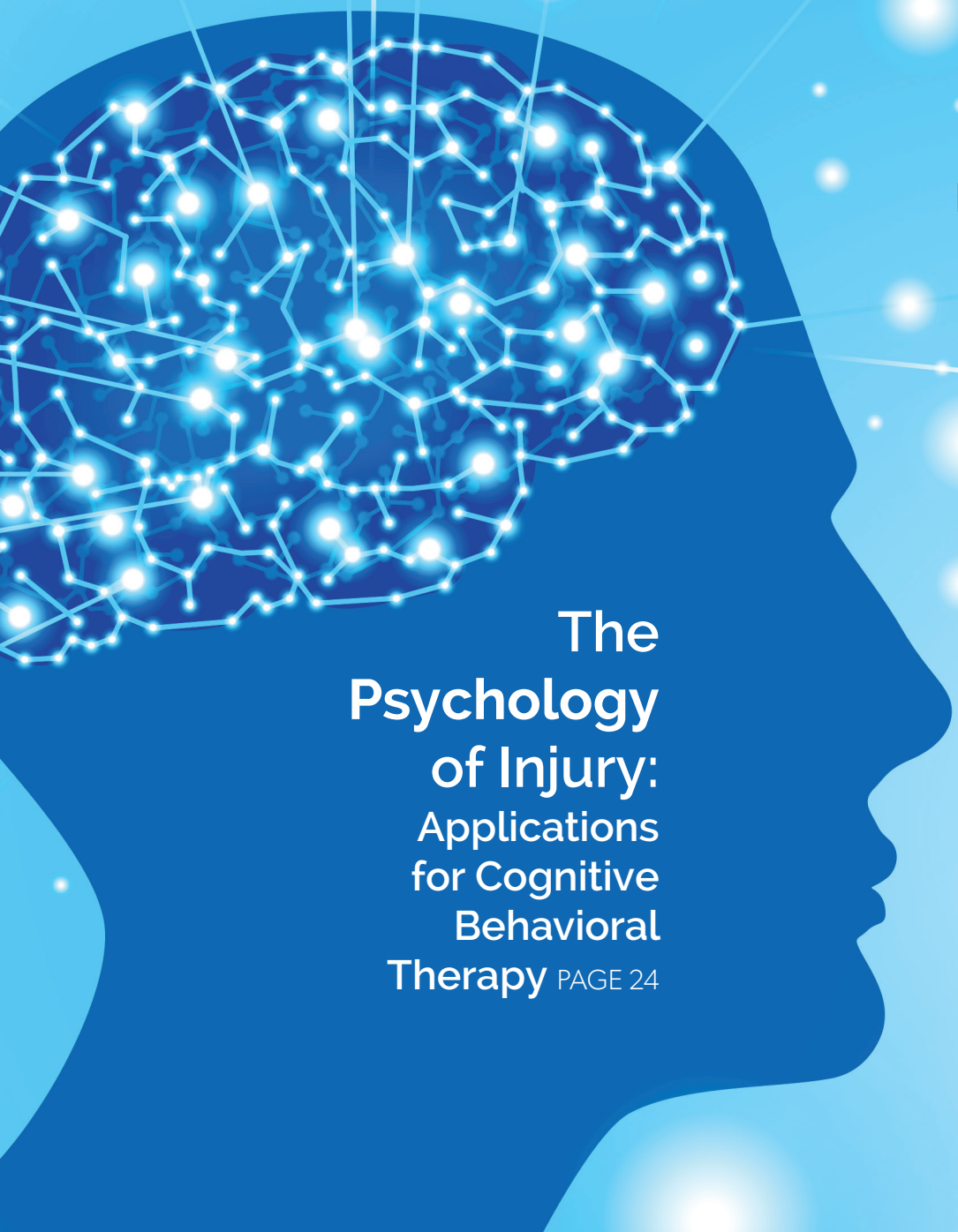
Healthesystems®

RxINFORMER

CURRENT AND EMERGING ISSUES IMPACTING WORKERS' COMP

FALL 2015



Making the Most of DRUG UTILIZATION Management Tools

PAGE 16

RAISING THE BAR **to Lower Opioid Risk**

PAGE 22

The **Psychology of Injury:** Applications for Cognitive Behavioral Therapy

PAGE 24

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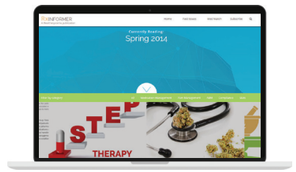

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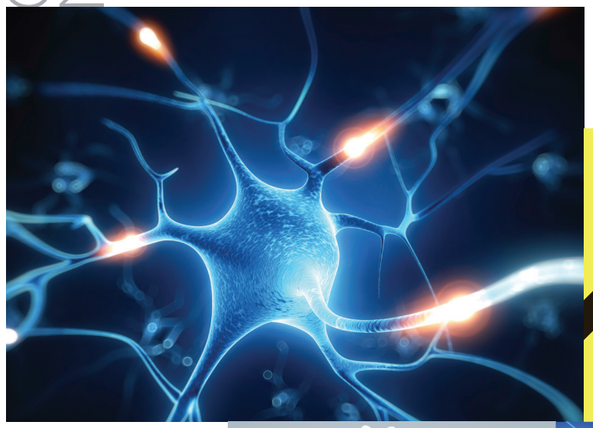
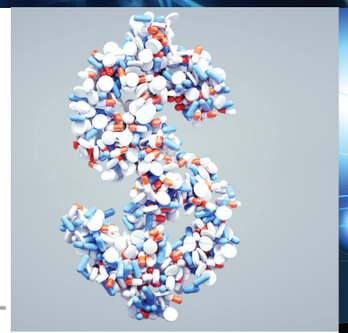
TABLE OF **CONTENTS**





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WE MUST CONTINUE TO **EVOLVE**

FORWARD-THINKING EFFORTS ARE NEEDED TO KEEP PACE WITH A CHANGING WORKERS' COMP LANDSCAPE

While it may sometimes seem that in workers' compensation we are fighting the same old battles, the reality is that they never truly remain the same, for the terrain itself is always changing. It wasn't long ago, in this very publication, that I lamented the rapidly growing opioid epidemic. The good news today is that we are beginning to see decreasing rates of opioid prescribing. However, challenges to patient safety continue to be a moving target. We are now witnessing an increase in heroin abuse rates throughout the country, which many have considered to be an unintended consequence of the newer abuse-deterrent opioid formulations and decreased physician prescribing of opioid medications.

This brings a quote to mind from Amazon founder and CEO Jeff Bezos that would seem to apply here: "What's dangerous is not to evolve."

So often we refer to the concept of risk when managing the injured worker. Opioids, inappropriate prescribing, aberrant behaviors, psychosocial barriers – in all of these forms, risk is cast as the clear opponent. But perhaps the greatest risk factor of all, one that cannot be found within a patient medical history, is complacency. As the stewards of care for injured workers, it is our responsibility to continue to evolve, to strive for improvement. If we don't, we will quickly fall behind the pace of change in workers' compensation and its new and ever-shifting challenges.

I am incredibly excited to share this issue of *RxInformer* because it focuses on progress being made across a number of industry channels – from policy changes, medical and technological developments, and improvements in the delivery of care, to innovative strategies for managing the cost and quality of care in the injured worker.

MOVING BEYOND PAIN MANAGEMENT

As an occupational medicine specialist, I have always reiterated the need to prioritize functional restoration as a treatment goal. Updates to evidence-based guidelines by ACOEM and Washington State over the last year are strongly supporting this mindset by shifting the emphasis away from opioid treatment, which is more often than not detrimental to functional improvement. More stringent guidelines regarding opioid prescribing are an important step, but at the same time there must be increased emphasis on active treatment modalities that promote functional improvement and return to work. The article *Escaping the Catch-22 of Chronic Pain Management* discusses newer research demonstrating the benefits of physical therapy and exercise regimens, from clinical and cost perspectives. It also highlights the need for objective measures to be built into a physical medicine strategy so that payers can effectively assess the value of services being provided to an injured worker.

MANAGING RISK PROSPECTIVELY

Chronic opioid use, dangerous drug combinations, excessive polypharmacy, therapeutic overlap – as a former treating physician, I am frustrated to see these and many other patient safety issues arise in a claim, because they are wholly avoidable. At Healthesystems we have always strived along with our payer partners to manage risk prospectively. (It is, after all, much more efficient to avoid a problem than to have to fix it later on!) *Making the Most of Drug Utilization Management Tools* outlines a proactive approach to managing utilization of prescription medications that includes strategies such as earlier prescriber communication and automated tools that enable claims professionals to take real-time action. We're seeing tremendous success with this approach, both from a clinical and treatment cost perspective.

POWERFUL POLICY

States continue to move forward with implementation of evidence-based treatment guidelines and formularies, with California recently passing a bill that mandates implementation of a closed drug formulary by July 2017. This September, in an effort to fight prescription drug abuse, the U.S. House of Representatives passed a bill that would provide federal grants to states for Prescription Drug Monitoring Programs (PDMPs). These programs are working, as demonstrated in Healthesystems' home state of Florida – the state has reportedly seen a decline in oxycodone-caused mortality of 25% since implementation of a PDMP in 2012. Meanwhile, medical marijuana remains a growing topic in workers' compensation as now more than half of states have either decriminalized or approved marijuana for use in specific medical conditions. Now, with a few courts ordering carriers to reimburse medical marijuana, we find ourselves navigating new territory.

There is great progress being made right now in the field of workers' compensation, progress that I believe will truly have an impact on the care of the injured worker and how this care is managed. It is my hope that this issue of *RxInformer* serves as a reminder not only of how far we've come, but how we want to move forward – and yes, evolve.

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.

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.

