind the differences between the medications listed on each chart are a result of the age of claims. Therefore, there aren't any conclusions that can be drawn by directly comparing the two tables. New claims are still within the first year of the injury and they usually don't have the types of clinical issues that complicate longer-term injury treatments.

The medication lists shown in Tables 1, 2 and 3 provide important information about prescribing patterns. Regardless of any drug's status as it relates to being in or out of formulary, insurance payers should always be asking: Where does the drug fit within the overall treatment plan? Is it the best short and long-term therapeutic option?

The callout in Table 1 highlights an issue of concern. Certain medications, such as Cyclobenzaprine and the others noted, are intended for short-term treatment but are likely being prescribed to treat chronic conditions – as evident by the fact that this table denotes legacy claims.

It is important to note in Table 3 (Top Out-of-Formulary Medications for Legacy Claims) that currently three of the top "N" drugs prescribed – Carisoprodol (Soma), Lidoderm, and Zolpidem – are also some of the most frequently prescribed drugs for all open legacy claims (they are each in the top 20 drugs of all drugs prescribed). As a result, these highly utilized drugs that impact a large number of claims need to start being addressed with physicians as soon as possible allowing the appropriate amount of time to manage the volume of claims.

When evaluating the therapeutic class mixes and the medications that are in-formulary versus out of formulary ("Y" versus "N" drugs), there is an overall savings opportunity of approximately 26% from the top medications. In addition, utilizing in formulary opioids saves 82% compared to utilization of non-formulary opioids. With strong conformity from prescribers and compliance efforts being applied by

Top In-Formulary Medications ("Y" Drugs) Legacy Claims

(D.O.I. prior to 9/01/2011)

Drug Name
Hydrocodone/Acetaminophen (various strengths)
Tramadol HCL
Cyclobenzaprine
Tizanidine
Ibuprofen
Zolpidem
Cymbalta®
Gabapentin
Lyrica®
Celebrex®

These three medications are indicated for short-term use only and typically should not be prescribed for long-term therapy

Table 1

Top In Formulary Medications ("Y" Drugs) New Claims

(D.0.I. 9/1/2011 and greater)

Drug Name
Naproxen
Cyclobenzaprine (various strengths)
Methylprednisolone
Ibuprofen (600 & 800 MG TAB)
Hydrocodone/Acetaminophen (various strengths)
Cephalexin
Tramadol
Meloxicam
Sulfamethoxazole/ Trimpethoprim
Metaxalone

Table 2

carriers and their PBMs, savings and quality of care are improving in Texas.

As we approach the next phase of the ODG adoption related to addressing the legacy claims, we expect to see similar compliance on claims with dates of injury prior to September 1, 2011. As noted in the tables, carriers (insurance payers) along with their PBMs should be proactively identifying legacy claims with continued dispensing of "N" drugs and communicating the upcoming compliance requirements to prescribers, injured workers and the pharmacies dispensing those medications. All notifications for legacy claims should be completed by 03/01/2013 with implementation by 09/01/2013. As seen by the preliminary data, prescribers appear to be changing their patterns with new claims. The evidence shows strong compliance related to prescribing in formulary approved medications. And the impact is significant – a 2-to-1 shift in prescribing habits.

While Healthesystems did not include information on the effects of generic availability or that of abuse-deterrent opioid formulations, the numbers are encouraging. If the habits of prescribers and the diligent efforts of the Texas Department of Insurance continue, Texas could soon become a model for ODG adoption and implementation.

Top Out-of-Formulary Medications ("N" Drugs) Legacy Claims

(D.O.I. prior to 9/01/2011)

Drug Name	Drug Class
Carisoprodol	**Muscle Relaxant**
Lidoderm®	**Neuralgia Therapy**
Zolpidem	**Sleep Aid**
Diazepam	Anticonvulsant/ Antianxiety
Clonazepam	Anticonvulsant
Flector® Patch	NSAID
Oxycontin® (ER formulations)	Opioid
Oxycodone (various strengths)	Opioid
Methadone	Opioid
Sertraline	Antidepressant

These three medications are also included in the Top 20 Drugs Prescribed for All Legacy Claims

Table 3

The Impact of the NCPDP D.0 Standard

PBMs now have an additional level of transparency into prescription drug transactions, specifically when it comes to processing compound drugs. Standardized in January 2012, the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard D.0, gives PBMs the ability to drill down into a drug compound to the ingredient level and see exactly what is being prescribed.

In the past, PBMs would see compound drugs submitted online but the NCPDP 5.1 standard did not enforce ingredient level processing and many pharmacies did not supply the ingredient level details for review. PBMs could identify a compound prescription, but the specifics were clearly missing. Accurate price adjudication, applying drug utilization review edits and determining medical necessity based on the components of a compound were nearly impossible. As a result, the pharmacy had complete control over the pricing structure when billing compound medications.

Also, until now, there was no way to tell if the PBMs and payers were approving necessary drugs or duplications. As a result of the new D.0 standard, all ingredients are listed, which helps PBMs and payers define a more accurate reimbursement level for particular compounds and allows for review of appropriate relation to the injury being treated.

Before, payers were faced with questions such as: Are we paying the appropriate amount for the ingredients that are being used in the compound? Is the injured worker receiving the most appropriate treatment for their injury, and are there any ingredients in the compound that may either overlap or have an adverse reaction with other prescriptions being provided? Now with the ingredient level information included, PBMs can process each of those ingredients against the drug plan formulary and drug utilization review (DUR) edits can now be applied.

The D.0 data standard can help PBMs and payers determine more easily whether the prescribed drugs are being charged properly; are commensurate with workers' compensation use; and are being used for the right therapeutic reasons.

