CURRENT AND EMERGING ISSUES IMPACTING WORKERS' COMP

RxINFORMER

SUMMER 2016

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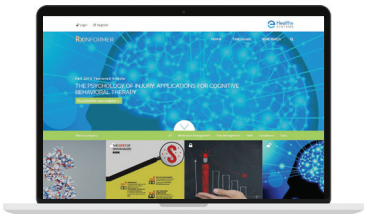

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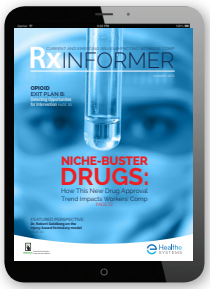

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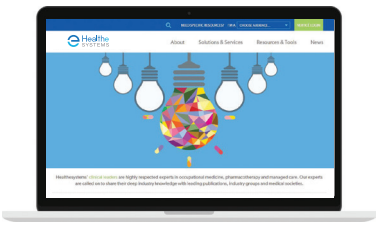

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TIME TO REVERSE THE OPIOIDS PENDULUM: IF NOT NOW, WHEN?

THE CDC OPIOIDS GUIDELINE HAS THE POWER TO CHANGE LONG-STANDING ATTITUDES TOWARD PAIN MANAGEMENT

Too often, market disruptions and healthcare trends create challenges for how we manage care within workers' compensation. So it's a brilliant moment when we can welcome a shift that is both significant in scale and positive in impact for our industry. The March 2016 release by the U.S. Centers for Disease Control and Prevention (CDC) of their much-anticipated *CDC Guideline for Prescribing Opioids for Chronic Pain* marks one of those moments.

The guideline comes at a particularly dark time in our country, with opioid- and heroin-related overdoses resulting in more than 28,000 deaths in 2014 – an increase from the previous year. Sadly these outcomes don't come as a surprise to those of us who are well-versed in the risks associated with opioids use and who have been voicing these concerns over the past decade. With overwhelming evidence that the negative impacts far outweigh their positive benefits, the question prescribers should be asking is: why prescribe opioids in the first place? Yet there persists a widespread and inexplicable acceptance for prescription opioids as a reasonable primary solution for pain management. As Dr. Thomas Frieden, Director of the CDC so astutely assessed in a perspective piece he co-authored with Dr. Debra Houry in *The New England Journal of Medicine:* "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently." How's that for a risk-benefit analysis?

While it would be appropriate to quote the oft-repeated medical maxim *primum non nocere* (first do not harm) or *agrescit medendo* (the cure is worse than the disease), with the release of the CDC guideline a better choice in Latin phrasing might be carpe diem! It is important not to underestimate or overlook the magnitude of the opportunity we have right now, not only as workers' compensation professionals, but more broadly as healthcare decision-makers and influencers. With the introduction of the CDC guideline, we will perhaps never be more empowered to play a role in changing attitudes about pain and treatment goals in the injured worker. While the guideline is voluntary, it can exert tremendous influence among healthcare decision-makers and help shape policy that will eventually drive behavioral change. Now is the time to reassess the role of pain medications within treatment, and the persistent and misplaced emphasis on pain relief vs. functional recovery, which is not producing the intended effect, i.e., returning the injured worker to a highly functional state and a successful return to work.

ABOUT THE AUTHOR

Robert L. Goldberg, MD, FACOEM, is chief medical officer and senior vice president at Healthesystems. He is board certified in Occupational Medicine and is recognized as one of the foremost authorities in the field. He has an extensive multidisciplinary background and 25 years of experience that includes working as a treating physician, researcher, professor, consultant, and corporate executive providing clinical direction to the development of evidence-based medical guidelines and workers' compensation public policy initiatives.

Even with a driving force like the CDC, it's important to remember that meaningful change cannot be achieved without a persistent and well-coordinated effort. As we make steps to shift attitudes and behaviors on the forefront of prescribing, there's still almost two decades of opioids aftermath to clean up, and we need to roll up our sleeves and get to work. In the article "The Making of an Addict" on page 16, we discuss the concurrent heroin epidemic and the causal role that prescription pain medications have played. The situation, frankly, is bleak. But it's not without hope. With the power of the CDC to bolster us, we have the guidance and the support to more aggressively attack the opioid problem from all angles. We should be using advanced clinical tools to support evidence-based prescribing from the start. But we also need strategies in place for when prevention has been bypassed or has failed. The introduction of opioids into a claim tends to have a runaway affect – the mere presence of opioids within the first four weeks of a claim reduces the chances that the claim will close within 90 days by 30 percent. This doesn't have to be the case. The article "Opioid Exit Plan B" on page 20 examines how intervention at any stage can successfully change the trajectory of a claim and the patient's life. It also explores evolving opportunities for detecting opioid concerns, including the introduction of opioid overdose reversal agents such as Evzio® and Narcan® to workers' compensation claims, and what this means for claims management.

It is the nature of a pendulum to seek its point of equilibrium. The opioid epidemic has been on the upswing for far too long in this country. It is my hope that the CDC proves to be the restoring force that begins to swing that pendulum back the other way. Carpe diem!!!

MED WATCH

WORKERS' COMPENSATION PROFESSIONALS SHOULD KEEP AN EYE ON THESE MEDICATIONS

The U.S. Food and Drug Administration (FDA) announced a number of approvals in recent months that could potentially impact workers' compensation, with additional approvals pending in upcoming months. These include new products and/or indications, new dosages or formulations of existing products, and generics introduced to the market.

- ✦ NEW PRODUCT/INDICATION
- ■ FIRST-TIME GENERIC
- ♦ NEW DOSAGE/FORMULATION
- ✱ SPECIALTY

2015

NOVEMBER

Narcan® (naloxone HCl) nasal spray ✦
OPIOID OVERDOSE
Reverses known or suspected opioid overdose

Xtampza™ ER (oxycodone) extended-release capsules ✦
PAIN
Extended-release opioid analgesic formulation for the management of severe pain. Contains abuse-deterrent properties
Note: While the FDA has approved Xtampza ER, the drug is now involved in a patent litigation which has delayed release to the market

Harvoni® (ledipasvir and sofosbuvir) ✦ ✱
ANTIVIRAL
New indication to treat hepatitis C infections of patients with genotypes 4, 5 and 6, and patients co-infected with HIV

Genvoya® (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) ✦ ✱
ANTIVIRAL
Complete regimen for treatment in certain patients with HIV-1

OCTOBER

Vivlodex™ (meloxicam) capsules ✦
PAIN
Nonsteroidal anti-inflammatory for osteoarthritis or rheumatoid arthritis in adults

Belbuca™ (buprenorphine HCl) buccal film ✦
PAIN
An opioid analgesic buccal film formulation for the management of chronic pain

MorphaBond™ (morphine sulfate) extended-release tablets ✦
PAIN
Extended-release opioid analgesic for treatment of pain severe enough to require daily, around-the-clock, long-term opioid treatment. Contains abuse-deterrent properties

Praxbind® (idarucizumab) ✦
CARDIOVASCULAR
First emergency reversal agent for the anticoagulant Pradaxa®

JANUARY 2016

Zepatier™ (elbasvir/grazoprevir) ✦ ✱
ANTIVIRAL
Used with or without ribavirin for chronic hepatitis C (genotype 1 or 4)

Cetylev™ (acetylcysteine) effervescent tablets for oral solution ✦
ACETAMINOPHEN OVERDOSE
Antidote for acetaminophen overdose indicated to prevent or lessen liver damage after the ingestion of a potentially hepatotoxic quantity of acetaminophen

DECEMBER

Uptravi® (selexipag) ✦ ✱
CARDIOVASCULAR
Treats pulmonary arterial hypertension

Bridion® (sugammadex) injection ✦
REVERSES NEUROMUSCULAR BLOCKADE
For the reversal of temporary paralysis caused by certain neuromuscular-blocking drugs that may be administered during surgery

Basaglar® (insulin glargine) ✦
DIABETES
To improve glycemic control in adults with type 2 diabetes mellitus

FEBRUARY

Xeljanz® XR (tofacitnib citrate) extended-release tablets ♦✱
RHEUMATOID ARTHRITIS
Treats moderate to severe rheumatoid arthritis (RA) in patients who have had an inadequate response or intolerance to methotrexate

Glumetza® (metformin extended-release) ▪
DIABETES
Adjunct to diet and exercise to improve glycemic control in adult type 2 diabetes

▶ ALWAYS ON THE WATCH

The new product landscape is ever-shifting. Visit MEDWATCH online for all of the latest updates, plus an expanded list of medications at www.healthesystems.com/rxinformer

PRODUCTS ON THE HORIZON

The following product New Drug Applications (NDAs) have recently been accepted for review by the FDA, and some could be approved in the near future.

Oliceridine

PAIN

Intravenous analgesic that treats moderate-to-severe acute pain with reduced frequency of opioid-related adverse events (e.g., nausea, vomiting, hypoventilation) when compared to intravenous morphine. Has been granted breakthrough therapy status.

Naldemedine

OPIOID SIDE EFFECTS

Oral, peripherally acting mu-opioid receptor antagonist that treats opioid-induced constipation (OIC) in patients with chronic non-cancer pain.

Rapastinel (GLYX-13)

PSYCHIATRY

Intravenous formulation for the adjunctive treatment of major depressive disorder. Has been granted breakthrough therapy status.

Sofosbuvir/velpatasvir

ANTIVIRAL

Once-daily, fixed-dose combination drug for the treatment of chronic genotype 1-6 hepatitis C infection. Has been granted priority review.

Arymo™ ER (morphine sulfate)

PAIN

Extended-release, potentially abuse-deterrent formulation of morphine. Resistant to methods of manipulation, including injection and snorting, as well as oral abuse.

Probuphine® (buprenorphine)

OPIOID DEPENDENCE

Opioid partial agonist subdermal implant formulation with six month duration in development for the treatment of opioid dependence. FDA decision moved from February 27, 2016 to May 27, 2016.

ALO-02 (oxycodone HCl and naltrexone HCl)

PAIN

Extended-release capsules for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

An abuse-deterrent formulation opioid, ALO-02 is an extended-release oxycodone specifically designed to reduce abuse via the oral, intranasal (i.e., snorting) and intravenous (IV) routes when crushed.