2015

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

JUNE

Pristiq® (desvenlafaxine succinate) ▪
PSYCHIATRY
For the treatment of major depressive disorder

Zetia® (ezetimibe) ▪
CHOLESTEROL
Inhibits intestinal cholesterol absorption as an adjunct to diet

Intermezzo® (zolpidem tartrate) ▪
HYPNOTIC/SLEEP AID
For treatment of middle-of-the night awakening/insomnia
NOTE: Schedule IV controlled substance

JULY

Daklinza™ (daclatasvir) ✦ ✱
ANTIVIRAL
For use with Sovaldi® for chronic hepatitis C (genotype 3)

Praluent® (alirocumab) injection ✦ ✱
CHOLESTEROL
For specific patients requiring additional lowering of LDL-C as adjunct with statin therapy and diet

Rexulti® (brexpiprazole) ✦
PSYCHIATRY
For treatment of schizophrenia or adjunctive therapy to antidepressants in major depressive disorder

Technivie™ (ombitasvir/paritaprevir/ritonavir) ✦ ✱
ANTIVIRAL
For use in combination with ribavirin for chronic hepatitis C (genotype 4)

AUGUST

Repatha™ (evolocumab) injection ✦ ✱
CHOLESTEROL
For specific patients requiring additional lowering of LDL-C as adjunct with statin therapy and diet

Abilify® (aripiprazole) oral solution ▪
PSYCHIATRY
Indications include adjunctive treatment of major depressive disorder

SEPTEMBER

Lescol XL® (fluvastatin) ▪
CHOLESTEROL
To reduce cholesterol as an adjunct to diet

Vraylar™ (cariprazine) ✦
PSYCHIATRY
For schizophrenia and bipolar disorder in adults

OCTOBER

Belbuca (buprenorphine HCl) buccal film ✦
PAIN
Anticipated approval date October 23, 2015. *An opioid analgesic buccal film formulation in development for the management of chronic pain*

▶ 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 by the end of 2015.

Narcan® (naloxone HCl) nasal spray
OPIOID OVERDOSE
Pre-filled device designed to deliver naloxone through nasal mucosa of opioid overdose victim. Has been granted priority review

ALO-02 (oxycodone HCl/naltrexone HCl) extended-release capsules
PAIN
Extended-release opioid analgesic formulation for the management of severe pain. Contains abuse-deterrent properties

Xtampza™ ER (oxycodone) extended-release capsules
PAIN
Extended-release opioid analgesic in development for the treatment of chronic pain. Contains abuse-deterrent properties

MorphaBond ER (morphine sulfate) extended-release tablets
PAIN
Extended-release, opioid analgesic formulation in development for the treatment of severe pain. Contains abuse-deterrent properties

CEP-33237 (hydrocodone bitartrate) extended-release tablets
PAIN
12-hour, acetaminophen-free formulation of hydrocodone for severe pain. Potential abuse-deterrent properties

MNK-155 (hydrocodone bitartrate/acetaminophen extended-release tablets)
PAIN
For moderate to moderately severe acute pain; potential abuse-deterrent properties

◀ Unfold for full timeline

DRUG ALERTS

OXECTA™ RELAUNCHES AS OXAYDO™

A new name for the first oxycodone IR formulation with abuse-deterrent properties

Pharmaceutical company Egalet announced the launch of Oxaydo in September. The product, which was formerly distributed by Pfizer as Oxecta, is now being marketed to pain specialists as the first-and-only oxycodone IR formulation to deter abuse via snorting.

Also in September, two FDA committees voted against approval of a different IR formulation of oxycodone owned by Purdue Pharma called Avridi™, due to concerns around food-related dosing requirements. However, the committees voted for approval of Xtampza, a new extended-release formulation of oxycodone.

CVS OFFERS NALOXONE WITHOUT PRESCRIPTION

The retail pharmacy has expanded access to the opioid overdose reversal medication

CVS/pharmacy has expanded access to naloxone in several states. The medication was already available at CVS/pharmacy without a prescription in Rhode Island and Massachusetts. Naloxone is now available without a prescription at CVS/pharmacy locations in 12 additional states: Arkansas, California, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, South Carolina, Tennessee, Utah and Wisconsin.

SENZA SPINAL CORD STIMULATION IS APPROVED

Reduces pain without paresthesia

In May, the FDA approved the Senza spinal cord stimulation (SCS) system as an aid in the management of chronic intractable pain of the trunk and/or limbs, including pain associated with failed back surgery syndrome, low back pain and leg pain. The Senza System can reduce pain without producing a tingling sensation called paresthesia that is typically associated with SCS.

FDA DRUG SAFETY COMMUNICATIONS

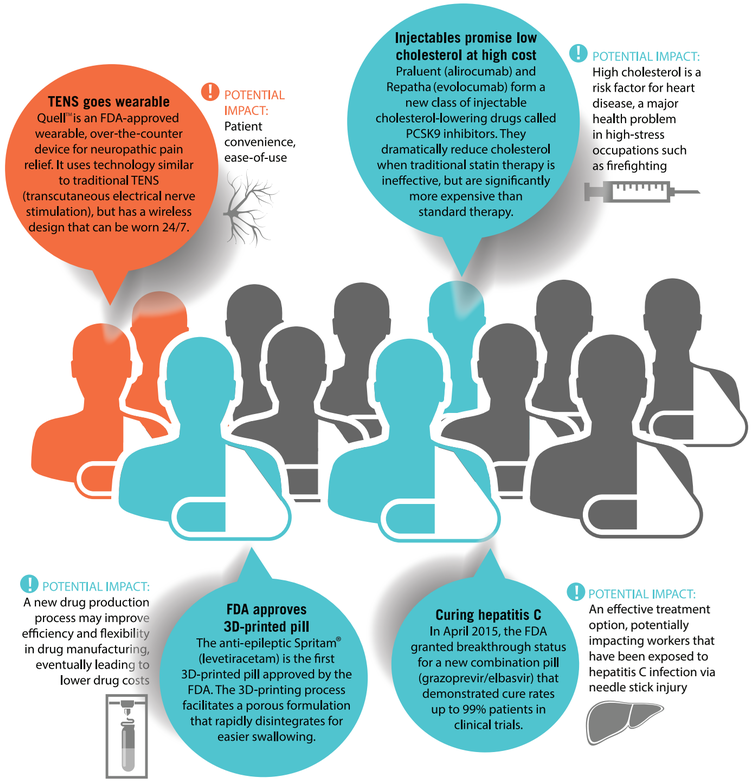
Product name confusion causes prescription and dispensing errors

The FDA warned in July 2015 that reports of confusion between the antidepressant Brintellix (vortioxetine) and anti-blood clotting medication Brilinta (ticagrelor) had resulted in the wrong medication being prescribed or dispensed. Depression is a potential comorbidity seen in workers' compensation claims.

Heart attack/stroke warning strengthened for non-aspirin NSAIDs

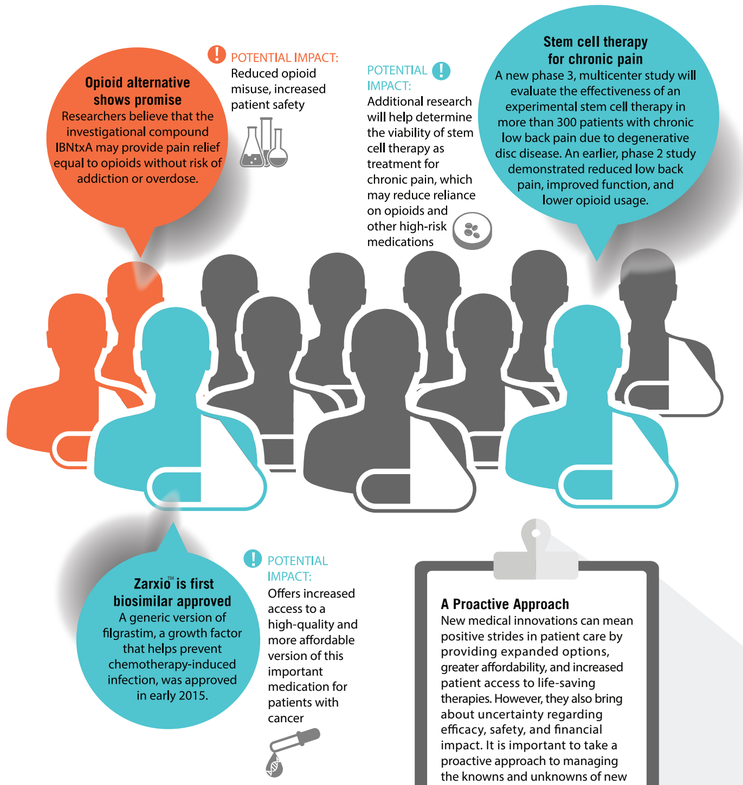
In July 2015 the FDA strengthened an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. NSAIDs are commonly used for the treatment of pain in injured workers.

NEW AND NOTABLE: MEDICAL INNOVATIONS THAT MAY IMPACT WORKERS' COMPENSATION



REFERENCES: 1. Memorial Sloan Kettering Cancer Center. Scientists find promising target for better pain drugs. 2. Medscape. FDA clears first 3D-printed drug (Spritam [levetiracetam]). 3. U.S. Food and Drug Administration. (2015). FDA approves first biosimilar product Zarxio [Press release]. 4. www.quellrelief.com 5. Monthly Prescribing Reference. FDA accepts grazoprevir/elbasvir NDA for chronic HCV. 6. U.S. Food and Drug Administration. (2015) FDA approves Praluent to treat certain patients with high cholesterol [Press release]. 7. CNN. FDA approves new cholesterol lowering drug. 8. Pain News Network. Stem cell study for back pain begins. http://www.painnewsnetwork.org/stories/2015/7/27/stem-cell-study-for-back-pain-begins

Many exciting discoveries are happening right now in the field of medicine. Healthesystems expects that some will have a significant impact on workers' comp. Others we are keeping an eye on — after all, history demonstrates that medical trends have a way of eventually finding their way into workers' compensation!



A Proactive Approach

New medical innovations can mean positive strides in patient care by providing expanded options, greater affordability, and increased patient access to life-saving therapies. However, they also bring about uncertainty regarding efficacy, safety, and financial impact. It is important to take a proactive approach to managing the knowns and unknowns of new drug developments and how they impact care of the injured worker.