Also, PBMs are able to see the AWP values associated with each ingredient within the compound. The implementation of the ingredient level detail now allows for re-pricing of compounds instead of using what was submitted by the pharmacy. Now PBMs are able to apply rates to these ingredients, thus providing an accurate price point for the compounds.

Possibly the most important aspect of D.0 is visibility. End users will soon be able to see a transparent picture of the drug, and will more easily be able to determine the drug's viability in a workers' compensation application. Is it work-related and related to the injury? Now each ingredient can be seen and the therapeutic need can be more easily traced. This can also help PBMs and payers save additional time. The effort usually required to check with prescribers is virtually eliminated.

Healthesystems has experienced a compliance rate of over 98% of all online submitted compound prescriptions when pharmacies process through our network.

So far, a number of states have adopted D.0 and some have adopted the NCPDP *Universal Claim Form*, though not all states have done so. Some states have also adopted compound regulations (see accompanying table) that follow these standards and some have passed their own compliance

standards, which makes enforcement across the board much more challenging. Since standardization of D.0, Healthesystems has experienced a compliance rate of over 98% of all online submitted compound prescriptions, which are visible in our Verticē claims portal, when pharmacies process through our network.

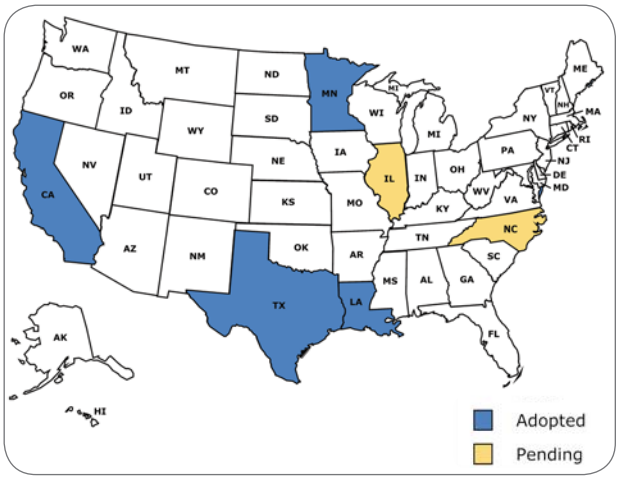
Still, one of the challenges is that D.0 is mandated from a point of sale transaction processing standpoint, which represents over 80 percent of Healthesystems' transactions. If a state hasn't adopted the NCPDP standard, enforcement of the ingredient-level processing for all retrospective paper transactions compliance isn't always possible.

We hope that as D.0 continues to reveal its value through NCPDP an ANSI-accredited standards organization, more states will consider adopting this standard. This well-known standard makes adjudication and pricing more accurate, and helps facilitate better patient care by ensuring transparency down to the ingredient level.

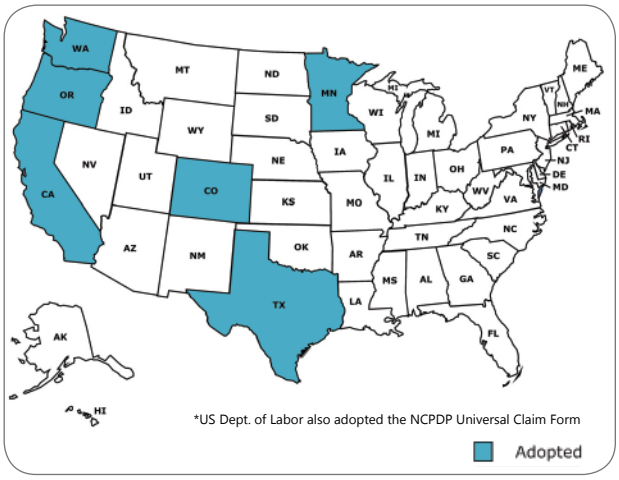
States that adopted compound regulations

State	Effective Date
AZ	01-Oct-09
CA	01-Jan-01
CO	01-Jan-01
MA	11-Sep-08
MS	01-Jul-10
NM	31-Dec-07
OH	01-Jan-12
OK	01-Jan-12
SC	01-Jan-12
TN	19-Apr-06
TX	01-Jan-01
WA	01-Jul-08
WY	01-Aug-08

States That Have Adopted D.0



States That Have Adopted NCPDP Universal Claim Form



Early Intervention: Triggers and Red Flags

Whether prescriber, PBM or insurance payer, one of the most important functions of a pharmacy benefit management program is helping ensure the safety and overall health of the workers' compensation patient. Typically a PBM is able to systematically identify and respond to certain prescription transaction triggers, but often there are red flags prior to that which can help identify and resolve a potential problem.

Abuse, addiction and diversion can all occur when opioids are prescribed, so it is important to have a plan in place to closely monitor these high risk claims.

One such problem that many payers are faced with in workers' comp today is the overprescribing of opioids and other powerful narcotic painkillers. Abuse, addiction and diversion can all occur when these drugs are prescribed so it is important to have a plan in place to closely monitor these high risk claims.

There are certain actions by the patient that should be identified and monitored by the prescriber and payer and investigated further.

Switches from abuse-deterrent formulas.

More modern formulations of drugs deliver the same effects of the opioid in a harder to abuse form. When patients switch from abuse-deterrent formulas to traditional opioid forms, this could be an indication that there is a potential addiction to opioids present.

Refill creep.

Continuous early refills of drugs is frequently a sign of a patient attempting to stockpile drugs. For example, refilling the prescription five days in advance every time over the period of one year, means the patient would get two extra refills.

Insistence on brand.

There are times when a brand name is indicated by the prescriber for legitimate reasons. Still, PBMs should be aware that often patients will request the brand because brand-name prescriptions have a higher street value than generic drugs. PBMs should speak with the prescriber to determine if the request was prescriber-driven or patient-driven.

The "Vegas cocktail."