Unfold for full timeline

DRUG ALERTS

NARCAN® NASAL SPRAY LAUNCHED TO REVERSE OPIOID OVERDOSE

Naloxone reformulated for emergency use

Adapt Pharma's Narcan nasal spray became available in February 2016 for the emergency reversal of known or suspected opioid overdose, manifested by respiratory and/or central nervous system (CNS) depression.

This is the first naloxone nasal spray approved by the FDA. Opioids are prescribed frequently in workers' compensation, creating a risk for misuse or overdose in select patients.

I.V. SPECIALTY PRODUCTS LACK STERILITY, SAYS FDA

FDA issues alert for product line

The FDA alerted healthcare professionals and patients not to use drug products intended to be sterile that are produced and distributed by I.V. Specialty Ltd., Austin, Texas, due to lack of sterility assurance. The FDA recommended that I.V. Specialty cease sterile production until appropriate corrective actions are implemented, and recall all non-expired drug products intended to be sterile, but the company has neither ceased sterile production nor initiated a recall. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death.

LICORICE COUGHING LIQUID CONTAINED MORPHINE

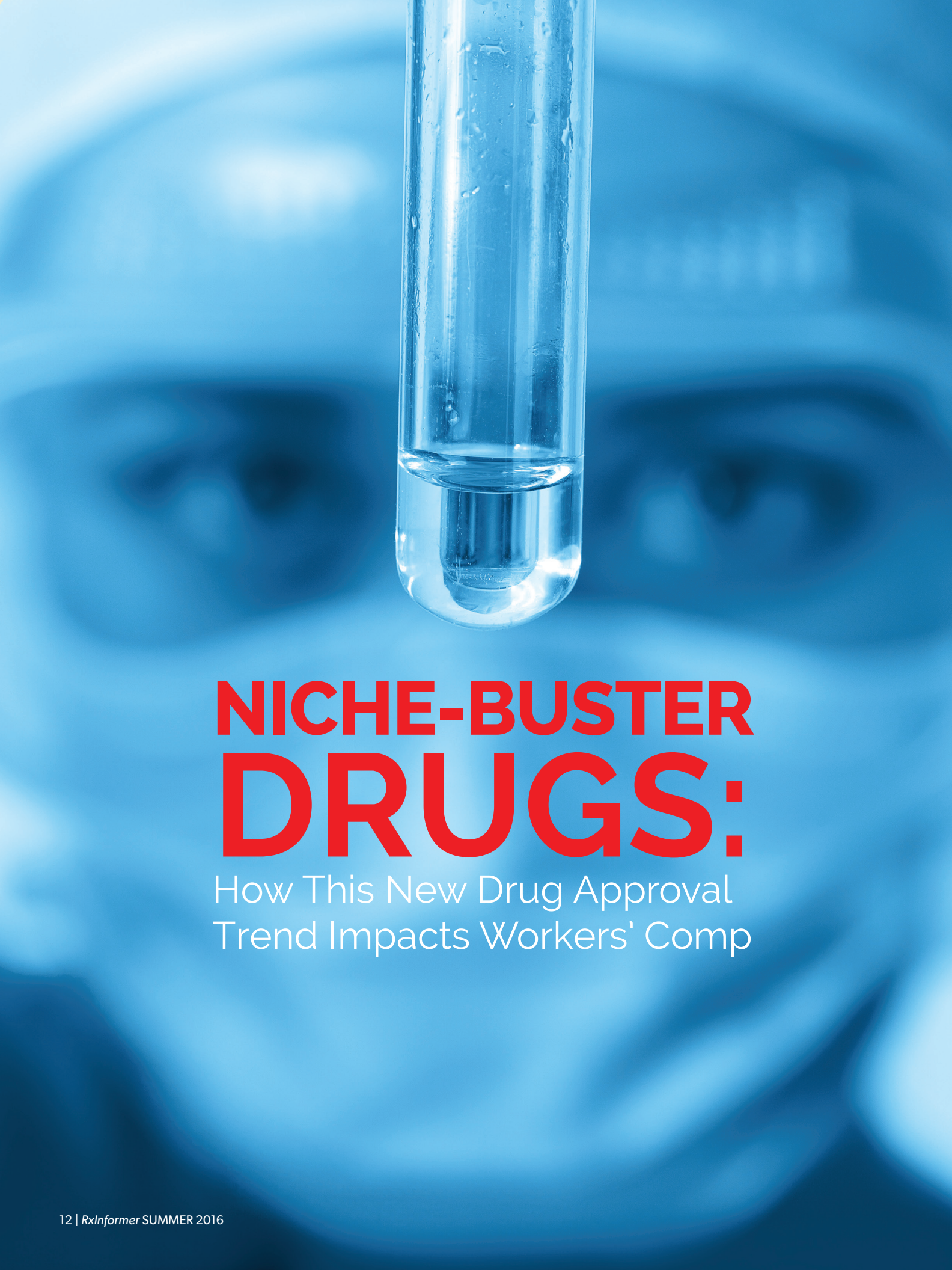
Unlisted opioid found in over-the-counter cough syrup

Master Herbs, Inc. voluntarily recalled all lots of Licorice Coughing Liquid, cough syrup in 100 mL bottles when it was revealed that an ingredient, compound camphor, contained morphine. This was not declared on the label and could lead to life-threatening respiratory depression and death. The opioid product morphine is a controlled substance and should not be available over-the-counter.

FDA ISSUES VOLUNTARY RECALL OF MORPHINE SULFATE DUE TO SUPER POTENCY

Lab results reveal super potency as serious adverse events affect infants

Pharmakon Pharmaceuticals issued a recall on morphine sulfate 0.5mg/mL preservative-free in 0.9% sodium chloride, 1mL syringe, for intravenous use after the product was found to be super potent. The February 2016 recall comes well after the FDA issued Pharmakon a warning letter in May 2015 for deficiencies found in facility inspections. Morphine sulfate is a controlled substance for pain management.



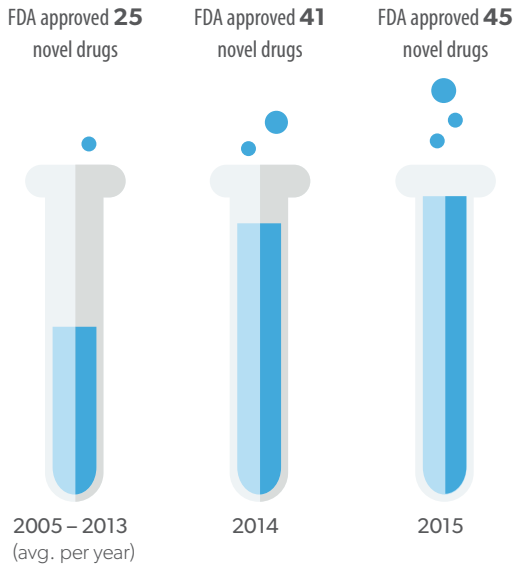
NICHE-BUSTER DRUGS:

How This New Drug Approval Trend Impacts Workers' Comp

FAST FOCUS

FDA approval rates of New Drug Applications (NDAs) have increased substantially in recent years. Blockbuster drugs are giving way to niche-buster drugs – drugs meant for specific disease subpopulations where limited treatment options were previously available. This influx of niche drugs helps address unmet medical needs, but it could contribute to increased pharmacy costs for payers as expensive, first-in-class drugs gain popularity.

In 2014, the FDA approved 41 novel new drugs (new molecular entities, NMEs), marking a record for the most novel drugs approved by the FDA in the last decade,[1] only to be broken in 2015 with 45.[2] The spike is surprising, considering that from 2005 – 2013 the average number of novel drugs approved was 25, even though the number of submissions to the FDA has remained steady.[1,2]



This increase in approvals stems from the fact that a high number of approved drugs qualified for expedited FDA approval pathways.

A BREAKDOWN OF EXPEDITED CATEGORIES

Priority Review

Drugs that could potentially provide a significant advance in medical care are given a target review of six months instead of the standard 10 months, providing a time advantage over non-expedited drugs.

Fast Track

Drugs that can treat unmet medical needs qualify as Fast Track. The FDA increases communication with drug developers and reviews portions of the NDA ahead of the submission of the completed application. By reviewing sections of the NDA submission early, these will likely already be preapproved once the application is sent.

Breakthrough

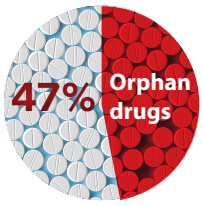
Drugs with preliminary clinical evidence demonstrating substantial improvement in at least one clinically significant endpoint (i.e., study result) over other available therapies qualify as Breakthrough. Breakthrough drugs receive all Fast Track benefits, as well as more intensive FDA guidance on an efficient drug development program, making their approval somewhat quicker than Fast Track drugs.

Accelerated Approval

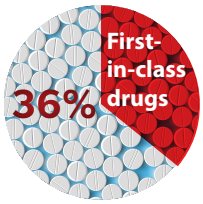
Drugs that treat a serious or life-threatening illness and offer a benefit over current treatments are given early approval. These are meant for dire scenarios, meaning their speed is the fastest since they are meant for patients who most need them. However, once approved, these drugs must undergo additional testing to confirm their benefits.

WHAT KINDS OF DRUGS ARE EXPEDITED?

At the most basic level, drugs that offer medical improvements over current options (if any options exist) receive more attention from the FDA, increasing that drug's chances of approval. In 2014, 78% of novel drugs were approved in their first review cycle,[1] meaning there were no requests for additional information about these drugs that would delay approval and lead to another cycle of review. This number increased to 87.5% in 2015.[2] Some examples of products that qualify for expedited approval pathways include:



Orphan drugs for small populations of patients with rare diseases, which made up 41% of all novel drugs of 2014[1] and 47% of novel drugs in 2015.[2]



First-in-class drugs with mechanisms of action different from those of existing therapies, making up 41% of novel drugs in 2014[1] and 36% in 2015.[2]

NICHE BUSTERS OVERTAKE BLOCKBUSTERS

Pharmaceutical companies have traditionally developed blockbusters, drugs that treat broad populations. When faced with such high demand to treat more common conditions, complex diseases that affected smaller populations often received less attention from the healthcare industry as a result.

However, as technology and research have evolved, the resources necessary to treat a range of specific and obscure conditions are now available. These niche-buster drugs treat conditions once thought too obscure to treat.[3]

With more novel drugs hitting the market than ever before, physicians may be more likely to prescribe them as they gain popularity. Their novelty alone will make them expensive, but it has been reported that 50% of high-cost medications will be made available only through specialty distributions,[4] complicating the situation. Specialty drugs often treat serious illnesses and require special handling, administration and monitoring. Even though specialty products make up a small portion of prescriptions, they can represent a significant percentage of prescription drug costs.