COUNTERACTING THE RISE OF GENERIC PRICING

FAST FOCUS

Generics have long provided cost-effective, clinically appropriate alternatives to their more expensive brand-name counterparts. But steep increases to average wholesale prices (AWPs) for some generic medications are becoming a significant driver for rising claim costs, leaving payers to seek more aggressive strategies for cost containment.

IMPACT TO WORKERS' COMPENSATION

Increases in the prices for many generic medications had a negative impact on many stakeholders in the healthcare industry. Within workers' compensation specifically, higher average wholesale prices (AWPs) for generics in some cases are driving higher per-claim prescription-related costs for payers.

DRIVERS OF AWP INCREASES

A number of possible contributors to rising generic prices have been proposed, including increased barriers or delays to generic entry in the current market. It is estimated that the U.S. Food and Drug Administration (FDA) approval time for abbreviated new drug applications (ANDAs), the process under which generics are approved, has increased since 2013. Drug shortages that may be the result of manufacturing issues or increased regulation on generic manufacturers have also been suggested.

But how do any of these explain the case for a product such baclofen? The AWP for generic baclofen **has risen as much as 150%** since 2013 depending on pill strength, one of the highest generic inflation increases observed among products prescribed to Healthesystems claimants.[1] Baclofen is a skeletal muscle relaxant and antispastic medication that serves as a generic therapeutic alternative to brands such as Flexeril®, Zanaflex® or Soma®. It also has a different mechanism of action and typically causes less sedation than other muscle relaxants. For these reasons, it is a product that Healthesystems sees commonly utilized among workers' compensation claims. Suddenly, what used to be a cost-effective and clinically appropriate product is becoming a financial concern for payers. And the drug's availability doesn't seem to be the cause. Baclofen is produced by multiple manufacturers. It is not on the FDA's current drug shortage list. So why has the AWP increased so dramatically for a product like baclofen, as well as many other generics?

AWP

What is AWP and why is it so important to workers' comp payers?

The AWP, or average wholesale price, serves as the benchmark for reimbursement for government and private payers, including those in the workers' compensation industry.

This is the question that Congress is trying to get answers to due to the impact of generic price increases on the Medicaid program. At their request earlier this year, the U.S. Department of Health and Human Services (DHHS) launched a review of generic drug price increases spanning the last decade.[2]

This is not only a Medicaid issue, however, and generic price concerns are impacting stakeholders in every corner of the healthcare world. While Congress was prompted to act based on data indicating that prices for certain generics had risen as much as 1,000% or more,[3] the rise has not been as dramatic for the majority of products. But even more modest increases have made a notable impact on overall claim costs, especially over the last few years. In many cases, such as the baclofen example, it has also been seemingly unsubstantiated.

While drug manufacturers cite approval backlogs and other barriers as drivers of increased prices, their own actions are contributing to the trend as well. Generic consolidation could be a contributor to price increases, as less product competition de-incentivizes competitive pricing. This year, Teva Pharmaceutical Industries Ltd. had made strong efforts to acquire Mylan NV, one of the largest global generic and specialty drug manufacturers. Had the deal come to fruition, it would have made Teva the largest pharmaceutical manufacturer globally and merged an incredible amount of market share for generic drugs under one roof. And with increased market share comes increased pricing power.

Potential reason(s) why the AWPs for many generics are increasing:

a. Increased regulation on generic manufacturers
b. Longer approval timelines for generic medications
c. Generic manufacturer consolidation/decreased competition among manufacturers
d. Manufacturing challenges leading to lower supply
e. Manufacturer inflation of AWP costs
f. **All of the above**

HOW CAN RISING COSTS BE CONTROLLED?

It is important to have visibility into the factors driving overall cost and trend of prescription medications. Generic prices are just one component of this. Thus it becomes increasingly important to use various strategies to reduce other components of pharmacy trend that can help mitigate the increases caused by rising generic AWPs while focusing on patient care. Payers can work with a PBM to put programs in place to address other factors that impact cost, such as appropriate drug utilization, patient safety, and drug mix.

The article on the following pages, *Making the Most of Drug Utilization Management Tools*, demonstrates the exceptional impact that aggressive and early application of clinical management tools can have on the care of injured workers and associated costs.

Generic drug products commonly prescribed in workers' comp are being affected by AWP increases, with **oxycodone/acetaminophen, pregabalin, and hydrocodone/acetaminophen** among those showing the most impact.[1]

MAKING THE MOST OF

Drug Utilization MANAGEMENT TOOLS

FAST FOCUS

Managing the clinical appropriateness of prescription medications is a critical component of controlling quality and cost of care in workers' compensation, but all too often utilization management tools are not applied in a way that taps into their full potential. Earlier and more aggressive application of utilization management tools can have a profound impact on improving patient care and achieving cost containment.

There is significant opportunity to enhance the way in which drug utilization management tools are applied to better manage overall claim costs and improve patient care. With rising generic drug prices, along with the volume of new drugs being introduced to the market, improving the impact of clinical management becomes increasingly important as payers seek every opportunity to control costs.

The concept of utilization management seems intuitive: by delivering the most appropriate care to a patient, better outcomes – and thus, lower associated claim costs – will follow. And utilization management tools have been used traditionally throughout the workers' compensation industry as a concerted effort between the PBM and payer. But a truly impactful clinical management strategy depends upon *when* and *how* these tools are applied. Having these tools in the arsenal is not enough to drive results. The payer must take full advantage by using them – earlier, and more aggressively. The key to success is the ability of the claims professional to take quick action. And this requires a comprehensive strategy that deploys tools as needed throughout the care continuum.

Managing Patient Risk and Claim Costs Along the Care Continuum

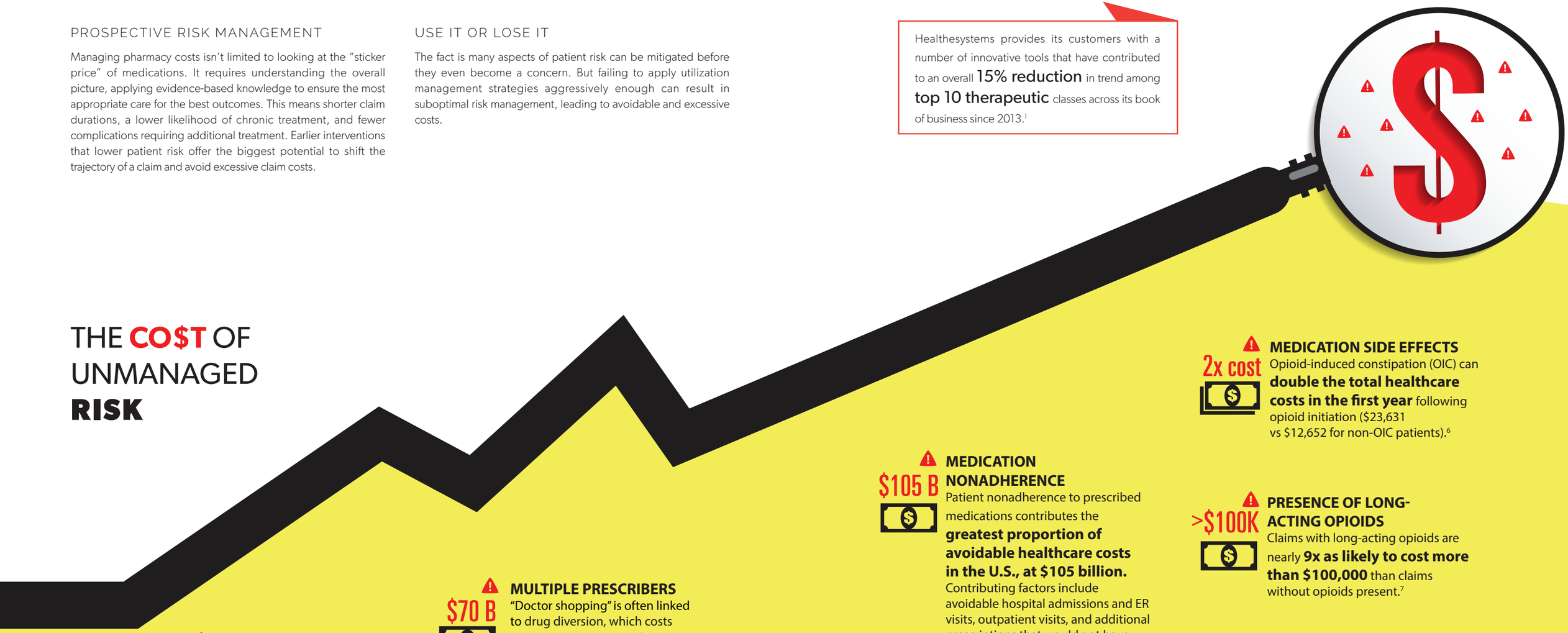
PROSPECTIVE RISK MANAGEMENT

Managing pharmacy costs isn't limited to looking at the "sticker price" of medications. It requires understanding the overall picture, applying evidence-based knowledge to ensure the most appropriate care for the best outcomes. This means shorter claim durations, a lower likelihood of chronic treatment, and fewer complications requiring additional treatment. Earlier interventions that lower patient risk offer the biggest potential to shift the trajectory of a claim and avoid excessive claim costs.

USE IT OR LOSE IT

The fact is many aspects of patient risk can be mitigated before they even become a concern. But failing to apply utilization management strategies aggressively enough can result in suboptimal risk management, leading to avoidable and excessive costs.