A term coined by drug abusers, this combination of Vicodin® and Soma® is often used by drug abusers to replicate a high similar to heroin.

The "Unholy Trinity."

Likewise a term coined by a pain management specialist to describe a particularly suspect combination of medications, the Unholy Trinity is a triple-threat combination of opioid pain reliever (Vicodin), anti-anxiety drug (Xanax®) and muscle relaxant (Soma), and is a huge red flag. Patients using all three simultaneously could be exhibiting addictive behavior.

Three or more prescribers.

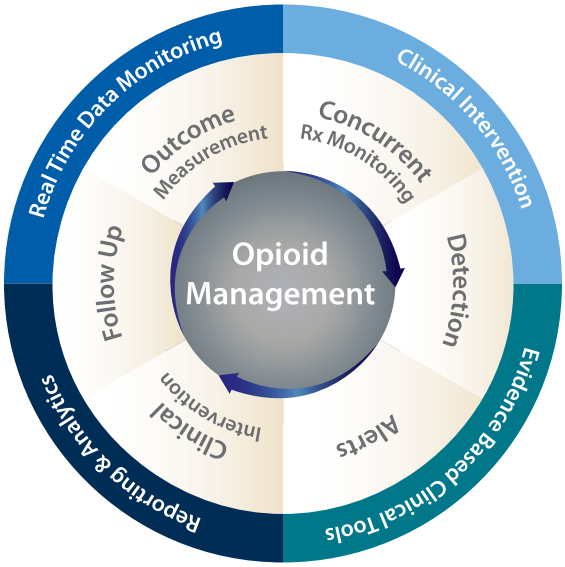
If a patient is intending to obtain opioids for reasons other than medical ones, they commonly "doctor shop" – going from doctor to doctor to receive more than one prescription for opioids. Closely monitoring prescriptions obtained from multiple prescribers is very important. Emergency room visits, trips to multiple prescribers, and several prescriptions for opioids and other drugs of abuse are all red flags for possible abuse.

Too smart or too dumb.

A little too much knowledge from the patient about the drugs being prescribed should be a red flag, especially if the patient requests by name a specific opioid. Likewise, the patient who appears to know very little about drugs is also a typical behavior found in drug-dependent patients who are trying to cheat the system.

The PBM plays a key role in the early intervention process. Setting up automated processes by which prescribers are alerted to potential problems with patient drug use is a key tool PBMs can utilize. A key intervention strategy includes the use of therapeutic alert (TA) letters. When the patient exceeds certain daily opioid dosage levels, such as the morphine equivalent daily dose (MED), the prescriber can be notified by a TA letter authored by a clinical pharmacist with drug therapy expertise along with alerts to the payer. Letters can also be sent to prescribers when brand drugs are being used when generics are available. Other criteria can be used in situations involving multiple prescribers, especially with overlapping or duplicate therapies. All prescribers can be notified by a clinician alerting each party about the situation.

A Proactive Opioid Management Strategy



This graphic 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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The key to decreasing the instances of opioid abuse is to have a strong prevention process in place. Prescribers and physicians should have steps in place that ensure patients are educated and monitored to avoid potential abuse. Similarly, payers should remain active in inquiring and communicating with prescribers about the progress of the monitoring or screening processes. Critical steps and strategies for proactively managing opioid use include the following:

Examine the underlying cause and determine whether the therapy fits the diagnosis.
For example, if the patient is getting increasingly higher doses of opioids and the initial condition was a back strain, there could be an addictive behavior present. Any time a seemingly minor condition is coupled with increasing doses, further investigation is needed.

Screen patients.
Look for dependency history or a family history of dependency – smokers in particular have a strong dependency on nicotine and may be more susceptible to addictive behavior. But also look for those patients with a history of using alcohol or drugs. The potential for dependency on drugs would be greater with these patients. Many screening tools exist, such as the Opioid Risk Tool® (ORT) and the Screener and Opioid Assessment for Patients with Pain (SOAPP®), which physicians can use to identify whether a patient may be predisposed or at higher risk for opioid addiction.

Check state monitoring programs.
By next year (2013) all states should have Prescription Drug Monitoring Programs (PDMP) in place to help prescribers and dispensing pharmacists track patient use of opioids. While many of the state's monitoring programs may vary in structure and oversight, the common goal is to use this tool to prevent and/or identify prescription drug abuse. The information is tracked within the PDMP systems.

Inform patient.
Share with patients what to expect. For instance, patients taking pain medication cannot expect to be pain-free, and they should understand that drugs aren't there to remove all the pain – just to manage the pain so that the patient is comfortable and able to function.

Make an agreement and set appropriate goals.
Let patients know what the therapy plan of action is and what drugs will come into use. Also, when using opioids, get a signed agreement from the patient, stating he/she will not seek opioids from anyone else.

Offer alternatives.
Physical and occupational therapy, yoga, and other tools are available to help the patient reduce pain without medication.

Monitor patient progress.
Especially important when patients are taking opioids, patients should be monitored for improvement and function. If function is declining, it's a flag for the physician to back off the opioids. Also, conduct urine and drug tests to ensure the patient is following the regimen.

Document opioid use.
Prescribers should maintain documentation for all patients using opioids.

Look for warning signs.
Patients who "lose" prescriptions, refill prescriptions early or ask for new prescriptions, or those who are resistant to changes in medication therapy may have developed a dependency.

Establish an exit plan.
Discuss with patients how long drugs will be used and how they will be tapered off the drugs.