THE FUTURE: NON-ADDICTIVE OPIOIDS?

Pharmaceutical companies have been developing non-addictive opioids to treat pain while fighting the opioid epidemic. Although none have been approved yet, non-addictive opioids have the potential to change the workers' comp industry.

Cara Therapeutics has developed CR845, a drug they claim targets the site of injury and does not cycle through the brain, preventing addiction and avoiding side effects such as nausea, vomiting, sedation and respiratory depression.[6] CR845 has recently completed Phase II human trials.[7]

Meanwhile, startup Blue Therapeutics is developing a yet unnamed opioid that avoids targeting pleasure centers to prevent addiction,[8] and Hydra Biosciences has a drug in early human trials that modulates the proteins that cause painful reactions in the body.[9]

Non-addictive opioids such as these will be in high demand if they can treat pain and counter opioid risks. The FDA could possibly expedite approval for these drugs as there is a medical need for pain relief without potential addiction.

The safety and effectiveness of these non-addictive opioids must be proven beyond a doubt in order to support large-scale adoption within the workers' comp industry. Their prices will be significantly higher than current opioids, but their application could greatly reduce the complications that arise from opioid misuse and abuse, leading to overall cost savings. Only time will tell, as these products are still in earlier stages of development.

WHAT THIS MEANS FOR WORKERS' COMP

Many novel drugs approved do not directly apply to conditions commonly seen in workers' compensation, with some major exceptions (see Claims Corner sidebar). However, this trend of niche-buster drugs will have its impact as yet another layer of complexity to consider when managing the care of injured workers.

When weighed alongside trends such as increasing generic prices, the rise of private-label topicals and compound prescriptions, physician dispensing, the high prices of orphan and specialty drugs, and the growing popularity of biologics, it is clear that pharmacy benefits management has long evolved beyond the one-dimensional brand vs. generic model. Traditional tools are no longer adequate to address the changing market dynamics. Effective management requires the application of evolved strategies that address current and future pharmacy trends from a comprehensive standpoint.

FUTURE CONSIDERATIONS FOR EFFICACY AND SAFETY

While novel drugs can potentially offer significant clinical benefits over existing therapies, an expedited review period may reduce the level of clinical evidence needed for approval.

Last July, the U.S. House of Representatives approved the 21st Century Cures Act, a piece of legislation developed to encourage innovation in healthcare. However, there are some concerns regarding its potential impact on the approval process for new drugs and medical devices. The act would expand the parameters of scientific evidence of a drug's efficacy to include evidence from sources other than randomized clinical trials, such as observational studies, registries, and therapeutic use.[5] This means that anecdotal evidence could be used to approve a drug, instead of rigorous scientific trials. The act is currently being reviewed in stages by the Senate.

While the intent of the 21st Century Cures Act may be to encourage drug innovation and address unmet medical needs, these relaxed standards may have safety and efficacy implications. Novel therapies often gain popularity due to their perceived clinical advantages. However, with changing standards of approval, these treatments must be considered carefully against tried-and-true drug therapies.

CLAIMS CORNER

Novel Drugs That Impact Workers' Comp

Keep up-to-date on new drugs – and why you may see them prescribed to your claimants. The following are novel drugs from the last two years that may be relevant to workers' comp:

PCKS9 inhibitors

PCKS9 inhibitors help to lower high cholesterol in patients with heart disease who are unresponsive to traditional therapy. Cholesterol management may be needed for injured worker conditions that are covered for high-stress jobs, e.g., heart conditions. Recently approved PCKS9 inhibitors include:

- **Praluent®** (alirocumab)
- **Repatha™** (evolocumab)

Hepatitis C drugs

Hepatitis C is seen in workers' comp when workers are infected via needle stick injury; for example, nurses or emergency professionals. Recently approved hepatitis C drugs include:

- **Daklinza™** (daclatasvir)
- **Viekira Pak™** (ombitasvir/paritaprevir/ritonavir) combination therapy
- **Harvoni®** (ledipasvir/sofosbuvir)

Other

- **Movantik™** (naloxegol) – Treats opioid-induced constipation in adults with chronic non-cancer pain. Injured workers who receive pain medications for their injuries could benefit from this drug when dealing with the side effects of prescribed opioids.
- **Zontivity®** (vorapaxar) – Reduces the risk of heart attacks and strokes in high-risk patients. This drug may be relevant to populations with heart conditions related to high-stress work environments.
- **Rexulti®** (brexpiprazole) – An add-on to an antidepressant to treat major depressive disorder. Injured workers who are incapacitated for an extended period of time could face depression, which can hinder a worker's efforts to recover.

THE MAKING OF AN ADDICT:

THE PATH FROM OPIOIDS TO HEROIN IN THE INJURED WORKER

FAST FOCUS

As the ongoing opioid epidemic gives way to an upsurge in heroin usage, we examine where the injured worker fits into this growing threat.

Addict. The term once conjured a bleak image of needles shared in back alleys or seedy apartments; a dehumanized view of a life stripped bare of everything that defined the individual prior to their addiction and replaced by a singular purpose – getting their next fix.

However, the face of heroin addiction has changed dramatically over the past decade, in large part due to an uptick in usage that coincides with the ongoing opioid epidemic. The rate of deaths related to heroin overdose within the United States increased four-fold between 2002 and 2013.[1] Notably, prescription pain medication misuse also increased four-fold during a similar time period.[2] This is no coincidence. The CDC has identified addiction to prescription opioids as the number one risk factor for heroin addiction.[1]

The injured worker population is particularly susceptible to this trend. People who are hurt on the job are often prescribed opioid analgesics to manage their pain. Unfortunately, the high rate of opioid prescribing among injured workers can also increase the risk for dependence or addiction within this population.

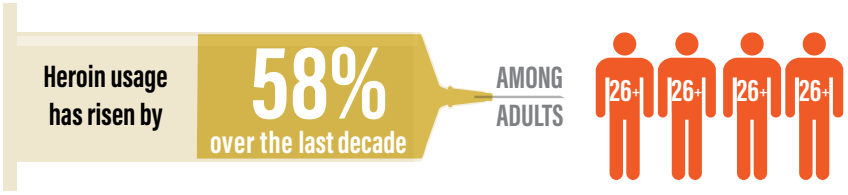
But as the face of heroin addiction continues to change, what hasn't significantly changed is a prevailing attitude that addicted individuals are beyond help or hope. Unfortunately, the dismal rates at which heroin users successfully undergo treatment for their addiction don't do much to dispel this perception. Only 11% of people who need specialty treatment for a substance use disorder (including heroin use) receive it.[3]

With statistics like these, one has to step back and take a look at where we can be doing better. Specifically when it comes to the injured worker, where are the breakdowns within the workers' compensation care system that allow an individual to devolve from patient to addict?

OPIOIDS AS A GATEWAY

Like a hurricane, opioids can leave a broad and devastating trail, with destruction that reaches well beyond the center of the storm. These prescription pain medications bear significant morbidity and mortality in their own right. In the short-term, opioids can have adverse effects on the body that include digestive system disturbances, respiratory depression, and changes in mental status that may include confusion or agitation. The long-term health and financial impacts of opioid misuse are significant. The CDC estimates that prescription pain medication overdose kills 44 people every day.[4] From a workers' compensation standpoint, opioid misuse often derails recovery in the injured worker. This can delay the person's ability to return to work or even to carry out typical daily activities. In fact, opioids may very well be the greatest barrier for patients getting back to work. Chronic work loss is six times greater for patients who are prescribed a schedule II controlled opioid.[5] From the insurer's standpoint, delayed recovery translates into longer claim durations, keeping injured workers from returning to work and cementing the healing process, as well as significantly increasing indemnity and medical costs.

Despite the myriad risks associated with opioid medications, inappropriate prescribing in the injured worker population remains a concern. We continue to hear stories of patients who were prescribed opioid analgesics for a headache, a back strain, or a – *insert minor injury with no proven medical need here!* – and the path of addiction was initiated. This is not a cautionary tale but the unfortunate reality. Individuals who are addicted to opioids are forty times more likely to develop a heroin addiction.[1]



Although the largest increases in heroin usage have been among youth (a byproduct of drug diversion and recreational use), adult populations are seeing significant increases. Heroin usage has risen by 58% over the last decade among adults older than 26 years of age[1] – an age group that represents a significant portion of the workforce.

A GROWING HEALTHCARE BURDEN

In addition to the devastating impact of addiction on the individual and his or her family, there is a growing burden of disease and cost to the healthcare system and society overall. Along with deaths caused by heroin overdose, there are a host of other factors contributing to the significant morbidity and mortality associated with heroin usage. The most notable trending health risk associated with heroin usage in the last decade is the rising incidence of new (acute) cases of hepatitis C virus (HCV). The virus spreads at high rates in populations using heroin due to the sharing of contaminated needles. Nearly a third of states reported a 200 percent increase in acute HCV cases from 2006-2012.[6]

The good news? The new antiviral medications for HCV are highly effective. If it weren't for the rising infection rates due to burgeoning heroin usage, we may have been a step closer to curing the disease. But these treatments come at a steep cost. One analysis estimates that the annual cost of care for patients with HCV increased from $7 to $21 billion following introduction of the new antivirals onto the market.[7] The same researchers also estimate that it will cost $106 billion over the next 25 years to make HCV a rare disease.

This is of course assuming that patients get treated at all. Half of the 3 to 4 million people who are infected are unaware of their HCV status – and of the ones that are, only a portion of them are treated.[8]

As we try to overcome the challenges in identifying and treating current HCV infections, we also need to stop new infections from occurring. Similarly, as we address the existing challenge of heroin addiction and its health consequences, at the same time we must focus on prevention.

A RESPONSIBILITY FOR ACTION

Those of us in the workers' compensation industry have a unique opportunity to be on the front line of preventive efforts against opioid misuse and its even darker sequel, heroin addiction. We are well-versed in the risks that opioids pose to the injured worker, and we have developed tools and resources that encourage responsible opioid prescribing. We are trained to recognize the early warning signs of opioid misuse. And when these red flags do arise within the individual's treatment (e.g., multiple prescription pain medications, high-risk drug combinations, prolonged opioid usage or higher-than-recommended dosages), we have the knowledge and ability to intervene with discontinuation or addiction management strategies as appropriate. These efforts are typically undertaken in workers' compensation with very specific goals to speed the patient's recovery and return to work, and to reduce overall costs. However, when these strategies are applied effectively, they can also significantly reduce risk for misuse and addiction.