Healthesystems provides its customers with a number of innovative tools that have contributed to an overall **15% reduction** in trend among **top 10 therapeutic** classes across its book of business since 2013.[1]



THE CO$T OF UNMANAGED **RISK**

$1K++ COMPOUNDS
Compounded pain creams are not clinically proven for safety or efficacy, and can cost **THOUSANDS of dollars for a month of treatment.** A comparable and FDA-approved topical such as Voltaren gel costs **$50.**

$3-4K/g
Compounding pharmacies may select expensive ingredients to steeply inflate costs. Price comparison of two similar corticosteroid powders: Triamcinolone $20-95/g AWP vs Fluticasone **$3,000-4,200/g AWP.**

$70 B MULTIPLE PRESCRIBERS
"Doctor shopping" is often linked to drug diversion, which costs health insurers **more than $70 billion per year.**[2]

3x cost HIGH-RISK DRUG COMBINATION
Adding benzodiazepines to a short-acting opioid regimen can **triple the average claim cost ($43,438 vs $123,311).**[3]

2x cost MEDICATION SIDE EFFECTS
Opioid-induced constipation (OIC) can **double the total healthcare costs in the first year** following opioid initiation ($23,631 vs $12,652 for non-OIC patients).[6]

$105 B NONADHERENCE
Patient nonadherence to prescribed medications contributes the **greatest proportion of avoidable healthcare costs in the U.S., at $105 billion.** Contributing factors include avoidable hospital admissions and ER visits, outpatient visits, and additional prescriptions that would not have been needed had the primary condition been controlled.[4]

>$100K PRESENCE OF LONG-ACTING OPIOIDS
Claims with long-acting opioids are nearly **9x as likely to cost more than $100,000** than claims without opioids present.[7]

$600/ MONTH DRUG-DRUG INTERACTIONS
Opioid-related drug interactions can **incur an additional $600 per month, per patient.**[5]

$15K/ PATIENT HIGH MORPHINE EQUIVALENT DOSE
Opioid misuse, abuse or dependence cost payers an **extra $15,000 or more per patient, per year** due to factors that include added drug costs, outpatient visits, and hospital stays.[8]

REINFORCING THE FRONT LINE

Claims professionals serve as the front-line decision maker in claims management, and this provides them with the perfect opportunity to make decisions that will have a positive impact on claims outcomes. Here is where the PBM can effectively support the role of the claims professional by providing the right mix of education, clinical decision support, and tools.

The following are some examples of drug utilization management tools that can have a significant impact on patient safety and overall claim costs when applied aggressively by the claims professional.

Prescriber Communications

WHAT: Providing claims professionals with tools, such as a Letter of Medical Necessity (LOMN) can empower claims professionals to evaluate clinically inappropriate or off-formulary prescriptions.

WHEN AND HOW: Intervening with the prescriber doesn't have to wait until the patient has already received treatment. An LOMN provides the opportunity for claims professionals to initiate communication with the prescribing physician regarding appropriateness of a medication at the prior authorization stage. In many cases, this can result in a change in the prescribed medication regimen to an appropriate alternative.

Employment of an LOMN strategy by Healthesystems customers led to a prescription change in 2 out of 3 instances, resulting in an average per-drug savings of $244.00.[1]

WHEN LOMN IS ISSUED. . .

67% RX CHANGED

Automated Clinical Escalation

WHAT: The decision to approve coverage of a high-risk or potentially inappropriate drug can benefit from a higher level of clinical expertise, especially when a more complex clinical decision is needed.

WHEN AND HOW: Applying an automated process at prior authorization that allows a clinically trained individual to be incorporated into the decision-making process regarding high-risk or inappropriate medications provides an additional patient safeguard, as well as tighter prior authorization protocols.

A clinically trained individual is more likely to uphold the decision not to approve inappropriate medications. In fact, a prior authorization reject is twice as likely to be upheld with application of this automated clinical escalation process.[1]

DECISIONS UPHELD

Automated clinical escalation

NO automated clinical escalation

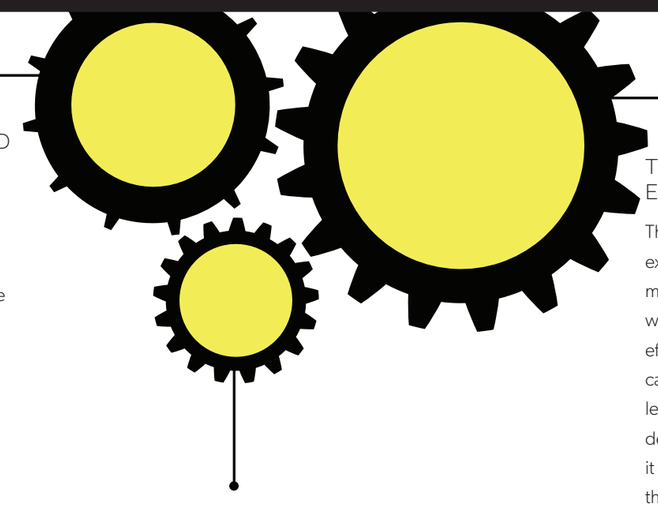
Prescriber Education

WHAT: Prescriber education is crucial to ensuring patient safety and associated costs. There are a number of factors influencing a patient's recovery that prescribers may not be considering or may even be unaware of: for example, if the patient is receiving medications from another physician.

WHEN AND HOW: Therapeutic red flags can arise at any point among the care continuum, and having the ability to intervene at the right time is critical to managing patient safety. Therapeutic alert communications that are automatically triggered by red flags – such as multiple prescribers, the presence of a topical compound, or prolonged use of opioids, benzodiazepines or other high-risk medications – are another interventional strategy that can successfully impact the trajectory of a patient's claim. In many cases, prescribers are amenable to modifying a medication regimen when they are alerted to potential risk within a claim.

IT'S ALL IN THE DELIVERY

Successful application of a drug management strategy relies upon having the right supportive infrastructure in place. Utilization management tools are only as effective as a payer's ability to implement and use them.



A COORDINATED EFFORT

An integrated drug-management strategy, rather than discrete sets of initiatives, will have the most profound effect on patient safety as well as cost.

TECHNOLOGICAL EXCELLENCE

The degree of technological excellence supporting clinical management goes a long way in determining how effectively these strategies can be applied. Technology leads to effective clinical decision support, because it is the backbone by which the information to make these decisions is gathered, interpreted, and delivered for right-time intervention.

A CUSTOMIZED APPROACH

Drug utilization management cannot be a one-size-fits-all approach. The ability to adapt to customer- and population-specific needs will deliver incremental improvements to the quality and cost of care. A PBM must have the capability to support different formulary designs based on factors such as state-specific or evidence-based guidelines, as well as the needs of specific patient populations (e.g., first responders, nurses) and their associated risk.

RAISING THE BAR TO LOWER OPIOID RISK

FAST FOCUS

While progress is being made to reduce opioid prescribing, institutions and groups are doubling down on efforts to lower the risk of opioid misuse, including more stringent guidelines.

The last couple of years have seen a decline in the number of opioids being prescribed, but evidence still shows that a significant portion of patients are receiving chronic treatment with opioids longer than 90 days. According to a recent study conducted in Rochester, New York, 1 in 4 patients receiving a new opioid prescription progressed to chronic use.[1] Further, patients receiving long-term opioid treatment were more likely to have a past or current history of substance abuse, even though treatment guidelines specifically recommend that these patients should not receive opioid therapy. And while prescribing habits and rates vary by state, it remains that millions of Americans are receiving long-term opioid treatment.

While strides are being made against the pervasiveness of opioid overprescribing in workers' compensation, there remains room for improvement, and recent guideline updates are part taking a strong stand to make this happen.

LOWER DOSING THRESHOLDS

Daily morphine equivalent dose (MED) of opioid medications directly correlate with negative outcomes ranging from abuse and overdose to increased risk of depression and other serious side effects. Increased risk for overdose has been documented at a MED as low as 20mg, with significant risk occurring at MED 100mg or higher.[2] The American College of Occupational and Environmental Medicine (ACOEM) updated their *Practice Guidelines* at the end of 2014 with the goal of providing more detailed guidance for all phases of opioid treatment.[3] The organization sets the bar for recommended daily MED thresholds at 50mg based on their analysis of studies that indicate a sharp increase in risk for overdose death at levels above 50mg.[4,5] This is an aggressive target compared with other evidence-based or state-specific guidelines, which set the maximum recommended daily MED between 80-120mg.

Current maximum recommended daily MED levels

ACOEM	50mg
California (DWC)	80mg
Official Disability Guidelines	100mg
Washington State (AMDG)	120mg

Although the recommended MED thresholds vary depending upon the guidelines followed, the approach to prescribing remains the same: when dealing with a medication with so much potential for risk, it is always best to err on the conservative side. Care management strategies should emphasize alternative pharmacological and non-pharmacological treatment whenever possible. When opioid treatment is clinically appropriate, opioid treatment duration should be minimized, and tools that enable close monitoring and ongoing clinical assessment are critical.

Healthesystems, in concert with its customers, takes a proactive and aggressive approach to opioid risk management. Among claims managed by Healthesystems, **more than 80% of injured worker claimants receiving opioid therapy fall below the ACOEM maximum recommended daily MED of 50mg**, the most stringent threshold set in the industry.[6]

93% of Healthesystems claimants receiving opioid therapy meet evidence-based standards for maximum recommended daily MED (<120mg)[6]

8 out of 10 claimants receiving opioid therapy
≤50mg Average Daily MED

PREVENTING CHRONIC USE

Keeping MED levels low is a positive sign that opioids are being managed appropriately. However the ultimate goal is to achieve an MED level of zero – whether that means seeking alternative treatment in patients upfront, or tapering them off opioids as needed following acute treatment in favor of a more appropriate long-term treatment strategy.

The state of Washington has taken a strong stance on this approach with their recently updated opioid prescribing guidelines. The 2015 Interagency Guideline on Prescribing Opioids for Pain places a greater emphasis on decision-making in the acute stage of treatment, as well as preventing transition to chronic opioid use.[7] It also includes expanded recommendations for non-opioid pain management options and stresses the importance of tracking clinically meaningful improvements in function as well as pain management to make decisions regarding opioid treatment. The previous 2010 guidelines had primarily focused on chronic non-cancer pain, and the new update represents a dramatic shift towards early intervention opportunities. And while the most recent Washington guidelines have kept the official recommended maximum daily MED at 120mg, they do acknowledge the potential risks associated with MED higher than 100mg/day. They also emphasize that there really is no "safe" opioid dose, and therefore chronic use should be avoided altogether, wherever possible.