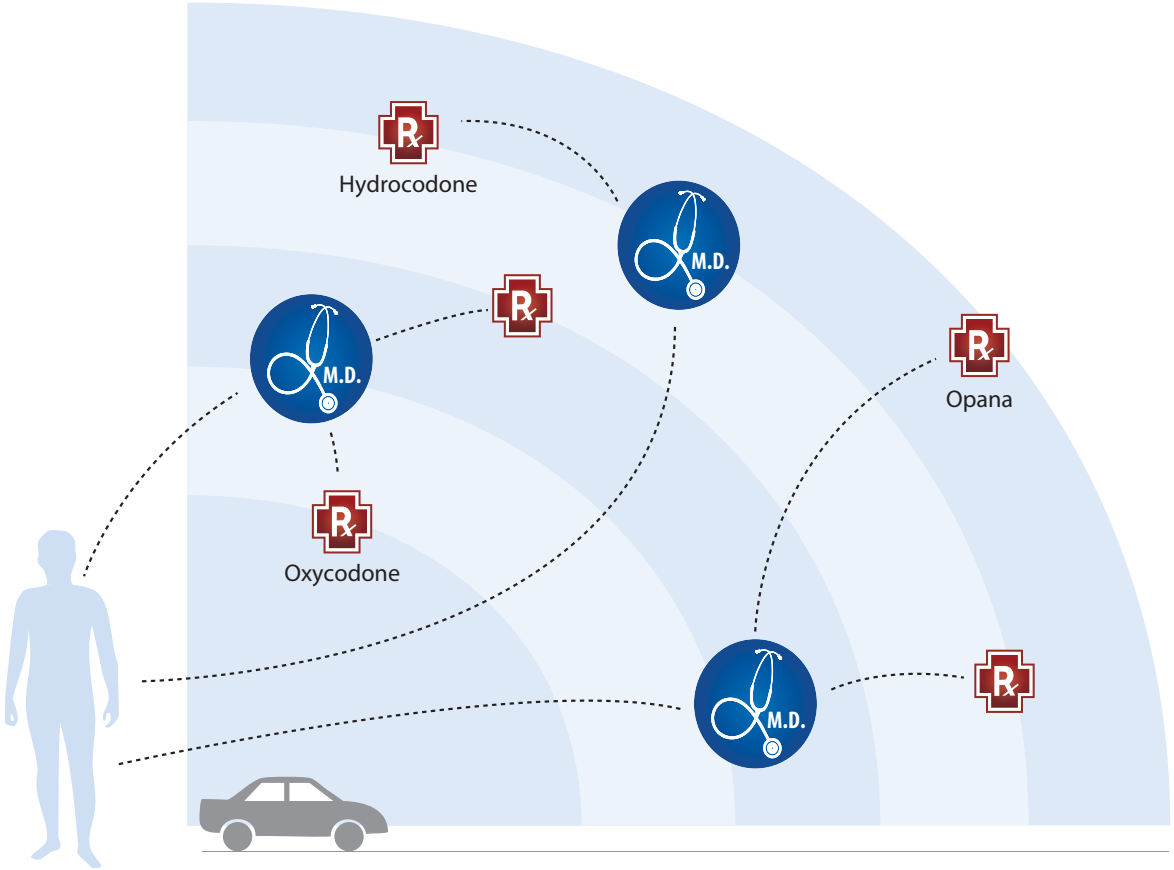
By understanding some of the more prevalent (and sometimes overlooked) red flags, prescribers can help patients maintain a healthy balance in any pain management regimen and give them a clear strategy toward wellness and coping. Also, when PBMs and prescribers work in concert to attach triggers and flags to uncover potentially abusive behaviors, they can help support even greater success and deliver a more balanced approach to patient health.

Fraud Detection and Prevention

Red flags, anomalies, unusual behavior – even when things seem normal, there may be something not quite right. Such is the case for workers' compensation claim files, especially when one looks closely and digs deep into the data. Some claimants have pharmacy transactions that are processed or prescribed in areas far removed from their residences. Is it fraud? Not necessarily. However, it is something that should be noted and reviewed.

When PBMs locate such deviations from the normal prescriber or pharmacy transaction patterns, the logical next step should be to present this information to the carrier's medical management team and/or potentially escalate it to a special investigations unit. It could be nothing – claimants may live in two places at two different times of year, they could be traveling, or the physician could have moved. Still, PBMs should consider any deviation from the normal behavior as a reportable incident. It just makes sense to check out those oddities.

Multiple Prescribers, Multiple Pharmacies, Multiple Opioids = Red Flags



What to Look For

Knowing what to report starts with understanding what are potential red flags. Some of the areas of concern include:

Claims history

- Is this a recurring claim?
- Does the claimant have a longer-than-expected history taking certain opioids or other habit-forming drugs?
- How frequently is the claimant going to the doctor or switching doctors or pharmacies?

Pharmacy transactions

- How many pharmacies is the claimant using?
- Are the distances between each pharmacy growing?
- Are there multiple drugs in a given class being prescribed?

Dispensing patterns

- Are there large quantities of medications being dispensed?
- How often is the claimant filling prescriptions?
- Could the drugs be working synergistically to cause enhanced euphoria? Are these drugs combining to create dangerous, if not lethal mixtures?

Alerts and edits

- How often has this claimant's file been flagged for therapeutic alert letters (i.e. physician outreach communications) or safety edits?
- Is this a pattern and if so, is there a reason why the prescriber is writing so many prescriptions?

Again, many reasons exist for a change in the claimant's behavior, and often those reasons are valid. Even if the data suggests a potential issue, it's hard to arrive at a conclusion on data alone.

PBMs should be looking for ways to team with the insurance payer's (carrier's) medical management professionals. Prevention comes through a collaborative drug plan design. Step therapy plans, for example, can assist in preventing fraud or abusive patterns. Employing therapeutic alert letters and independent pharmacotherapy evaluations (IPEs) to review prescribing behaviors can also help uncover potential problems. While use of these tools is not always an indicator of fraud or abuse, it's part of the consideration process.