But with patients continuing to slip through the cracks, we must be critical of ourselves as an industry. This means acknowledging where the system is failing – and coming up with new and better solutions. And it also means using the tools we already have more effectively. There is a lot we're doing right – but there's much room for improvement. Collectively, we have the potential to influence care of the injured worker in a way that reaches beyond workers' compensation to impact the individual's family, their community, and the healthcare system. There is just more work to be done.

HOW A BACK STRAIN CAN TURN DEADLY: FROM OPIOIDS TO HEROIN TO HEPATITIS

Opioid misuse can initiate a pathway of addiction that leads to illicit drug abuse, most notably heroin. Injured workers are susceptible to addiction due to the prevalence of opioids in workers' compensation. The associated health consequences – which can include viral infections, heart disease, and lung damage – are detrimental to the individual and his or her family, to society, and to the health care system.

Opioid Addiction: #1 risk factor for heroin addiction[1]

People who are addicted to prescription pain meds are **40x more likely to be addicted to HEROIN**

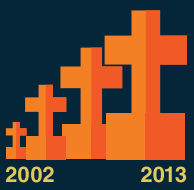
45% of people who used heroin were also **addicted to prescription opioids**

Signs of potential opioid dependence, misuse, or addiction

- Multiple prescription pain medications
- High-risk drug combinations
- Long-term use or high dosages

Increasing heroin usage, overdose

Heroin usage has increased over the last decade in adults **>26 yrs old by 58%**[1]



Between 2002-2013, **heroin-related overdose deaths almost quadrupled in the US.**[1] Coincidentally, the rate of prescription pain medication misuse also quadrupled[2]

REFERENCES: 1. CDC Vital Signs: Today's Heroin Epidemic. http://www.cdc.gov/vitalsigns/heroin/ 2. Rudd RA et al; CDC. MMWR Morb Mortal Wkly Rep. 2016;64:1378-82. 3. Zibbell JE et al.; CDC. MMWR Morb Mortal Wkly Rep. 2015; 64:453-458. 4. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C www.hcvguidelines.org. 5. CNN. How heroin kills you. http://www.cnn.com/2014/02/04/health/how-heroin-kills/ 6. Chhatwal J et al. The Cost of Making Hepatitis C a Rare Disease in the United States. Presented at: American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2015. http://www.natap.org/2015/AASLD/AASLD_115.htm. 7. Chhatwal J et al. Hepatitis C disease Burden in the United States in 2015 and Beyond. Presented at: American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2015. http://www.natap.org/2015/AASLD/AASLD_57.htm 8. National Institute on Drug Abuse. Principles of Drug Addiction Treatment: A Research-Based Guide. https://www.drugabuse.gov/sites/default/files/podat_1.pdf

Health Risk: Lung Damage

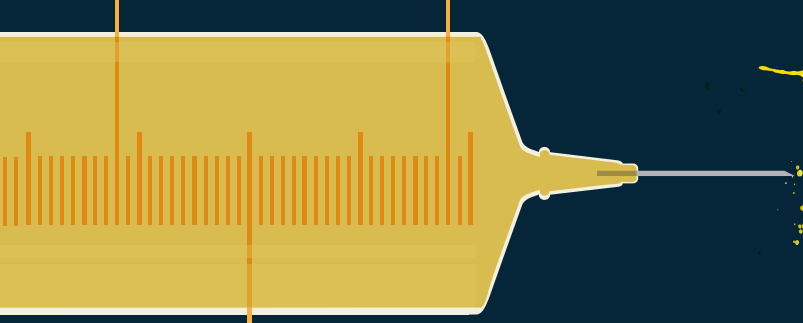
Heroin overdose can cause excess fluid in the lungs; in rare cases, this can be **fatal**

Health Risk: Hepatitis C Virus (HCV)

15 states reported more than a **200% increase** in acute HCV cases, from 2006-2012[3]

HCV occurs at high rates among heroin users due to sharing infected needles

3 to 4 million individuals in the U.S. have chronic HCV infections[4]



HEALTH CARE BURDEN

Health Risk: Heart Disease[5]

IV heroin users are **300x** more likely **to die** from an infection on the surface of the heart

Heroin use can cause heart problems ranging from irregular heart rhythm to **heart attacks**

It will cost $106 billion over the next 25 years to make hepatitis C a rare disease.[6]
But if current trends continue:[7]

317,000 people will still **die from HCV** during that period

154,000 will develop **liver cancer**

198,000 will develop **decompensated cirrhosis**

31,000 will undergo **liver transplantation**

Every dollar invested in addiction treatment programs yields a return of **~$12** in reduced drug-related crime and theft, criminal justice costs, and **health care savings**[8]

Prevention vs. Intervention

When substance abuse treatment is successful, it can significantly reduce future disease burden and costs to society. But responsible opioid prescribing can reduce the risk of a patient developing addiction to prescription medications in the first place. Faced with the current trend of addiction, increased heroin use and rising HCV rates, prevention remains our most powerful strategy.

OPIOID EXIT PLAN B:

Detecting Opportunities for Intervention

FAST FOCUS:

Defining a clear opioid treatment strategy that prevents prescription medication misuse should occur prior to initial prescribing. However, ongoing monitoring creates the opportunity to detect red flags at any stage of a patient's treatment. Interventions deployed early in treatment can avoid more serious consequences such as opioid dependence or misuse. But for patients who are already facing dependence or addiction, there is still a significant opportunity for positive impact.

The prescribing of opioids, even conservatively, brings with it inherent risk. For some injured workers, prescription opioid use can be a slippery slope to dependence or even addiction. From a claims management perspective, these behaviors can extend the life of a claim (in some cases indefinitely) and delay or prohibit return to work, dramatically increasing both medical and indemnity costs. Opioid use doesn't have to be long-term to delay recovery and extend the life of a workers' compensation claim. A claim is 30% less likely to close within 90 days if an opioid is prescribed in the first 4 weeks.[1]

Claims are 30% less likely to close within 90 days if an opioid is prescribed in the first 4 weeks following injury[1]

With overwhelming evidence that the negative impacts far outweigh their positive benefits, the first question we should be asking is: should opioids even be prescribed in the first place? The answer to this, in many cases, is a resounding no. However, when a prescriber does choose to utilize opioid therapy, ongoing monitoring and evaluation throughout the course of treatment can identify warning signs that warrant timely intervention. Earlier intervention is ideal, because it creates greater opportunity to impact the trajectory of a claim. In the majority of cases, identifying red flags within claims can initiate a conversation around the appropriateness of opioid therapy before any negative consequences can occur.

4/5

employers reported observing some type of opioid-related issue in the workplace[2]

&

In 2014, nearly

19,000

drug overdose fatalities were tied to prescription opioids[3]

But national statistics tell us that many individuals are still slipping through the cracks. In a recent National Safety Council survey of 200 employers, 4 out of 5 reported observing some type of opioid-related issue in the workplace.[2] And in 2014, nearly 19,000 drug overdose fatalities were tied to prescription opioids.[3] While these numbers speak to a broader population, the same risks apply to the workers' compensation industry – perhaps even more so due to the prevalence of injury and prescription drugs for pain management.

For injured workers who are struggling with dependence or addiction, there is still a significant opportunity to impact their claims – and their lives.

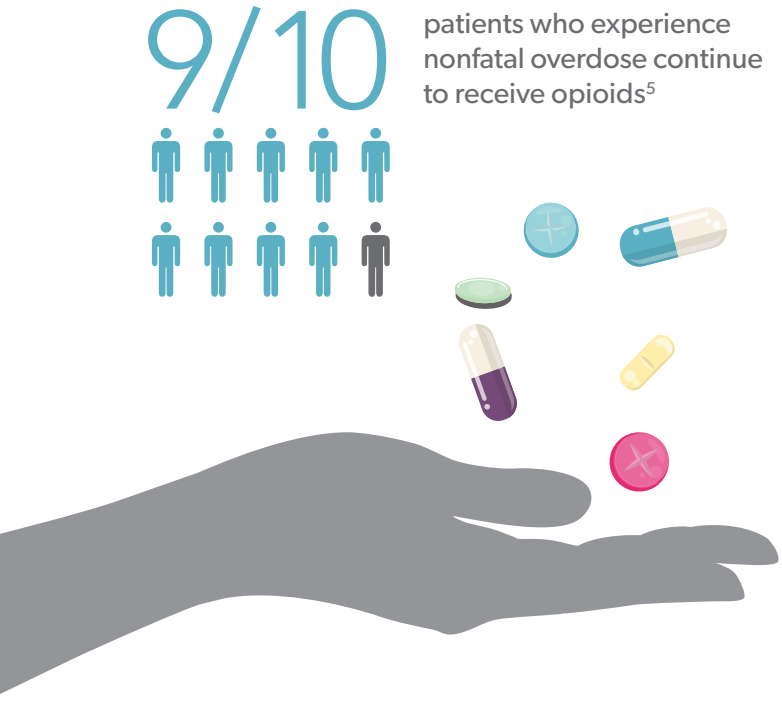
IDENTIFYING PATIENTS AT RISK

Identifying and treating opioid-related concerns, including addiction, provides a significant opportunity to change the course of a patient's recovery for the better. Unfortunately, individuals with substance use disorders – including addiction to prescription pain medications – frequently do not receive the treatment they need for their disorder.[4] In some instances, this may be due to patient motivation, or to limited access to treatment options. In other cases, it may be due to the opioid misuse going undetected.

Continually assessing therapy red flags that can identify individuals who may be misusing prescription pain medications creates an opportunity for a qualified professional to intervene with the prescriber, who can then determine whether opioid dependence or addiction is in play, and appropriate next steps, e.g., a detox program. Connecting the individual with the treatment they need plays a significant role in avoiding additional consequences of addiction and the resulting healthcare costs.