The California Division of Workers' Compensation (DWC) has also initiated a process to update the chronic pain section of its Medical Treatment Utilization Schedule. The updates include a new, standalone chapter for opioid guidelines that stress the exploration of alternative treatments such as physical activity, yoga and acupuncture, as well as non-opioid medications. For patients in whom opioids are appropriate, California guidelines recommend a maximum daily MED of 80mg.[8]

GUIDELINES AS A TOOL FOR PAYERS, PBMS

Guidelines serve not only as recommendations for prescribers in making appropriate treatment decisions; they also serve as a powerful tool for payers and PBMs to enforce clinically sound decisions. State-implemented guidelines can support claims professionals in making decisions regarding high-risk, high-cost medications such as opioid analgesics.

The application of evidence-based guidelines in treatment of the injured worker has a proven impact on both clinical and cost-related outcomes. This extends to pharmacologic and non-pharmacologic treatment – from recommendations for appropriate opioid prescribing to guidance on when physical therapy is preferred over surgery or imaging services. Healthesystems incorporates evidence-based medicine from leading guidelines into all of its solutions, ranging from automated tools to enhanced clinical decision support.

CALIFORNIA PASSES CLOSED FORMULARY BILL

California legislature passed a bill in September that mandates implementation of a closed-drug formulary by July 2017. Lawmakers and stakeholders within the California workers' compensation industry are hopeful that application of an evidence-based formulary will mimic the success seen in states such as Texas and Washington that currently have formularies in place. Both states have seen reductions in prescribing of certain medications, including high-risk drugs such as opioids. The California Workers' Compensation Institute projects that the formulary could save California up to $420 million. An evidence-based, closed-drug formulary is not only a powerful tool for cost containment, but helps ensure appropriate and safe prescribing of medications for the treatment of injured workers.

THE PSYCHOLOGY OF INJURY:

Applications for Cognitive Behavioral Therapy

FAST FOCUS

Cognitive behavioral therapy (CBT) has been considered a "gold standard" treatment approach in a range of psychosocial disorders, but only in recent years has its value truly begun to materialize in workers' compensation. New and emerging applications, including work-focused CBT and expanded delivery channels, continue to increase its viability as an effective strategy in the injured worker population.

It has been well-discussed throughout the workers' compensation industry that a successful path to recovery is built through a concerted effort on the part of all involved stakeholders; that the contributions of one without the others are limited in their ability to impact outcomes. But truly, there is one stakeholder on which the trajectory of the claim hinges: the injured worker patient.

Return to work relies on the patient's understanding of what to expect on their journey to recovery – and most importantly, their willingness and motivation to see this journey through.

But sometimes, a patient can get in his or her own way.

THE PSYCHOLOGY OF INJURY

There is an undeniable psychological component to injury and recovery. Anxiety, depression, catastrophizing, fear avoidance – these are all factors that influence the course of a claim in a very real way. In some cases, these psychosocial factors can be even more detrimental to claim outcomes than physiologic factors. In a recent study of workers undergoing surgery following traumatic occupational hand injury, negative affect was a much stronger predictor of delayed return to work than was severity of injury.[1] In another study of patients with minor injury, depression was the foremost inhibitor of restored function during the 6 to 12 months post-injury – more so than type of injury.[2] Fear avoidance represents another psychological hurdle to physical recovery in that the patient is afraid to participate in active treatment modalities such as physical or occupational therapy. This obstacle to functional improvement leads to poor treatment outcomes, including higher pain and disability levels, and lower return-to-work rates.[3]

Psychosocial factors not only inhibit strides toward physical improvement, they also can negatively impact the pharmacological aspect of treatment. Depression, anxiety, and catastrophizing are all high-risk predictors for prescription opioid misuse,[4] a pattern of behavior that is detrimental to claim outcomes in its own right.

CBT'S GROWING ROLE IN WORKERS' COMP

The psychotherapeutic intervention known as cognitive behavioral therapy (CBT) is hardly a new concept. With its roots arguably reaching back to the 1960s, one might describe it as "retro." For some time it has been considered a front-line treatment for a range of psychosocial issues and conditions – such as alcoholism, social anxiety, and various sleep and mood disorders. But over the last few years, something interesting has been happening in workers' compensation. Increasingly CBT has been recognized as a valuable component of treatment among injured workers. Payers are now much more likely to recommend CBT for chronic pain claimants who exhibit psychosocial concerns. And this approach is having a profound effect on functional outcomes as well as pain symptoms.

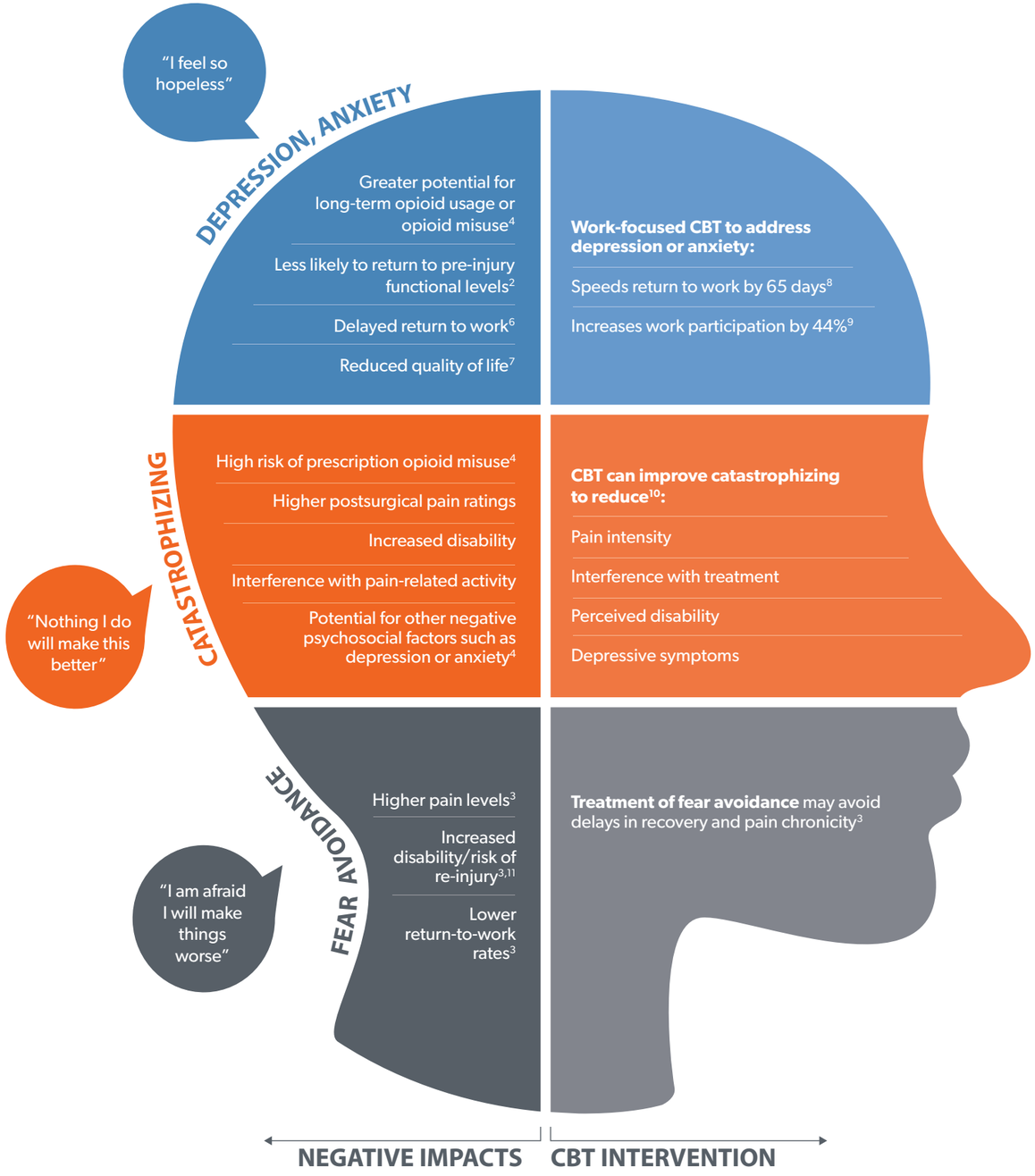
COGNITIVE BEHAVIORAL THERAPY: THE BASICS

- A common form of mental health counseling
- Traditionally conducted by a therapist or other qualified healthcare professional
- A low-cost, low-risk component of overall treatment
- Modifies negative patterns of thinking or behavior
- Helps patients develop healthy coping skills
- Changes the patient's understanding of pain
- Empowers patients to take a hands-on approach to their recovery
- Can reverse neuroremodeling,[5] or the "rewiring" of the brain that may occur following injury

To learn about the effect pain can have on the brain's neurocircuitry, read the article *Understanding Pain: Neuroremodeling* in the Spring 2014 issue of *RxInformer* at www.healthesystems.com/rxinformer

Pain does not always mean the injury is getting worse; it is also a part of recovery

ADDRESSING PSYCHOSOCIAL FACTORS TO INFLUENCE OUTCOMES



It is important to note that standard CBT is not tailored for a workers' compensation setting. Its applications are much broader, and therefore there is no built-in focus on return to work. That being said, incorporating return to work strategies into a CBT program that address common mental disorders reaps significant benefits. Not only can this approach speed return to work,[8] but application of CBT during job re-entry can address residual depression or a patient's anxiety about their ability to perform at a pre-injury level, both of which pose obstacles to successful return to work. A patient's treatment journey does not stop at Day 1 of being back on the job. CBT during the transition can get them over the initial "hump" and ultimately increase work participation as well as the likelihood that the patient's re-entry to the workforce will be successful over the long term.[9]

Work-focused CBT to address depression or anxiety . . .

EXPANDING CONVENIENCE, ACCESS

New approaches to CBT are putting a technological twist on this gold-standard treatment strategy, and they are proving effective. Over-the-phone CBT has demonstrated results that are comparable to in-person therapy in disorders that include major depression.[12,13] Similarly, Internet-based CBT has a positive impact on work-related outcomes, including improved work engagement.[14,15] Smartphone apps are also proving to be a viable tool in the treatment of psychosocial disorders. For example, the mood journal app Moodnotes launched in August and is based on the principals of CBT. The app is designed to aid self-awareness and help patients self-manage their stress and anxiety. For the right patient, putting mental health management right in their hands – literally – can be empowering as well as effective.