By paying attention to the minor details, PBMs can be a valuable resource in identifying and preventing fraud. They can also help deliver a safer, more therapeutically effective experience for the patients.

Morphine Equivalent Dose: Effectively Estimating Opioids

One of the key tools being used by the clinical community to assist in controlling and monitoring opioid use is calculating a patient's daily morphine equivalent dose (MED). While MED does provide a great baseline from which clinical analysis can be formed, like most things in the medical world, it is a tool that must be used in conjunction with a larger medical management and/or opioid management strategy.

On a broad scale, most opioid potency can prove difficult to determine, even when calculating the morphine equivalent dose (MED) to look for a more normalized usage guide. What works for one opioid does not necessarily work for another.

Physicians use the MED scale as a frame of reference when determining potential opioid potency in a patient. However, due to various physical and pharmacological factors, the estimate would be different per patient. What the MED does provide is a starting point for prescribers to discuss therapies, pain management, and opioid use strategies.

Where it becomes challenging is when the opioids have no clear conversion equations to morphine. Conversions do not exist for every type of opioid or for every dosage form. Certain variables come into play, which can affect the opioid levels. Some instances in which approximations cannot be made include:

New routes of administration of existing drugs

A drug may be available for years as an injection. Then new dosage forms are developed. These new forms can be patches, topicals, and nasal sprays. For patches or topicals, so many factors affect drug absorption through the skin, such as hydration and body fat, that it's difficult to assess with any accuracy how to compare a new dosage form to the standard of morphine. Often there is no clinical data to support calculating the MED of the new formulation.

New drugs

Often the drugs are so new that the data isn't there to support any decision making – sometimes for years.

Older drugs

Methadone is an example of an older drug that is very difficult to estimate the MED. It has very unusual and complex actions depending on the dose taken and length of therapy. A number of experts have suggested conversion equations. However none have been widely adopted.

Even when the MED is known, prescribers still need to make opioid usage decisions on a per-patient basis. PBMs can also play a key role in this process by assisting with assessing a claim to ensure patient safety and drug efficacy. For prescribers, the following guidelines may be helpful:

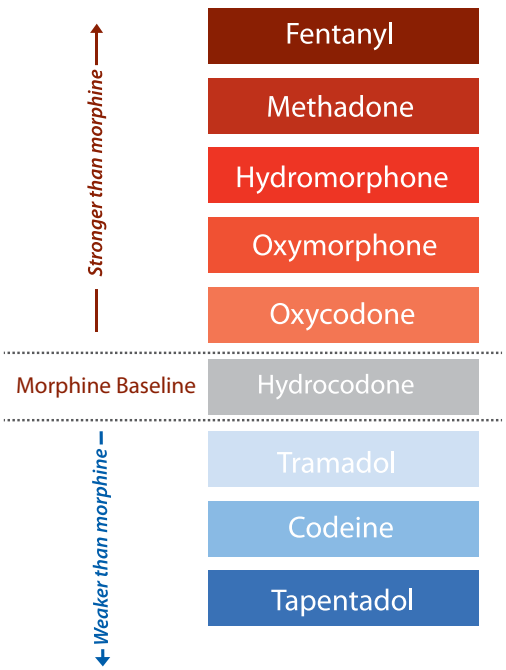
- Consider medication the patient is taking and determine if the dose matches what the manufacturer is recommending.
- Pay attention to published ranges for each medication, keeping in mind what patient factors may come into play.
- Take your own position on what constitutes a warning/high alert zone. Anything from 120-200 mg morphine-equivalent dosage is a red zone, however, planning to begin physician alerts and intervention processes may be necessary much earlier in the process (i.e. 70 – 90 mg., etc.)
- Look to the patients for clues. Are they heavy or thin? What is their liver function? Test the patient's genomics to determine their rate of metabolism. Also, consider the patient's addiction history, either familial or personal. Alcohol, drugs or smoking habits come in to play.

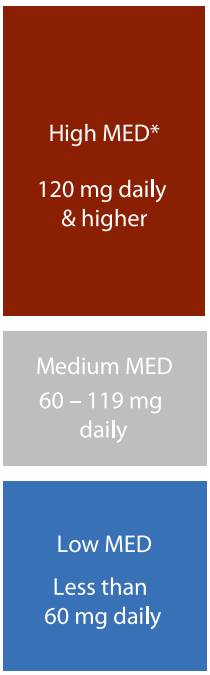
PBMs can utilize the following tools:

- Published clinical trial information
- MED scale – prospective alerts to claims and nurse case management professionals combined with ongoing monitoring and reporting of "red-zone" information
- Identifying and presenting drug equivalents that could be adequately substituted

Nothing is simple. When in doubt, the nurse case manager or claims professional may need to have a conversation with the prescriber to ensure that the drug formula being used is necessary and that the patient has been properly evaluated for the dosage given. PBMs working in concert with insurers and prescribers can bring about more effective, accurate opioid dosages that deliver the best patient results while also incorporating PharmD clinicians and/or peer to peer communications directly with the prescribing physicians.

Morphine Equivalent Dose (MED)





The MED scale on the left illustrates how some of the most commonly prescribed drugs in workers' comp compare in strength to morphine.

The MED gague on the right illustrates the high, medium and low MED levels patients may be presrcibed, based on mg per day.

**There are various opinions about what a "high" dose of opioids is. Healthesystems clinicians have adopted the guideline that 120 mg daily or higher is a high dose.*[16]

By the Numbers: A Detailed View Into Repackaged Drug & Physician Dispensing Activity

Repackaged drugs and the process by which physicians dispense them are continuing to have a growing impact on the total cost of workers' compensation claims. For example, in just three years, physician dispensed prescriptions grew from 22% to 63% of all drugs dispensed in Illinois according to a WCRI study.