Payers, PBMs and employers all play a role in spotting red flags in therapy, which is the first step in identifying potential candidates for intervention. Workers' compensation claims professionals and PBMs are especially well-positioned to flag the signs of potential opioid misuse within a claim – dose increases, irregular refill patterns, switching or using multiple prescribers or pharmacies, high-risk drug combinations, or escalating morphine equivalent dose (MED) levels. Healthesystems reported in-depth on this topic in the Fall 2013 issue of *RxInformer* (see "Red Flags in Opioid Therapy" at www.healthesystems.com/rxinformer). However, in a changing healthcare landscape, new opportunities for intervention need to be explored and tested.

For example, the introduction of opioid antidotes into workers' comp claims provide a new decision point that didn't previously exist. Evzio®, an auto-injection formulation of the opioid overdose reversal agent naloxone, has surfaced in workers' comp claims over the past year. Narcan™, the first FDA-approved nasal spray formulation of naloxone, also launched earlier this year and may soon begin to surface in workers' comp. Either of these products may be prescribed if the physician feels their patient is at risk of opioid overdose. However, a one-time prescription of either of these agents does not necessarily mean that the patient is struggling with addiction or misuse. Anecdotal reports show that some doctors are more likely to co-prescribe an opioid antidote as a precautionary measure. Regardless, the presence of Evzio or Narcan in a treatment warrants in-depth evaluation of the current opioid treatment plan. If a patient is at a risk level that necessitates the prescribing of an opioid antidote, the continued appropriateness of opioid therapy should be reconsidered. Frequently this does not happen. A Boston Medical Center study last year found that the large majority of chronic pain patients who were hospitalized for overdose continued to be prescribed opioids following the event – often because the original prescriber is unaware that the overdose occurred.[5] This shocking statistic underscores the need for improved communication among stakeholders involved in the patient's care.



INTERVENTION AT ANY STAGE CAN BE SUCCESSFUL

While prevention remains our best strategy in fighting the opioid epidemic, it is important to understand that individuals who are addicted to prescription opioids are not beyond hope. Intervention even at this later stage can have a positive impact.

Addiction is a complex and chronic disease comparable to cancer, HIV or diabetes, and it must be treated with the same level of persistence. Just as cancer treatments must be selected according to histology or patient characteristics, so must a drug addiction treatment plan take into account individual patient factors. And while addiction relapse rates can be disheartening, it's important to keep in mind that they are similar to relapse rates in other chronic conditions such as diabetes, hypertension or asthma.[6] These are obstacles that can be overcome, as they can be with most chronic diseases.

Addressing addiction can also be cost-effective. Though addiction treatment can be expensive, it can significantly reduce overall costs to the healthcare system and to society. Every dollar invested into an addiction treatment program yields $12 saved in drug-related crime, criminal justice costs, theft, and healthcare costs.[6]

Prescription Drug Misuse and the Workplace

Employers also have a stake in helping to identify and address prescription opioid misuse. Workplace costs associated with the misuse of prescription opioids are upwards of $25 billion per year.[7] Individuals misusing prescription pain medications can pose an increased risk to themselves or other employees. They are also more likely to be tardy, absent, or impaired, resulting in reduced productivity.

Employers can play an active role in identifying employees who may benefit from addiction therapy through drug testing programs. Many employers who screen for illicit substances do not also screen for prescription opioids – in some cases because the additional testing represents a significant cost burden for them, or because the employer also believes it isn't their place to monitor medications that employees have obtained legally from a physician. However, with the growing impact of opioid misuse in the workplace, the potential benefits of screening for prescription drugs may have to be reconsidered.

For employees who are recovering from addiction to prescription pain medications, Employee Assistance Programs (EAPs) can be an important part of staying on track with their sobriety. These programs can also decrease the need for inpatient addiction treatment services, reducing costs for these services. However, EAPs are not utilized as often as they can be. Employees may not be aware of the scope of services EAPs offer; in other instances, they may fear negative repercussions. Employers have a responsibility to make their workers aware of the benefits and confidentiality of these programs.

In some cases, employer education is also needed, as they are not necessarily aware of the prevalence of the problem or may not be equipped to manage it. The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that 9 percent of the full-time workforce are illicit drug users, including nonmedical use of prescription drugs.[4] This number doesn't even account for the portion of workers who are being prescribed pain medications for legitimate medical reasons, which still brings a degree of risk for dependence or misuse. Further education is needed on the direct and indirect risks posed by opioid misuse within the workplace, especially as they relate to the injured worker.

NEW DEVELOPMENTS IN TREATMENT

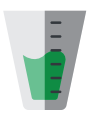
Healthesystems reported extensively on pharmacotherapy and behavioral therapy components of treating opioid addiction in the Fall 2014 issue of *RxInformer* (see the article "Getting Unhooked" at www.healthesystems.com/rxinformer), including traditional medication-assisted treatment with methadone or buprenorphine. Since then, there has been some development of new formulations that represent expanded or flexible treatment options that may meet the different needs of patients.

Bunavail® A buprenorphine/naloxone buccal film that adheres to the inside of the patient's cheek was introduced to the market in late 2014.

Probuphine® In January of this year, the FDA Panel recommended approval of an implant that delivers six months of stable buprenorphine treatment to the patient. Probuphine was initially rejected by the FDA in 2013, but is now being reconsidered in light of additional study data provided by the manufacturer. If approved, this product may help improve the success of outpatient buprenorphine treatment by removing any patient behavioral factors that can impede adherence.

$1 spent on addiction treatment yields **$12 saved** by the overall healthcare system and society[6]

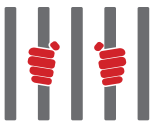
Societal cost of not treating addiction



1 YEAR OF METHADONE TREATMENT:

$4,700 per patient

COMPARED WITH



1 YEAR OF INCARCERATION:

$24,000 per person

CLAIMS CORNER

Detecting Opioid Red Flags

Dose increases

Dose increases may be medically necessary to adequately control pain over a period of time. However, high morphine equivalent dose (MED) levels resulting from dose increases are associated with an increased risk for opioid misuse and should be flagged. ACOEM Practice Guidelines, as well as the new *CDC Guideline for Prescribing Opioids for Chronic Pain*, recommend that MED should stay below levels of 50 mg/day.

Irregular refill patterns

A patient who refills their opioid prescription on time, but refills their neuropathic agent late or not at all, may be practicing what is known as selective adherence. This may be a sign that they are relying too heavily on opioids and not adhering to other aspects of their overall treatment.

Switching or using multiple physicians or pharmacies

Also known as "doctor shopping," this may be a sign of a patient attempting to gain access to multiple opioid prescriptions. The physicians or pharmacies should be alerted to the behavior.

Lost prescriptions

Losing a prescription can happen, but a pattern of this behavior warrants giving the claim a closer look.

Overdose reversal medication prescribed

Evaluate whether opioid treatment continues to be appropriate in the patient, given the doctor's decision to prescribe an opioid antidote.

Evidence of psychosocial factors

Opioid misuse often coincides with psychosocial or behavioral factors. Look for behaviors or language that may indicate disorders such as depression, anxiety, or catastrophizing.

Other behaviors

Sometimes there aren't obvious red flags in a claim. Look for language that indicates drug-seeking behavior or a dependence on opioid medications during conversations with claimants.

Drug Formularies – Will the Future Start in California?

By Robert L. Goldberg, MD, FACOEM, Chief Medical Officer

California is the place I call home, so it's not unusual that it would be on my mind. But since the state's legislature passed a bill in late 2015 requiring implementation of a workers' comp drug formulary, it has been a prevailing topic on a lot of minds in the industry. Although the date of July 1, 2017 has been set as a deadline for implementation, the question remains how exactly the formulary will manifest.

I find it only fitting that, as a state that historically has been a trendsetter, California has the unique opportunity to usher in a new breed of formulary. Although it is certainly not the first state to implement a workers' comp drug formulary, could be the first state to take steps to adopt and implement an injury-specific formulary. I'm talking of course about the newly developed drug formulary based on the American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines.

I say "of course" because I was directly involved with the development of the new formulary. Am I biased? Well, yes. I'm biased in the way that anyone involved in healthcare should be biased toward wanting the best possible outcomes for the patient. And a formulary that puts the patient at the center of the decision-making process is a reasonable approach.

PUTTING THE PATIENT AT THE CENTER

Determining the clinical appropriateness of therapy is not merely a matter of sorting the good apples from the bad. Whether or not a drug is appropriate depends as much on the patient and the specifics of their injury as it does the risk-benefit profile of the drug itself. Even ibuprofen, a drug that is in many instances a safe option for pain management, can have serious or even fatal adverse effects if prescribed at excessive doses or for the wrong patient. To return briefly to my apple metaphor, there is absolutely nothing wrong with a Red Delicious apple – but if you try baking it in a pie, it will fall apart. My point: decisions regarding prescription drug therapy must be made in the right context, or the outcome may be less than optimal.

A formulary is best developed in the context of a robust clinical evidence base. For the ACOEM-based formulary, recommendations were developed first based on each chapter of the practice guidelines as they relate to injury, and then with increasing specificity in terms of condition, and acute vs. chronic phase of treatment. These criteria are then applied to medication class, and finally individual medication.

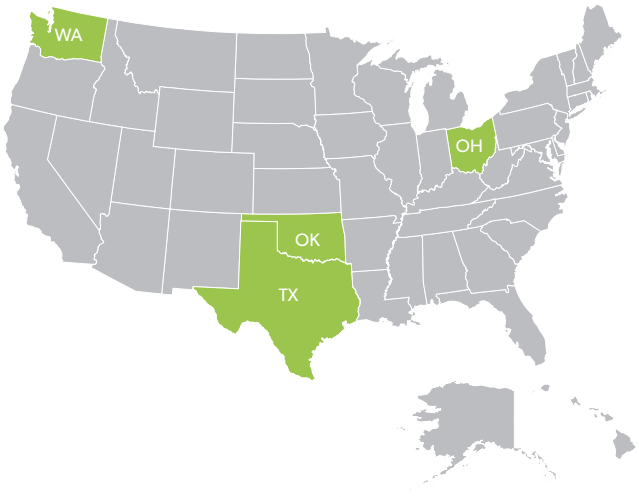
When recommendations are tied specifically to a clinical diagnosis, they can better define what is appropriate for a particular condition or phase of treatment. The benefits of this are reciprocal. We ensure that patients are getting the most effective treatment for their specific injury. At the same time, we deter prescribing of otherwise "approvable" medications in inappropriate conditions. This avoids incurring expense for medications that don't provide any significant benefit in a given condition. The injury-based formulary is a complex methodology that goes much deeper and broader than a basic drug list. Which raises the question: how does one actually implement and leverage this type of formulary?