There are other benefits of delivering CBT through nontraditional channels, including expanded access to services for patients living in rural or low-population areas where mental health services are limited. It can also reduce or eliminate the need for office visits, which is beneficial from an employer perspective because it reduces time needed away from work for injured workers who are not on leave or have already returned from leave. From a payer perspective, CBT via telemedicine offers potential cost benefits in terms of fewer office visits and transportation services in situations where these would otherwise be necessary.

CBT WITHIN A COMPREHENSIVE STRATEGY

Application of CBT is triggered by the presence of specific risk factors. There are many opportunities throughout the care continuum that can provide the payer with insight into psychosocial factors that may be impacting the claim trajectory. As with any negative factor influencing treatment outcomes, earlier intervention is better, and indeed there is research being undertaken to assess the impact of upfront pain education in individuals at high risk for chronic pain.[16]

However, psychosocial barriers to recovery can arise at any point of the patient's journey – whether they are preexisting or they develop 3 weeks or 3 months into a claim. More than 20% of patients develop a new psychosocial disorder within the year following moderate-to-severe injury.[17] A comprehensive management strategy takes into consideration these potential factors throughout the entire course of the injured worker's treatment, and across all aspects of treatment, including pharmacy as well as ancillary components. For example, a full review of medical history triggered by high opioid doses may reveal evidence for comorbid depression, a significant predictor of opioid misuse. In a patient prescribed physical or occupational therapy, when the right data are collected from the treatment provider, signs of fear avoidance or other psychosocial factors that may be impacting therapy adherence are revealed.

The incorporation of CBT into the care of the injured worker demonstrates clear value for its positive impact on both pharmacologic and non-pharmacologic aspects of treatment, while new delivery methods increase the cost-effectiveness and efficiency of this traditional intervention strategy. The future impact of CBT in workers' compensation looks even brighter as the industry continues to improve its ability to identify the patients who need it.

ESCAPING THE CATCH-22 OF CHRONIC PAIN MANAGEMENT

FAST FOCUS

Prescription medications can be an important part of managing an injured worker's pain; however, focusing too heavily on pharmacological pain management can hinder rather than help recovery and return to work.

TREATING PAIN VS INJURY

Pain management is an all-too-familiar phrase within workers' compensation. While it is a critical component of overall treatment, too often pain management takes center stage while other components of recovery – such as physical, occupational, or other forms of therapy – are less emphasized. And judging from the 9 million people in the United States who report long-term medical use of opioids,[1] there is a disproportionate emphasis on pharmacological pain management, and not enough progress being made on the other piece of the equation, functional recovery efforts.

When considering the injured worker, it is important to remember that pain itself is not the primary affliction being treated; rather, it is a roadblock to healing that affliction. But it would be unreasonable here to "separate the symptom from the disease." Injury and its symptom – pain – have a frustratingly symbiotic relationship. Pain exists where there is injury. But where there is unmanaged pain, significant efforts to improve the injury cannot be made.

Conservative, evidence-based pharmacological treatment of pain can serve to relieve patient discomfort as they work towards functional recovery. But too often opioid medications are prescribed that ultimately hinder rather than help recovery, sending the patient into an endless cycle as they rely on powerful opioids to mask the pain without gaining any functional improvements. More likely, their injury, overall health, and quality of life will actually deteriorate.

Not only does opioid overuse contribute to poorer claims outcomes, it also has a price tag associated with it. Claims for long-term opioid users cost an average of approximately $28 thousand more than those not using opioids long term.[2] And claims containing opioids are up to 8 times as likely to cost more than $100 thousand compared with claimants who were never prescribed opioids.[5]

That being said, shifting treatment emphasis to functional outcomes goes beyond encouraging physicians to write prescriptions for physical therapy. For example, how is the right patient identified? Has that patient adhered to the exercise regimen? Is the service being provided of high quality? And most importantly, is the therapy working?

This requires not only an understanding of what true treatment success looks like, but also the ability to objectively measure whether these goals are being met.

A HEAVY EMPHASIS ON PHARMACOLOGICAL PAIN MANAGEMENT CAN HINDER FUNCTIONAL OUTCOMES

197 DAYS

Opioid use after lumbar fusion is associated with delayed return to work by an average of 197 days as well as a higher probability of second surgery[2]

There is a direct association between claim longevity and opioids:

Oxycodone comprises

1% of drug cost in claims <3 years old
and more than **10%** in claims >10 years[3]

1 out of 4
patients is on opioids longer than **90 days**[4]

PAIN IS AN UNRELIABLE OUTCOME

It's not "new news" that no two patients are alike and that the course of injury and its treatment are highly individualized. This is due to a number of known or suggested variables that include attitudes toward pain, existing comorbidities, adherence to treatment, and psychosocial factors such as depression, anxiety, and catastrophizing. (See *The Psychology of Injury: Applications for Cognitive Behavioral Therapy* on page 24.) And research continues to uncover factors that may explain why certain people are more susceptible to chronic pain than others.

A recently published 6-year study of more than 2000 patients shows that adverse life events are direct indicators of chronic pain onset risk, with occurrence of a single event increasing risk of chronic pain onset by 13%. When multiple life events were added, risk increased even more. And individuals who had experienced financial hardship (an event that could very well be applicable to an injured worker) were 54% more likely to develop chronic pain.[6]

Variability in pain susceptibility underscores that pain control in and of itself is not a reliable outcome, and therefore pain management is not a true measure of successful treatment. Rather, controlling pain enables the application of active modalities that can achieve more objective, functional outcomes.

ACTIVE TREATMENT MODALITIES AND FUNCTIONAL RECOVERY

Active treatment modalities such as physical therapy or an exercise program can have a profound effect on functional recovery and are a necessary component of an overall treatment plan in patients at risk of developing chronic pain. Risk-appropriate prescribing of physical therapy reduces time off from work and costs,[7] and it can also lower the odds of other, often higher-risk and/or higher-cost interventions such as surgery, injections, and specialist or emergency department visits.[8] An exercise program not only has the potential to increase strength and range of motion, it can also address the potential comorbidity of obesity, which can have a significant impact on claims in its own right, as lost workdays and cost per claim also increase with increasing BMI.[9] The direct and indirect benefits of exercise were recently demonstrated in a 6-week indoor hand-bike exercise program in people with spinal cord injury lowered body mass index (BMI) and insulin levels, and also increased strength and extension in the shoulder and elbow.[10]

THE IMPORTANCE OF OBJECTIVE OUTCOME MEASURES

The goals of treatment within workers' compensation are tangible and objective: restore function to the injured worker and reduce time away from work. Therefore it follows that the measures to determine whether this is being achieved should also be tangible and objective. If measures such as range of motion and strength are not being assessed, how can it be determined whether therapy is in fact working? The ability to apply these objective outcome measures enables payers to determine the effectiveness of treatment and ensure that they are making the most judicious use of their funds while providing patients with the best possible opportunity for functional improvement and return to work. Conversely, if therapy is not working, the payer should have a means to identify negative impacts treatment effectiveness, such as patient nonadherence or psychosocial factors such as fear avoidance. Yet these measures have often been missing from traditional physical medicine management programs within workers' compensation.

A greater emphasis on active therapy that addresses functional improvement versus passive, pharmacologic therapy that only addresses symptomatic pain is necessary to break this "catch-22" of pain management that so many injured workers are stuck in. But payers need the right tools to manage utilization of physical medicine services in a way that departs from tradition, and instead supports a more outcomes-driven model that can maximize the effectiveness of care to help speed recovery and return to work, shorten claim durations, and reduce overall costs.

Healthesystems has developed a new physical medicine program that provides payers with unprecedented outcomes data to more effectively manage the quality and utilization of physical medicine services. More information can be found online and in our white paper *Physical Therapy in the Injured Worker* at www.healthesystems.com/physicalmedicine.

"MAKING FUN" OF PHYSICAL THERAPY: VIRTUAL REHABILITATION

A recent study found that the Nintendo® Wii can be an effective rehabilitative tool for home use. Post-stroke patients with hemiparesis who underwent virtual rehabilitation with the Wii™ experienced improvement in measures that included passive movement, pain scores, motor function of the upper limb, balance, and physical functioning.[11]

For some patients, popular gaming technology can be a convenient and motivating recreational therapy alternative to conventional physical therapy.

Thinking Beyond Pain Management WITH **TENS TECHNOLOGY**

FAST FOCUS

This well-established technology was developed to suppress pain. But therapy with transcutaneous electrical nerve stimulation (TENS) may also help reduce prescription medication overuse and facilitate physiotherapy.

Devices that utilize TENS technology have long been used to provide pain relief as an adjunct to other components of an injured worker's treatment plan, both pharmacologic and non-pharmacologic. However, although TENS is a form of passive therapy, its benefits may go beyond temporary pain management to impact other aspects of a patient's treatment course. When used properly, TENS may reduce the risk of opioid misuse or slow the rate of opioid dose escalation. It can also help facilitate active treatment modalities such as exercise or physical therapy programs.

ADVANTAGES OF TENS THERAPY

+ Non-opioid pain relief treatment
+ No drug-drug interactions
+ No risk for chemical dependence, addiction, or prescription drug misuse
+ Impacts opioid use
+ May slow opioid dose escalation
+ Complements physical therapy or exercise by controlling movement-related pain
+ Few side effects or safety concerns
+ Therapy can be stopped at any time without tapering
+ Inexpensive when managed appropriately

THE RELATIONSHIP BETWEEN TENS AND OPIOIDS

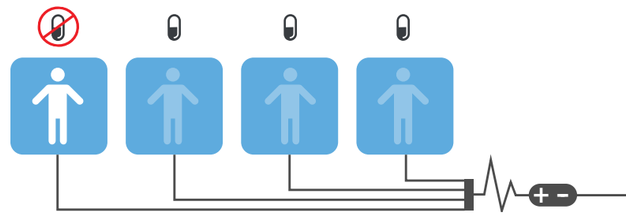
The relationship between TENS and opioid therapies is a prime example of why injured worker care must be managed through a comprehensive approach. Although seemingly from two different arms of medical cost management – one therapy falling under the purview of pharmacy benefits, one under durable medical equipment (DME) – they are closely linked and must be considered within the context of a complete treatment plan.