According to research conducted by NCCI Holdings, Inc., workers' compensation costs rose sharply in 2008 thanks to physician dispensed drugs. The research also uncovered some unsettling news – three-fourths of all repackaged drug costs in workers' compensation cases originate from physicians.

All too often, these costs go uncontrolled due to many payers and pharmacy management programs inability to effectively process and adjudicate these drug transactions. Many states have been incorporating either laws and/or fee schedule guidelines to address this complex issue. While there hasn't been an adoption of any universally applied approach, at a state level the different strategies target either the costs or the process by which repackaged drugs and physician dispensing can be applied.

The following tables illustrate the drugs and drug classes most frequently found in drug repackaging and physician dispensing activity within workers' compensation.

Top Drug Classes by Script Volume

Drug Name
Analgesic Opioid
Analgesic Anti Inflammatory
Musculoskeletal Therapy Agents
Anticonvulsants
Antidepressants
Ulcer Drugs
Hypnotics
Dermatologicals

Top 5
Drug Classes

The top 5 Drug classes make up approximately 80% of all repackaged drugs being dispensed.

Top Repackaged Drugs

Drug Name
Hydrocodone-Acetaminophen
Meloxicam
Tramadol HCL
Gabapentin
Oxycodone-Acetaminophen
Carisoprodol
Cyclobenzaprine HCL
Ibuprofen
Zolpidem Tartrate
Omeprazole
Naproxen
Tizanidine HCL
OxyContin
Lyrica
Lidoderm
Celebrex
Cymbalta
Oxycodone HCL
Methocarbamol
Ranitidine HCL

Top Repackaged Drugs DISPENSED BY PHYSICIANS

Drug Name
Hydrocodone-Acetaminophen
Meloxicam
Tramadol HCL
Gabapentin
Oxycodone-Acetaminophen
Carisoprodol
Cyclobenzaprine HCL
Naproxen
Ibuprofen
Zolpidem Tartrate
Celebrex
Omeprazole
Lyrica
Cymbalta
Lidoderm
Tizanidine HCL
Oxycodone HCL
Methocarbamol
Clonazepam
OxyContin

The top 20 drugs make up over 75% of all the repackaged drug scripts (which includes those that are dispensed by physicians).

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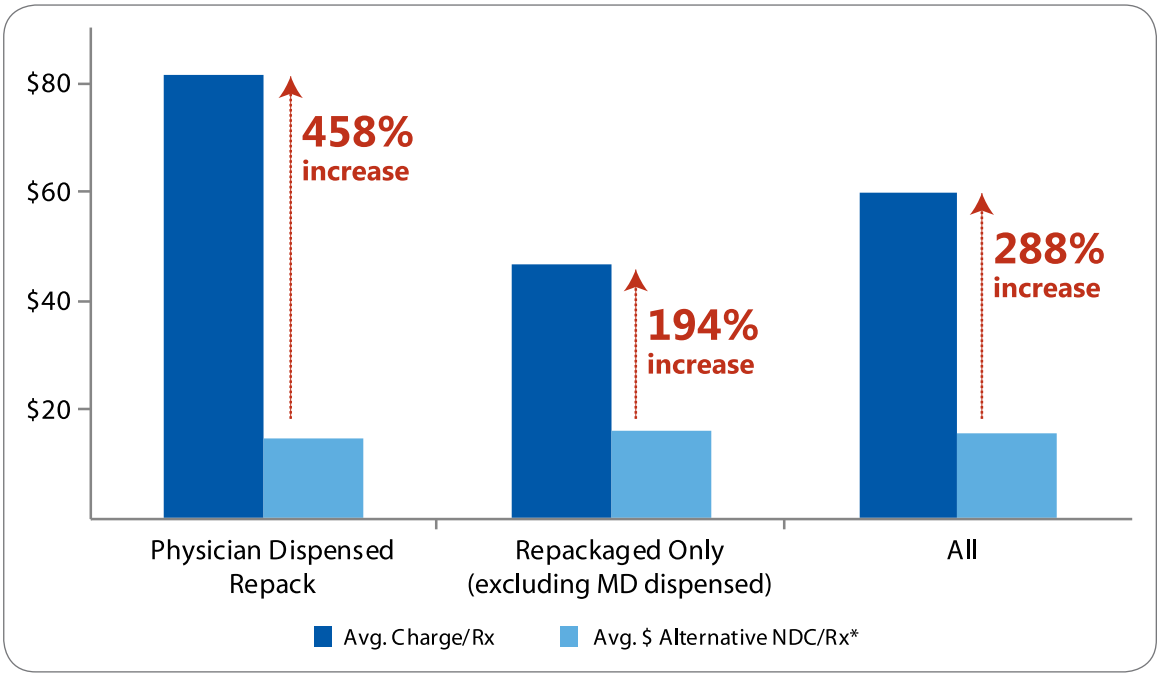
As illustrated throughout the following graphs, the savings opportunities that exist for payers are quite significant. The statistics provided are actual representations of results Healthesystems has been able to achieve for customers. Since the initial development of our repackaged drug management tools in 2008, we have demonstrated over 60% in savings for customers. The initial step required to achieve this success, however, begins with the capability to identify the repackaged and physician dispensed drugs during the pharmacy bill adjudication process, while applying all the appropriate state rules when available. In addition, Healthesystems developed a proprietary analytics and drug forensics tool capable of identifying the originating manufacturer and corresponding price of the repackaged drug in order to maximize savings opportunities. This has been the most crucial component for achieving this success.