IMPACT ON CLAIMS MANAGEMENT

Touting the potential cost and care benefits of an injury-specific formulary is very easy from an aspirational point of view, but let's consider the reality of this model from a claims management perspective.

While the methodology itself is more complex, such a model should create dramatic efficiencies downstream. The formulary creates a set of rules around which all stakeholders involved with the care of an injured worker can align themselves. Recommendations

States with workers' comp formularies implemented



What does the formulary mean for states already using the ACOEM Practice Guidelines?

A number of states including California, Colorado, Montana, New York and Nevada have previously adopted the ACOEM Practice Guidelines or incorporated sections of the guidelines into their state-specific evidence-based treatment standards. The addition of the injury-specific formulary now provides these states with a new tool for managing the medications prescribed for injured worker claimants. However, it has yet to be determined how, when or if the formulary will be implemented within these states' regulations. Thus far, there have been no regulatory measures undertaken to implement or enforce the formulary. Healthesystems will continue to track and report on any developments.

for the large majority of treatment decisions as they relate to drug therapy – probably 90% of these decisions – come built into the formulary. From a prescriber standpoint, this means having clear guidance up front on which medications will be approved for their patients. From a claims management standpoint, this means that decisions will be made based upon a strong clinical evidence base. More than ever, we will be able to get the right treatments to the right patients efficiently, freeing up more time to focus on managing more complex issues.

When implementing any formulary model, there are factors to consider that will help determine its success. First and foremost, a formulary must be broadly understood, and a benefit to the ACOEM practice guidelines is that they are widely used. But part of this understanding also relies on ongoing education to increase awareness among prescribers. If physicians are using the formulary to guide prescribing from the start, then the battle is already won.

Finally, the exceptions process that is implemented along with the formulary cannot be overly cumbersome. Just as no drug should be given an unequivocal green light, patients cannot be denied medically necessary treatment. As much as we look upon opioids as the enemy, there are instances where these medications are necessary. For example, patients with severe or catastrophic injury who may require opioids to manage their pain to facilitate recovery and maintain quality of life. In the final analysis, patients and their condition must be at the heart of drug therapy decisions.

Formulary success factors

- Strong base of clinical evidence
- Broadly understood
- Ongoing education/awareness
- Efficient exceptions process

THE FUTURE OF FORMULARIES

There is a quote regarding the Golden State that goes, "Whatever starts in California unfortunately has an inclination to spread." I tend to take a much more optimistic view of this sentiment. A more clinically based, patient-centric model is the future of state-implemented drug formularies. And my hope is that the future does in fact begin with California.

This perspective was originally published on March 1, 2016 in the Leaders Speak section of WorkCompWire.

ABOUT

Robert L. Goldberg, MD, FACOEM

Robert L. Goldberg, MD, FACOEM, is chief medical officer and senior vice president at Healthesystems. He is board certified in Occupational Medicine and is recognized as one of the foremost authorities in the field. He has an extensive multidisciplinary background and 25 years of experience that includes working as a treating physician, researcher, professor, consultant and corporate executive providing clinical direction to the development of evidence-based medical guidelines and workers' compensation public policy initiatives.

THE NEW WAVE OF CONVENIENCE PACKS: TOPICAL PACKS & KITS

FAST FOCUS:

Healthesystems continues to keep watch for developing trends that contribute to pharmacy and overall claims costs. In this issue, we take a look at convenience packs and kits involving topical products, a new co-pack trend that dramatically increases the price of relatively inexpensive products.

A tube of Voltaren® Gel, a commonly prescribed topical non-steroidal anti-inflammatory drug (NSAID), typically will cost a payer $60. Yet when it is packaged together with antibacterial wipes, its list price may be about nine times this cost, at $500.

Convenience packs, or "co-packs," are not a new or original concept in workers' compensation. A previous popular trend was the combination of a medical food with a generic prescription pain reliever in a convenience pack at a price that was substantially higher than the combined value of the individual components.

However, there has been a significant uptick in these combination packs or kits as they relate to topical analgesics. The packs typically contain two or three products that are readily available individually, either over-the-counter or by prescription. Common combinations are a cream or a lotion paired with an oral agent. In another example, the lotion is paired with antiseptic wipes. In many cases there is a significant and unwarranted cost mark-up on these kits without any real additional value for the patient. With new kits becoming available on the market on a near-weekly basis, this marks a troubling and growing potential driver for claims costs.

Identifying topical packs and kits can be challenging because they can show up in a claim in a variety of ways. They may be categorized based upon a single ingredient or product in the kit, such as a dermatologic, steroid or anti-inflammatory. In other instances, they could fall under a true private-label topical designation.

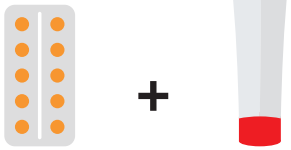
While packs and kits do not reflect a large percentage of prescription drug transactions, it is among a group of multiple cost drivers that are collectively contributing to overall increases in pharmacy claims costs. These drivers include topics previously reported on by Healthesystems, including private-label topical products, compounds, specialty drugs, and generic price increases.

As new trends emerge and existing ones continue to evolve, there is a need to continually develop new strategies for identifying and mitigating cost drivers in workers' compensation. Healthesystems will continue to track and report on this growing trend.

Examples of currently available topical packs and kits

DermaSilk DicloPak

If purchased separately



$120
Diclofenac DR (Rx)
60 tablets (75mg)

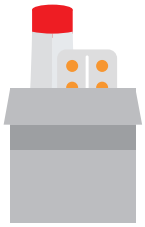
+

$20
Capsaicin cream (OTC)
0.025% 60gram

$140

$3,460 markup

If purchased as kit



Includes:
Diclofenac tablets
Capsaicin cream

$3,600

Napro Pak

If purchased separately

$145
Naproxen (Rx or OTC)
60 tablets (550mg)

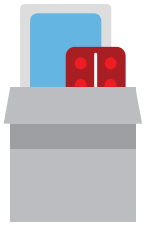
+

$10
Menthol (OTC)
2% gel

$155

$1,845 markup

If purchased as kit



Includes:
Naproxen tablets
Menthol patches

$2,000

DS Prep Pak

If purchased separately

$60
Voltaren (diclofenac; Rx)
1% gel

+

$16
Benzalkonium chloride
cleansing wipes
100 wipes OTC

$76

$424 markup

If purchased as kit

Includes:
Diclofenac gel
Cleansing wipes

$500

COMPOUNDS & PLTs:
Are They the Same, Or Different?

Claims professionals in the workers' compensation industry continue to see an increase in the prescribing of private-label topicals (PLTs) and compound drugs. But what makes the two categories of products different? While they may have similar impacts on workers' comp claims, the intricacies of compounds and PLTs are unique.

3 of 4 private-label topicals examined by Healthesystems **exceed FDA thresholds** for ingredient levels by **2-3 times**

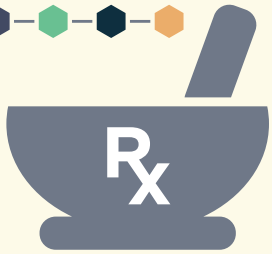
HOW THEY ARE SIMILAR: LESS REGULATION

- Neither compounds nor PLTs are FDA approved. Neither has undergone controlled studies to support clinical efficacy or safety.

WHY THEY ARE DIFFERENT

- **PLTs** are mass produced. They often contain active ingredient concentrations higher than FDA standards, which can pose an increased risk for skin burns. Nearly 3 of 4 PLTs examined by Healthesystems exceed FDA thresholds for ingredient levels by 2-3 times.
- Because each **compound** is custom-made by an individual pharmacist, there is no process in place to regulate the composition of each compound created. Furthermore, compounds are often made with 4-10 ingredients, some of which may have duplicative effects.

Compounds are often made with between **4 and 10 ingredients,** often resulting in unnecessary duplicative effects

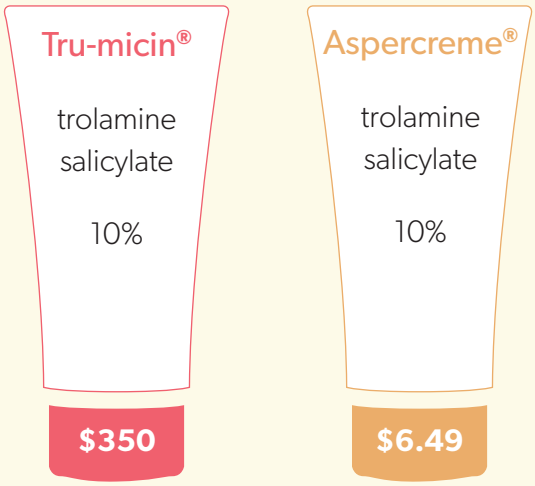


HOW THEY ARE SIMILAR: COST

- Neither compounds nor PLTs are cost effective.

WHY THEY ARE DIFFERENT

- **PLTs'** ingredient makeup overlaps heavily with inexpensive OTC products. The PLT Tru-micin® and the OTC Aspercreme® both contain the active ingredient trolamine salicylate 10%. Yet Tru-micin costs $350 per tube, while Aspercreme costs $6.49 per tube.
- **Compounds** are often comprised of expensive ingredients that often have more affordable counterparts. For example, the corticosteroid powders fluticasone and triamcinolone yield similar functions, yet fluticasone, at $3,000-$4,200/gram, is used in compounds more often than triamcinolone, which costs $20-$95/gram.



HOW THEY ARE SIMILAR: PERCEPTION

- PLTs and compounds are both marketed as superior alternatives. However, neither have any major advantages when compared to FDA-approved or OTC products, and may actually be harmful to patients.

WHY THEY ARE DIFFERENT

- **PLTs** are marketed with clinical sounding names such as Medi-Derm and Medrox® Rx, touting unique formulations and special ingredient blends. In reality, they are similar in makeup to OTCs.
- **Compounds** are created to counter the notion of "one size fits all" so that patients can have medication customized to suit their needs. However, many of the drugs in compounds are only FDA approved for oral use and are ineffective for topical use. Furthermore, some compounds include drugs already available commercially, negating the need for a customized product.