Similar to opioid analgesics, TENS technology is thought to suppress pain signals sent by the central nervous system by activating opioid receptors.[1-3] More importantly, it does this without the use of opioids, thereby eliminating not only the potential for addiction and misuse, but a list of potential other adverse events typically associated with opioid medications such as sedation, nausea, dizziness, constipation, physical dependence, and respiratory depression.

The downside of these two therapies working in similar ways means that opioids can negatively impact the effectiveness of TENS therapy. Patients who have already built a tolerance toward opioid analgesics may also exhibit a tolerance for the analgesic effect provided by TENS.[3] This may be a contributing factor in studies of TENS technology where there is conflicting evidence on its effectiveness. It also further supports the need to explore non-opioid treatment options early in a claim, when these options have the best chance at driving successful outcomes in a claim.

The upside is that this relationship can be exploited in a beneficial way to combat opioid usage. Just as opioids can impact the effectiveness of TENS, the employment of TENS therapy in an injured worker can have an impact on opioid use.

Healthesystems analyzed a large claims segment that included both TENS and opioid therapies. It was observed that approximately **1 out of 4 patients stopped using opioids after TENS was supplied.** While this trend could be the outcome of a combination of factors, including prescribing as well as patient behaviors, it may indicate a positive effect of TENS on opioid usage.[4]



Adjusted survival regression analysis also indicates that TENS is a predictor for reduced risk of opioid dose escalation. **Introduction of TENS therapy within a claim increased the number of days showing a morphine equivalent dose (MED) of zero.[4]**

TENS AS PART OF ACTIVE REHABILITATION

Another contributing factor for the lack of consensus regarding the efficacy of TENS is the type of pain for which it is being assessed. Research demonstrates that TENS treatment is more effective at alleviating movement-related pain versus resting pain.[5,6] This is good news in the treatment of injured workers, because it means that TENS can serve as an effective adjunct to active treatment modalities designed to improve functional outcomes, such as a physical therapy or exercise regimens.

The role of TENS in rehabilitation is supported by a recent placebo-controlled trial of more than 300 patients. The trial evaluated the efficacy of TENS as part of rehabilitation following total knee arthroplasty. Patients receiving TENS therapy experienced less range-of-motion pain during activities that included active knee extension and fast walking.[6] Since the goal of treatment in workers' compensation is improved function, the ability of TENS technology to manage pain while employing active modalities underscores its importance in overall treatment. That it can accomplish this without the use of opioids, with little-to-no side effects, and for a low cost only enhances its benefits.

CONSIDERATIONS FOR EFFECTIVE TENS THERAPY[6,8]

Dosage
Intensity of stimulation, stimulation frequency, and duration of therapy all play a role in the effectiveness of TENS and are dependent on the individual patient

Psychosocial factors
Patients exhibiting certain traits, such as high anxiety or pain catastrophizing, are less likely to benefit from TENS therapy

Prescription medication usage (opioids)
Because TENS technology acts on opioid receptors, opioid-tolerant patients may not experience the analgesic effect provided by TENS

Use in conjunction with PT or exercise program
TENS is most beneficial when paired with an active treatment modality to promote functional improvement

EFFECTIVE APPLICATION AND MANAGEMENT OF TENS THERAPY

As mentioned previously, there has been a lack of consensus among studies measuring the effectiveness of TENS therapy. While some suggest that it is primarily effective in nerve-related pain such as fibromyalgia or diabetic neuropathy, other studies and meta-analyses demonstrate efficacy in chronic musculoskeletal pain.[7] Patients may also build up a tolerance to the effect of TENS therapy decreasing its effectiveness over the long term, similar to the way in which opioid tolerance is developed. It has also been argued that there is a placebo effect associated with TENS treatment that contributes to perceived pain relief.

Initial Prescribing: While it is true that effectiveness varies among patients and is dependent on a number of variables, there are a significant number of patients who receive valuable pain reduction benefits from TENS technology. The trick, as with any treatment, is to ensure appropriate prescribing for the right patient.

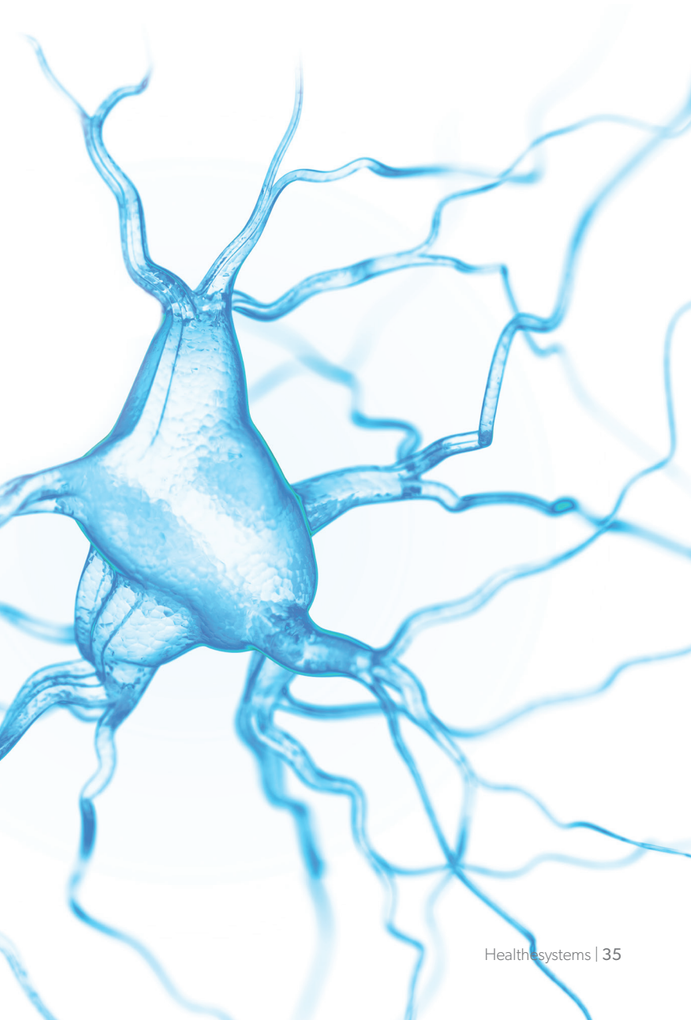
Product Selection: There are many brands and models of TENS units available ranging from inexpensive (e.g., 20 USD) to very expensive (e.g., 1,000 USD), all of which are based upon the same technology. Just like drug medications where there are "generic" and "brand" versions of TENS devices, selection should be guided by the same factors of clinical appropriateness and cost. Often, a device can be purchased for an amount equal to or less than the cost of a single month's rental. A DME program that provides transparency can help payers avoid inflated prices for what should be, when managed appropriately, a highly cost-effective treatment approach – not only in terms of direct cost, but for the potential it has to reduce risk of opioid dose escalation and the financial implications of high MED within a claim.

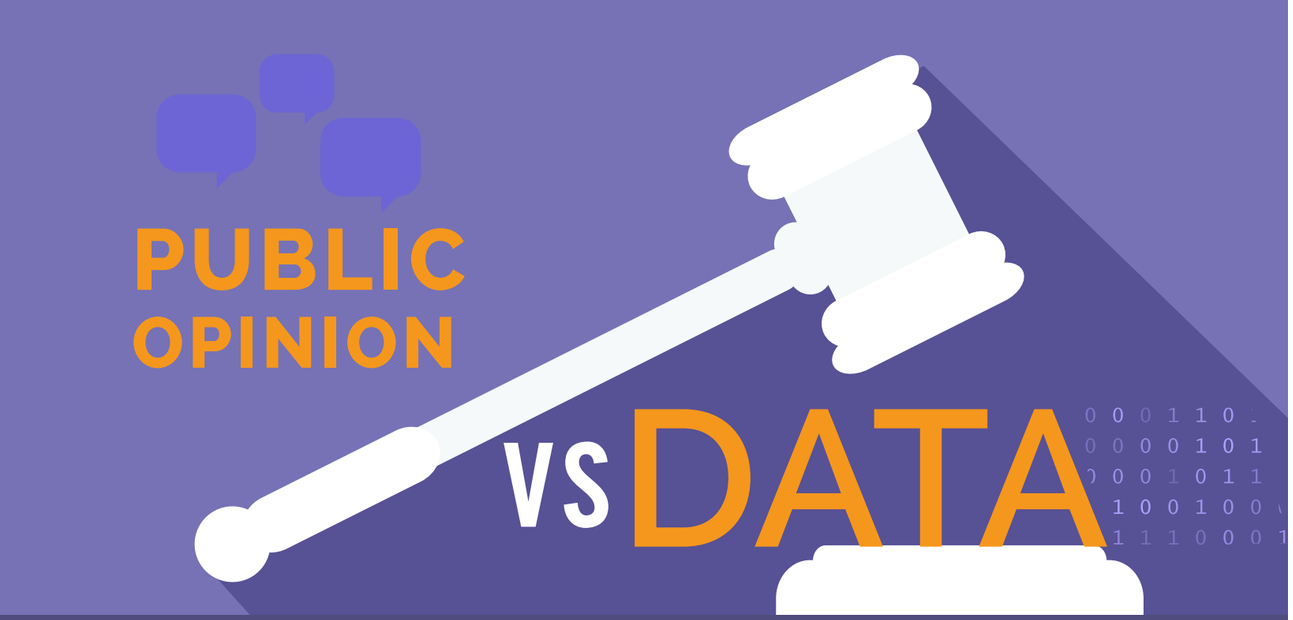
Continued Management: Monitoring patient benefit and electrotherapy supplies utilization is an important component of managing TENS therapy throughout the care continuum, both from the patient-care and cost-savings perspectives. It is important to validate that an injured worker patient is continuing to use and benefit from TENS therapy. Although many TENS devices themselves are inexpensive, associated supplies can contribute to more than 90% of overall TENS-related costs in long-term use claims. These costs can add up unnecessarily when patients stop using the device, but continue to receive supplies. Ongoing, prospective management of long-term electrotherapy significantly reduces wasted spend and ensures the patient is receiving beneficial care.