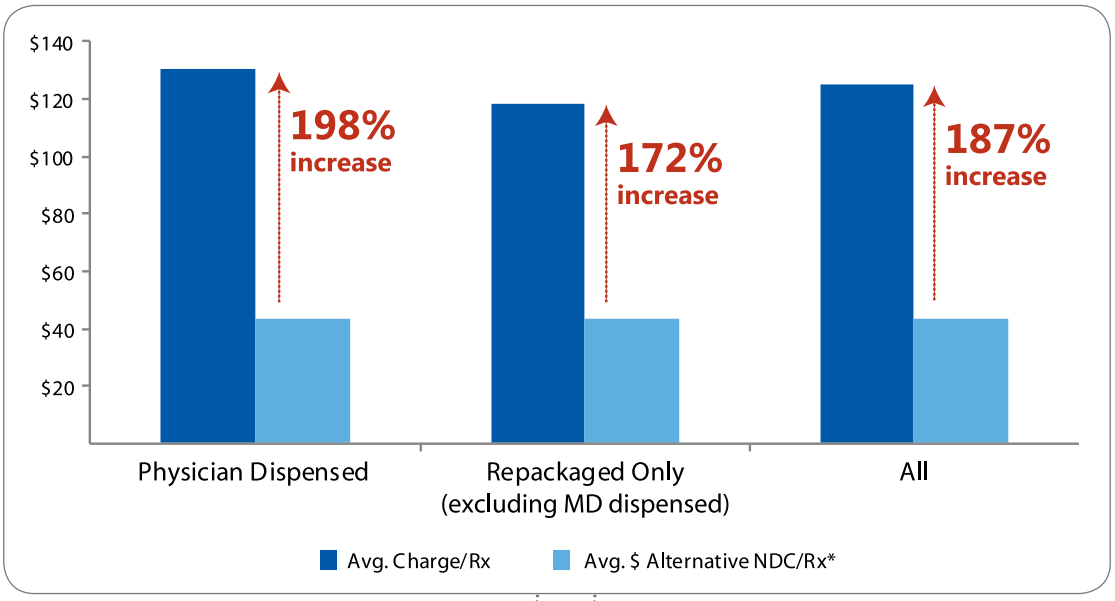
A good example of this can be found when analyzing some of the most frequently utilized repackaged drugs. For example, it is crucial to identify the drugs which have significantly higher inflated charged amounts when they are repackaged. In addition, there also must be visibility into the significant impact physician dispensing also adds to the cost. The following charts analyze two frequently prescribed drugs, Hydrocodone-Acetaminophen and Ibuprofen. Both examples illustrate the significant pricing discrepancies between the cost of a repackaged drug and the incremental impact when physician dispensing is involved. In addition, the analysis further identifies how much the prices are inflated compared to the originally manufactured drug.

Average Cost/Ibuprofen Rx (Physician Dispensed vs. Repack) Compared To Alternative NDC Cost

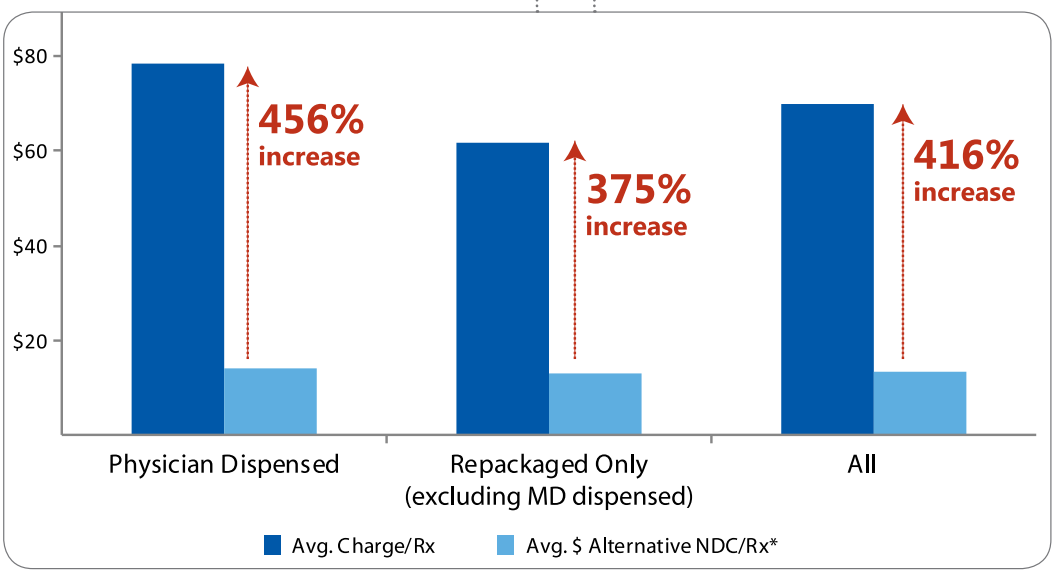


**Alternative NDC includes criteria such as cost of underlying NDC and lowest therapeutic equivalent*

Average Cost/Script for Hydrocodone/APAP (Physician Dispensed vs. Repackaged Only)



Hydrocodone/APAP TAB 5-500MG



When further analyzing difference in the average per script charged amounts for the various dosage strengths of Hydrocodone – Acetaminophen, the most highly prescribed tablet strength 5-500MG has a significantly higher inflated price than the others.

Illinois Preferred Provider Programs Under Scrutiny

In 2011, Illinois passed a major health care reform bill. The goal of HB 1698/Public Act 97-18 was to cut 30 percent of medical and indemnity costs across the board. It was an attempt to bring under control one of the most expensive workers' compensation programs in the country.

Alas, how plans can go awry. The new rules proposed to expand the existing Preferred Provider Program (PPP) regulations into the workers' comp arena, a move that has the potential to deliver disorder and additional pressures into an already strained system.