HOW THEY ARE SIMILAR: COMMERCIAL AVAILABILITY

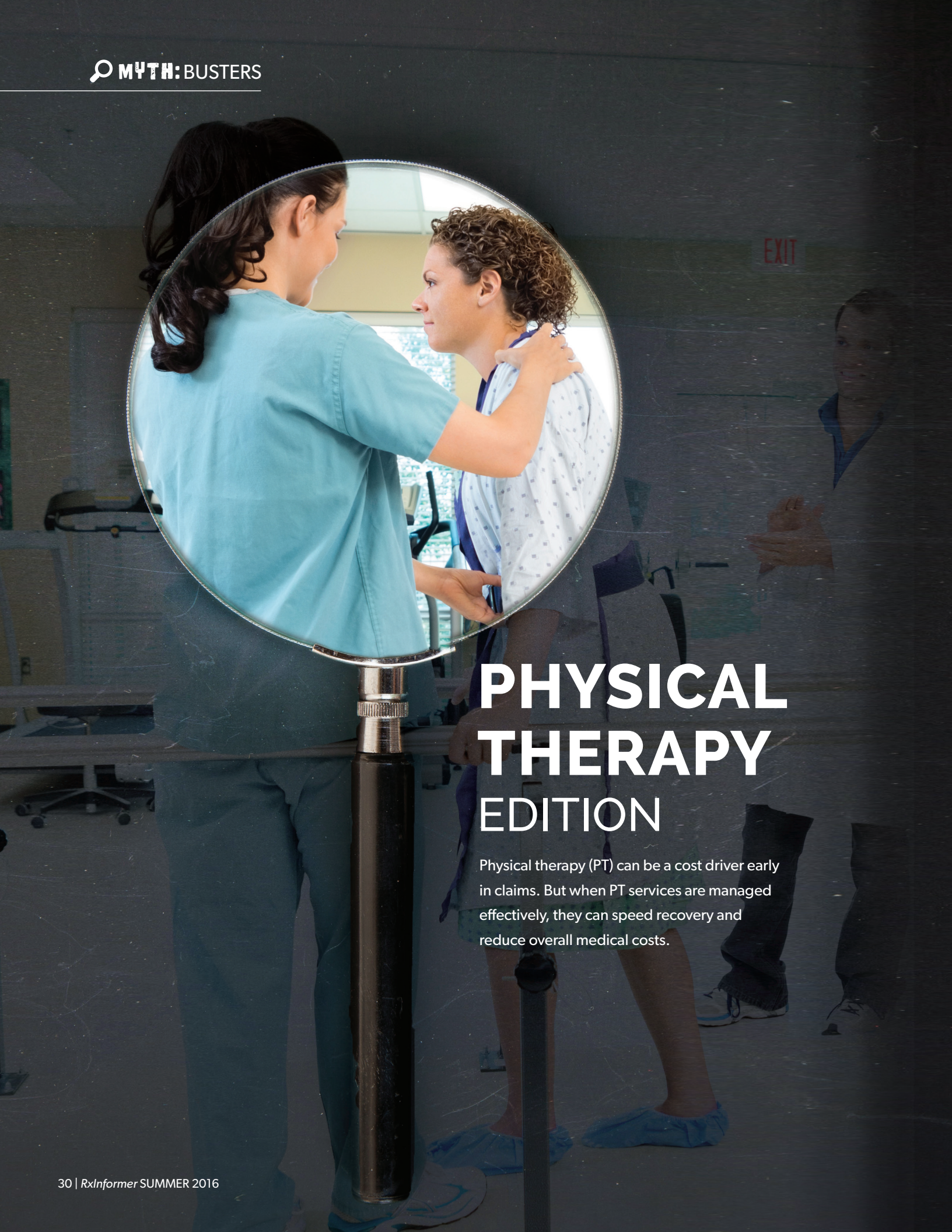
- Neither compounds nor PLTs are available in retail stores.

WHY THEY ARE DIFFERENT

- **PLTs** are often prescribed by physicians who dispense medications in-house, bypassing PBM software systems that would typically trigger drug utilization clinical review, as well as prior authorization activity, prospectively at the point of sale.
- **Compounds** require patients to visit special pharmacies that may be out of network, also bypassing PBM software systems at point of sale.

FINAL THOUGHTS

In the event a PLT or compound is prescribed, proof of medical necessity will go a long way in discerning if and when PLTs or compounds are appropriate. There are few proven clinical benefits to prescribing PLTs or compounds. FDA-approved or OTC products should be used whenever possible.



PHYSICAL THERAPY EDITION

Physical therapy (PT) can be a cost driver early in claims. But when PT services are managed effectively, they can speed recovery and reduce overall medical costs.

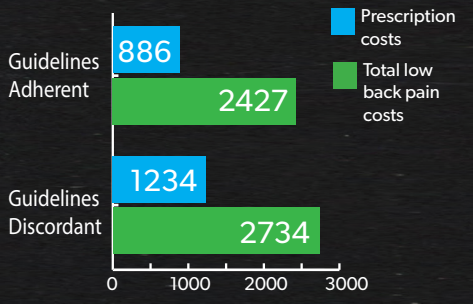
MYTH:

Initiating PT early leads to increased utilization and costs

Fact

Although PT can increase upfront treatment costs, over the longer term it can reduce prescription and total medical costs[1]

2-YEAR COSTS ARE LOWER WHEN PT ADHERES TO EVIDENCE-BASED GUIDELINES



Fact

Early initiation of PT in the right patients can decrease PT utilization and avoid expensive, unnecessary procedures including[1]:

ADVANCED IMAGING SERVICES

LUMBAR SPINAL INJECTION

SURGERY

MYTH:

PT greatly increases costs without a commensurate clinical benefit

Fact

Prescribing PT up front to patients who will derive the most clinical benefit decreased disability scores and reduced mean time off from work by 50%[2]

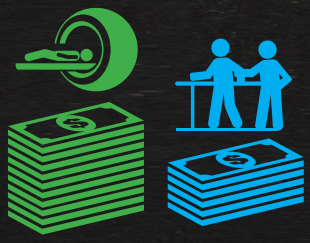
50% REDUCTION IN TIME OFF FROM WORK

MYTH:

The need for PT is determined by MRI results

Fact

In patients with low back pain, initial referral for MRI instead of PT increased costs, as well as odds of surgery, injections, and specialist or emergency department visits[3]



AVG 1-YEAR COSTS $4,800 HIGHER FOR EARLY MRI VS. PT

EFFECTIVE APPLICATION AND MANAGEMENT OF PHYSICAL THERAPY RELIES ON:

- Identifying patients who will derive the most clinical benefit from these services up front
- Assessing the appropriateness of PT prescriptions against evidence-based medicine
- Regular checkpoints to determine if therapy is having a positive clinical impact

THE COST OF CARE: WHO IS GOING TO PAY?

FAST FOCUS

Evolving regulation and workplace practices are shifting or even blurring the lines between workplace- and non-workplace injuries. In some instances, this raises the question: who is responsible for the cost of the patient's medical care?

THE PUSH-PULL EFFECT OF AFFORDABLE CARE

More than five years after the Affordable Care Act (ACA) was enacted, the debate remains: is the ACA helping to reduce the number of injured worker claims, or is it actually directing more patients into the workers' compensation system? In reality, there are drivers on both sides.

HOW THE ACA MAY PULL PATIENTS **OUT** OF WORKERS' COMP

Fewer non-workplace-related injuries being claimed as work-induced

When the ACA was passed into law in 2010, it was predicted that, with more workers insured under private healthcare or Medicaid, the number of work-related injury claims would decline. The rationale? Insured patients won't feel like their only option for coverage is to submit a questionable claim through the workers' comp system; they may be more inclined to seek care under their own insurance.

Estimates show the ACA has **reduced** the number of uninsured people under the age of 65 by

17 MILLION[1]

HOW THE ACA MAY PUSH PATIENTS **INTO** WORKERS' COMP

Capitated plan case-shifting

Last year the Workers Compensation Research Institute (WCRI) reported findings that certain categories of injury tend to shift from group health to workers' compensation when there is a capitated plan in play. The WCRI attributed this to financial incentives on behalf of the treatment provider. With more patients covered by capitated health insurance plans under the ACA, there is concern that a portion of injuries will shift into workers' comp. These are typically soft tissue conditions, including non-specific back pain, where it may be more difficult to identify the specific cause of injury.[2]

WCRI estimates that a mere **3% shift** in soft tissue injuries from group health would **increase workers' comp costs**[2]:

California **$225M**

Pennsylvania **$100M**

Iowa **$25M**

What is a capitated health plan? In traditional fee-for-service plans, treatment providers are reimbursed retroactively for individual services. Under a capitated plan, treatment providers receive a fixed annual payment per patient up front. They are not compensated for additional care that goes beyond this fixed amount. For this reason, treatment providers may be incentivized to treat under the workers' comp fee-for-service structure rather than a plan under the ACA.

HOW THE ACA MAY PULL PATIENTS **OUT** OF WORKERS' COMP

A healthier employee population

With employer incentives to implement wellness programs in their organizations, it should follow that their employees will be healthier. And a healthier workforce can mean less work-induced conditions or injuries. It can also mean that when injuries do occur, there is a potential for fewer complicating health factors and a faster recovery.

Claims with a comorbid condition typically have medical costs **2X higher** than claims with no comorbid factors[3]

2X

Examples of comorbid factors:

- **Smoking**
- **Obesity**
- **Diabetes**
- **Depression**
- **Hypertension**

With all of this push and pull, where are things netting out?

Because we are still in the beginning stages of the ACA, it is difficult at this juncture to determine its overall net impact with any clear certainty. While the WCRI presents their case that capitated plans have historically created a shift in certain conditions toward workers' comp, it is based on some assumptions that may not be fully applicable under the ACA. Conversely, one can look at Massachusetts, which passed state healthcare reform in 2006, and argue that healthcare reform similar to the ACA has coincided with the decline of workers' comp claims – by nearly 17% between 2005-2009.[4]

BLURRING THE LINES

It's not just healthcare reform that plays a role in reallocating responsibility for medical care reimbursement. There are other trends that are blurring the lines. Telecommuting has continued to rise over the last decade. The latest Gallup Work & Education poll indicates that 37% of workers telecommute at least a portion of the month.[5] More employees are also logging on and performing work functions during non-work hours. And in an even newer trend called "co-working," individuals who do not work for the same company can come together in third-party office suites to work and collaborate under the same physical roof.