It happened in part because the Illinois Department of Insurance received so much feedback and advice from numerous stakeholders on how to craft a functional set of workers' comp PPP regulations. The Department chose to propose near identical PPP regulations as those which existed in the general health care world, and then invited commentary prior to passage. The comments were numerous; existing broad-based and specialty networks, insurers, the plaintiff's bar, labor unions and PBMs joined others in voicing their concerns. What was initially drafted just scratched the surface toward fulfilling the mission of expanding carrier direction of care in the state.

The Illinois Joint Committee on Administrative Rules met on September 11, 2012 to review the Department's proposed set of rules. After a review and further discussion, the Committee sent the rules back to the Department for further development. Months have passed since the initial meetings in late 2011 and early 2012. To date, the Department has not made any firm commitments on when the new PPP rules will be finalized, although they are statutorily required to have the new rules in place by April 2013.

Still, we can learn from Illinois' example. State regulators were overwhelmed with feedback. Even when provided proactively, feedback can create a larger issue. In this case, it was an impasse.

The good news is there are groups that support a more collaborative response to legislation. Stakeholders often join alliances and coalitions to work together in order to create a more powerful voice.

In the government affairs world, there needs to be a focus on ensuring access to services, fostering competition and delivering positive patient outcomes.

The way to make good policy is to look at all sides of the issue. The best case scenario on PPP rules will need to:

1. Ensure good access to medical services.
2. Promote an open marketplace that fosters competition and values specialization.
3. Recognizes early return to work and disability management tools as an essential component of positive patient outcomes.

In the compliance and government affairs world, there needs to be a focus on all three areas in order to meet the needs of the injured worker while still balancing the cost and quality of care.

Creating Consensus: How Good Public Policy Can Become a Reality

Payers face many challenges in navigating the workers' compensation legislative and regulatory landscape. For those who pay attention to the workers' comp newswires and blogs, there is no lack of issues facing the claim community. Healthesystems, constantly strives to be more than merely an informed participant; we engage with state agencies on topics which impact the industry and our customers. For example, Healthesystems participates in creating medical treatment guidelines, closely monitors physician dispensing legislation, and works towards establishing responsible opioid prescribing practices. We also advocate for system-wide efficiencies – employing our technology platform to exchange standardized medical billing data and reporting to the states where required by law or regulation.

It takes input from many sectors of the marketplace to make good policy; that is, policy that serves the interests of the injured worker, the employer and the payer. Sometimes the lines between good public policy and the needs of special interest groups get blurred and the result is a scenario like what is occurring in California.

It has been widely reported by many news sources that the reform bill in California was done behind closed doors and involved a small number of large employers and labor interests, with little, if any, carrier involvement. California Senate Bill 863, signed into law on September 19, 2012, has some stakeholders calling foul; in particular those who did not have a place at the bargaining table.

So what's all the fuss about? In short, it's because of the impact of changes to medical services. Changes include major system and process changes, expedited dispute resolution processes, bill review changes, and a number of new fee schedules. All are major changes to the existing system with aggressive timeframes for implementation. New fee schedules will be developed for physician services, interpreters, implantables and home health care.

All of these changes will require rule making as is required for all California state agencies under the Administrative Procedures Act, a process which can be lengthy when done with balanced stakeholder input. Even when expedited, the changes are too numerous to be done as quickly as would be required to meet the January 1, 2013 effective date, when many of these provisions go into effect. So what does this mean to payers who did not have a seat at the negotiating table?

It means that now it's even more important to pay attention to rulemaking notices, state registers and other notifications regarding emergency rules, which will be required in many cases, as well as proposed permanent rule drafts when they are circulated. Customers should examine not only the overall impact to their businesses, but also survey their claim professionals, who in many cases are the ones who have to revamp their daily claim handling processes to meet the new requirements of the law. One of the best resources any payer has is its adjusters, who are closest to the claims process, the injured workers and the medical providers. These claim professionals are an excellent source of information, know what works, what does not work, and why.

Despite the closed-door discussions during the California reform process, stakeholders are not at the mercy of regulators. The Division of Workers' Compensation (DWC) held its first of several stakeholder meetings on October 2 in Oakland, for the purpose of soliciting feedback on four major provisions of the reform bill. One thing is for sure – in California, change is coming.

The State of the States

California

On September 19, 2012 the state passed a wide-sweeping workers' compensation reform bill. The largest effects of the new law will hit health care and home health areas, but the impact for workers' comp will be in the yet-to-be-written rules.

Some of the key provisions in the new law include increased benefits for permanently injured workers, and reduced systems costs.

Illinois

With the implementation of Preferred Provider Program regulations in a workers' comp setting, the Department of Insurance has created a maelstrom of controversy. The criticism comes in various forms, one of which questions why the Department was charged with creating the regulations when the job would have been better suited to the Workers' Compensation Commission. The key issues were not cleared up, so the Joint Committee on Administrative Rule kicked it back to the Department for a second attempt.

It appears Illinois is effectively addressing repackaged drug regulations with a current proposal that would amend the reimbursement of repackaged drugs in the development process. In July 2012, Illinois Workers' Compensation Commission suggested rule changes that would require prescriptions filled and dispensed outside a licensed pharmacy to be billed at the average wholesale price (AWP) for the underlying drug. The dispensing fee would be limited to $4.18.

This would be a big victory for Illinois. Currently, physician dispensed drugs make up 43 percent of all prescriptions dispensed in the state; likewise, the costs of these drugs make up 63 percent of all prescription payments in the state[17].

Michigan

Michigan is joining Illinois in attempting to curb physician dispensing and reimbursement. While not as costly and prevalent in Michigan as it is in Illinois, the practice has caught the attention of regulators. Michigan's proposed average wholesale price formula is $3.50 for brands $5.50 for generics.

North Carolina and Oregon

Both states are proposing rules that establish electronic billing rules in workers' compensation application. The states are expecting to help payers and carriers improve efficiencies, speed up processes, track medical costs, and deliver more accuracy with regard to rate setting.

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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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