All of these factors potentially expand the criteria for what constitutes a work-related injury, and subsequently expands the gray area regarding financial responsibility for the cost of a patient's care. If an employee suffers vehicular injury when taking a work-related call while driving, who is responsible for reimbursing that individual's care? Depending on the circumstances, it could go in either direction. Workers' compensation is no longer defined by traditional boundaries; and as these boundaries continue to expand and shift, it becomes even more difficult to ascertain whether an injury is work-related or not.

SHIFTING THE TIDE THROUGH WORKERS' COMP REGULATION

Case-shifting is a two-way street; in some cases, workers' comp regulation can direct patients out of the system and into group health.

Republican leaders in Illinois are attempting to toughen the standards for proving whether an injury is work-related, which includes limiting the ability of an employee to claim injuries incurred when traveling to or from work. If such rules passed, it could narrow the criteria for what constitutes work-related injury, thus shifting some of these cases into the group health space. However, recent reports indicate that it is unlikely the proposed changes will pass.

Determining causality has always been critical when assessing an injured worker – not just due to the high rate of fraudulent claims within workers' compensation, but to ensure proper diagnosis so that appropriate treatment can be administered. But with the expanding gray area, it becomes even more important to define parameters around which causality and liability are determined.

With all of these moving parts, alongside the pending change in our country's leadership, only one thing is certain – the changes will continue to come. It is important that workers' compensation professionals stay aware of disruptive trends, on both a national and state level, that have the potential to influence their claimant populations.

STATE OF THE STATES

CALIFORNIA
Payment Data Changes – IAIABC

The Division of Workers' Compensation (DWC) recently implemented medical state reporting changes, effective April 6, 2016. All carriers and claims administrators must transmit medical payment data in an updated standard, based upon the IAIABC Medical 2.0 Implementation Guide. The changes were originally adopted in April 2015 to allow reporting entities a full year to code and test the new requirements. Recently, the state proposed a number of technical updates which are currently the subject of rulemaking. These changes are needed in order to conform to the updated IAIABC standards for the reporting of repackaged and compounded medications.

Workers' Comp Formulary

California will soon release a draft proposal of formulary rules as required by Assembly Bill 1124. The DWC has held a number of public meetings to gain input from the stakeholder community on the construct of the closed formulary. Consistent themes include:

- The inclusion of medications dispensed from both pharmacies and physician's offices
- A phased-in implementation timeframe for new and legacy claims
- Better controls around compound and physician-dispensed medications
- The adoption of a nationally recognized formulary over a "do it yourself" version

Some have raised concerns about utilization review for medications which would not require preauthorization, and others have suggested allowing only the lowest cost equivalent for generic drugs. The California Workers' Compensation Institute delivered its report to a Joint Committee on March 2 about the implementation of a closed formulary, projecting up to a half billion dollars in savings on overall drug costs if the formulary is developed taking these principles into consideration.

The new formulary is required to be implemented by July 1, 2017, and rulemaking is expected to begin in May 2016. Healthesystems has been a frequent visitor to the DWC offices, providing both clinical and regulatory perspectives on how the formulary construct could drive the best patient outcomes while balancing cost and efficiency. We will continue to be very involved in discussions with the DWC and the medical community to ensure the formulary rule adopted will complement the existing regulatory framework while delivering the best patient outcomes.

The California DWC is also working on regulations which would implement Home Health and Interpreter fee schedules, updates to the Medical Treatment Utilization Schedule, and state reporting data quality penalties. The report is available at http://ains.assembly.ca.gov

FLORIDA
New Standards for Pharmaceutical Payment Data

Starting in July, payers will begin testing a new reporting platform with the DWC, which will allow the state to capture more robust pharmaceutical payment data. All reporting entities are expected to move to the new reporting platform upon successful completion of testing before November 29, 2016. The state has also recently changed its provider fee dispute process, impacting how providers and payers respond to Petitions for Dispute Resolution. The new rules will specifically exclude any dispute arising from a provider-payer contract. The rules will also require physician dispensers to supply proof of their paid cost for medications along with NDC pedigree information, and extend the timeframe for both filing a reimbursement dispute petition (45 days) and answering a petition (30 days).

NEW MEXICO
Medical Marijuana Reimbursement

A recent fee schedule change has taken place, incorporating a requirement for insurers to reimburse injured workers for medical marijuana. The new requirement has many experts concerned about how this will play out in the political environment, as well as the injured worker communities. A bill which would have banned medical marijuana from the Workers' Compensation fee schedule failed to be considered in 2016. Some think this opens the door for other states to adopt a similar approach. Insurers and employers are highly concerned about the consequences of this action. It remains to be seen how other states workers' compensation systems will respond, or if the New Mexico legislature will revisit this issue in 2017. Twenty-three states have adopted medical marijuana laws, and four states and the District of Columbia have legalized marijuana for recreational use. Fortune magazine recently reported that legal marijuana sales could hit $6.7 billion in 2016.

NORTH CAROLINA
Considering a Closed Formulary

State regulators are expected to report how a closed formulary could impact workers' comp claim outcomes and costs. Healthesystems has been in discussions with regulators about the topic. Stakeholders are not united on the need to incorporate a state-mandated formulary for all employees, but in the prior year budget bill lawmakers have authorized a study on how a formulary would affect state employee claims. Recent changes in the leadership at the industrial commission may have an impact on the speed of this effort; enabling legislation is likely to be considered in 2017. More specifics will be available in the report to the legislature, expected to be delivered by the Industrial Commission in April.

SOUTH CAROLINA
Legislation for Mandatory PDMP Use for Opioids

Narcotics Use Ad-Hoc Committee (NUAC) released its report to the Workers' Compensation Commissioner Chair in February. The report highlights the recommendations of the committee, following a two-year project during which they studied the impact of narcotics in workers' compensation claims. NUAC recommended the commission support efforts to enact mandatory use of the state's prescription drug monitoring program (SCRIPTs) by opioid prescribers, the enforcement of specialized educational requirements, and standard-of-care guidelines as set forth by the Board of Medicine for prescribers of narcotic medications, except for acute pain care. NUAC also recommended that the commission, to the extent possible, extend access of SCRIPTs data to pharmacy benefit managers. NUAC members included insurers, self-insured employers, physicians, several attorneys, pharmacy benefit managers, and members of the business community. The report may set a foundation for legislative recommendations during the 2017 session. The report is available at http://www.wcc.sc.gov

TENNESSEE
Closed Formulary and Medical Treatment Guidelines Enacted

Tennessee has adopted Medical Treatment Guidelines and a closed formulary. The treatment guidelines consist of the Official Disability Guides (ODG) and the Chronic Pain Guidelines developed and maintained by the Tennessee Department of Health. The new rules went into effect on February 28, 2016, following a year-long stakeholder outreach process. The closed formulary component of the treatment guidelines goes into effect at the end of August 2016. The closed formulary incorporates a staggered implementation timeframe for dates of injury before and after January 1, 2016. This is similar to what has been done in other states that adopt formularies. The staggered implementation timeframe is intended to ensure continuity of care for injured workers who may need to be transitioned to other types of medications. The state has posted a new webpage with information about the new treatment guidelines and formulary implementation at https://www.tn.gov/workforce

VIRGINIA
Fee Schedule Coming Soon

State regulators will soon be developing the state's first ever medical fee schedule. This mandate comes after years of debate by legislators and will include fee caps on all professional services, hospital, pharmacy, and DME. Commission staff has done some formal outreach to stakeholders and is gathering feedback in order to develop its draft regulation, though rule development has not yet begun. The fee schedule is projected to become effective by the January 1, 2018 deadline, as is required by the legislature. Virginia regulators are also in the process of drafting e-billing rules which are required by statute to become effective before December 2018.

TEXAS AND OKLAHOMA
ODG Drug Formulary Changes Impact Texas and Oklahoma Injured Workers

For many injured workers in Texas and Oklahoma, a change in medication therapies may be coming as a result of updates to ODG, Appendix A Closed Formulary. Texas and Oklahoma currently require providers to obtain preauthorization for all of the approximately 175 medications designated as "N" drugs, across multiple drug classes. Starting February 1, 2016, four long-acting opioids which previously did not appear on the "N" list, will now require an adjuster's approval prior to dispensing. The four medications are: Fentanyl transdermal patches, MS-Contin, Levorphanol (Levo-Dromoran), and Morphine ER/Naltrexone (Embeda). The ODG guidelines now list these long-acting opioids as "not recommended" as a first line therapy for pain management. Per a public notice, distributed by the Texas Division of Workers' Compensation, system participants are encouraged to work together to discuss and coordinate the ongoing needs of individual patients if any of these four medications are currently prescribed. Healthesystems' clinical staff has been working closely with our customers to assist in the coordination of discussions with prescribers since these changes were first announced in October 2015. The public notice is available at http://www.tdi.texas.gov

BY THE NUMBERS

EMPLOYER IMPACT

Injuries that result in **6+ days** of lost work cost employers **$62 billion annually.**

Liberty Mutual Workplace Safety Index, 2016

Injury claims dropped

10%

for employers that participate in a **state safety grant program.**

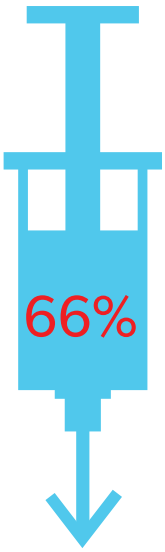
Ohio Bureau of Workers' Compensation, 2016

OPIOIDS

die every day as a result of **prescription opioid overdose.**

Centers for Disease Control and Prevention, 2015

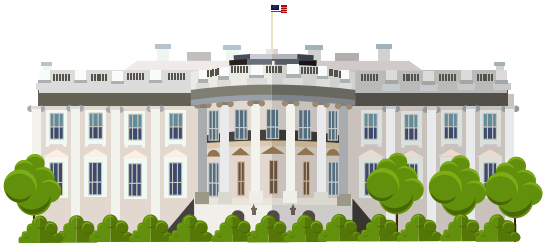
Colorado's PDMP INFLUENCED A



DROP IN MORPHINE Milligram Equivalents (MME) per capita

Public Health Reports, 2014

POLICY



The White House proposed a **$1.1 billion PLAN** to **BATTLE HEROIN** and Rx opioid abuse.

The White House, 2016

20 STATES updated their rules regarding **physician dispensing** since August 2015

Workers Compensation Research Institute, 2016

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