NEW DEVELOPMENTS IN TENS TECHNOLOGY

Although TENS technology has existed for decades, new products continue to be developed. Last year, the U.S. Food and Drug Administration (FDA) approved Quell, an over-the-counter device for the 24-hour treatment of neuropathic pain. Another upcoming product is the Cūr modulated TENS system, which has an anticipated FDA approval of November 2015. This device is designed to stick directly to skin like a bandage, and like the Quell, does not contain any wires or require electrode placement. While these new devices have some features that may appeal to consumers, such as no lead wires or the ability to wear during sleep – there is no evidence to date that they provide any improvement in outcomes compared with standard TENS units. The same clinical benefits can be achieved with generic units at a fraction of the price.

In general, adjunctive TENS is a valuable part of an injured worker's treatment plan. It is inexpensive (much more so than other electrical modalities such as Interferential Frequency Current [IFC] and H-wave), and has very little risk of complications or side effects. The use of TENS has been shown to impact opioid use and help facilitate functional improvement by reducing the amount of pain experienced by patients during their active components of therapy. It provides similar benefits to opioid medication without the associated risks. The inclusion of TENS technology must be considered not based only on its immediate, short-term benefits, but in a comprehensive context that includes other non-pharmacologic as well as pharmacologic components of therapy.





Which One Drives Change in Regulation?

By Sandy Shtab, *Director of Regulatory and Legislative Affairs*

The workers' compensation industry is constantly evolving due in part to politics, policy, and public opinion. As healthcare costs continue to escalate, insurers and regulators are becoming increasingly sensitive to the quality, duration, and cost associated with delivering medical benefits to injured workers. Those costs translate to real premium dollars for employers and detract from the bottom line; for some employers the impact can make or break a business. In rare instances, public entities can be so loss-sensitive that they are driven to bankruptcy.[1] Some say regulation changes can make a difference in costs and outcomes. We agree, but it is important to first understand what drives this change. While public opinion has traditionally been a strong influence, there must be a greater effort to rely more upon objective medical cost and outcomes data.

First we look at the body of data that is amassed in the workers' compensation system and how this data is used. The National Council on Compensation Insurance (NCCI) estimates that approximately one-third of all legislation during the first part of this decade was related to medical services.[2] Proposals on issues including fee schedules, choice of medical provider, medical networks and prescription drugs were then – and remain now – hot topics for the industry. Policymakers needed credible information to help them make good decisions instead of relying on anecdotal evidence and unsubstantiated opinions. Enter the NCCI Medical Data Call.

30%

OF LEGISLATION IS RELATED TO MEDICAL SERVICES

NCCI MEDICAL DATA CALL

State and federal agencies have been collecting medical data for years, but rarely were these data specific to workers' compensation claims. Starting in 2010, state workers' compensation agencies supported a national effort to begin collecting workers' compensation–specific medical billing and payment data through the NCCI Medical Data Call. Most insurers in the majority of states were already reporting Unit Statistical Data with lost time claim costs to either NCCI or to their local rating bureau. With the addition of the Medical Data Call, NCCI was able to compile a massive body of information from which to analyze medical trends, project outcomes, and estimate future costs as a result of proposed legislative changes. Nearly 5 years into the data collection effort, NCCI has been able to use these data to support policy decisions in many states; previously, NCCI had to rely upon voluntary data submission from carriers, which may have been incomplete or inconsistent from one carrier to the next.

The data are made available to legislators on request and to member companies on demand. Carriers can use this information to submit legislative proposals to state regulators or directly to the legislature through their trade organizations. Some issues which have been addressed using these data include the movement away from state-developed or charge-based fee schedules to Medicare-based fee schedules, as well as physician dispensing of medications. Both of these have seen ample regulatory impact since the NCCI Medical Data Call began.

EVIDENCE-BASED MEDICINE & TREATMENT GUIDELINES

Another effort in flight by states is to implement treatment guidelines as a standard of care to ensure appropriate utilization of medical services. In many states, there are physicians who balk at the concept of using evidence-based medicine, referring to it as "cookbook medicine." Recent discussions in states like Florida and Kentucky have produced strong opinions from physicians who vehemently oppose the concept. Many physicians indicated that they would consider this approach if they were personally involved in the development of a "consensus-based" treatment guideline. In Florida, one occupational medicine specialist proclaimed that East coast medicine is practiced differently than West coast medicine, arguing that guidelines developed by a company in California, Ohio or Texas, for example, would not be applicable in Florida. This public opinion is difficult to overcome absent any data to the contrary. Although research organizations are working on studies that measure the impact of treatment guidelines on claims outcomes, until such data are available, public opinion will continue to table the concept of evidence-based medical guidelines for many states.

MEDICAL CANNABIS – A REPLACEMENT FOR OPIOIDS?

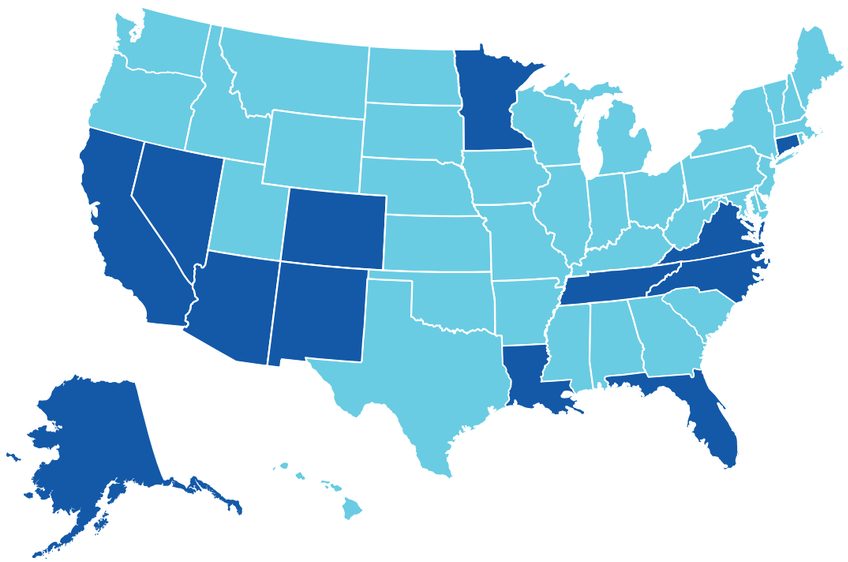
Another hot issue in workers' compensation is the long-standing opioid crisis, which has been widely covered in both industry publications and by the mainstream media. The majority of studies indicate that opioids are inappropriate for long-term use in chronic non-cancer pain; however, the effort to wean patients off these medications remains challenging. Complicating the issue is the fact that more than half the states have now either decriminalized or approved medical marijuana use for specific medical conditions. Physicians in a number of states are recommending marijuana for relief of chronic pain or related conditions such as anxiety, depression, or insomnia. Due to the many legal and political barriers, sufficient research on the efficacy of marijuana for these conditions has not been conducted; while there is some moderate evidence for the effectiveness in treating chronic pain, additional studies are needed. Despite the need for more evidence, some judges are now ordering carriers to reimburse injured workers for medical cannabis. The rationale behind these decisions was expressed at a recent regulator roundtable, when one judge asked a packed room of regulators and industry leaders, "Why shouldn't carriers pay for cannabis, when it is less expensive and less dangerous than opioids?"

This speaks to the impact of public opinion on policy decisions. One survey by CBS News found that 80% of Americans supported medical marijuana.[3] While marijuana may currently demonstrate a narrow application for terminally ill patients, treatment of epileptic seizures, and children with rare diseases, regulators must respond to court orders in states like New Mexico, where a carrier was recently ordered to reimburse an injured worker for marijuana he used to relieve back pain. However, until the FDA revives its efforts to study the drug, and the Drug Enforcement Administration (DEA) reschedules marijuana to Schedule II, carriers' hands are tied. They simply cannot issue payments through any banking system to pay for an illicit substance, regardless of public opinion. Even a judge's order can not compel them to do so. All of this puts all stakeholders – carriers, regulators, employers, and injured workers – in a difficult position. Without sufficient studies or data to support medical marijuana as a treatment option for work-related injuries, there is no solution on the horizon.

CLOSING THE GAP

Public opinion can be a powerful impetus for change. However we are learning as an industry to rely more on facts and data and less on anecdotal evidence. For this reason the use of data is an increasingly important tool for our industry. We collectively produce billions of lines of information each year in claims information, medical billing and payment data, electronic medical records, employment, and statistical data. Organizations like NCCI and the Workers Compensation Research Institute (WCRI) are listening to their members and working to address existing gaps. With the implementation of ICD-10, the coming years will bring us a new, more granular data and a fresh look at outcomes in workers' compensation claims. Access to such detailed information on the diagnosis and cause of injuries will allow us not only to produce better claim outcomes, but to potentially prevent and reduce workplace injuries. It is certain that public opinion will continue to influence how public policy is made, but we will be better armed with tools to either support or refute the unsubstantiated arguments that are so prevalent today.

THE STATE OF THE STATES



ALASKA
Physician Dispensing Legislation, Fee Reductions

In its first session this year, the House read legislation (HB31 & HB32) that would limit physician dispensing for workers' compensation claims. The bills were referred to the Labor & Commerce and Judiciary Committees, but did not advance through the legislature. Both are eligible for carryover in 2016. In related news, the Medical Services Review Board (MSRC) recently published and later withdrew a rule proposal that would make deep cuts to provider and pharmacy reimbursement starting in 2016. The MSRC conducted a hearing and publically indicated they will be moving forward with a fee reduction for all providers in 2016 independent of the rules process.

ARIZONA
Evidence-based Medicine Rule Development Faces Delays

The Arizona Industrial Commission Workers' Compensation Advisory Board indicated its intent to promulgate rules on evidence-based medicine starting with pain management and opioid prescribing. The Commission recently published a report that it would work with payers to implement a pilot program; however, there was a lack of consensus regarding how the preauthorization process might work in the pilot and those efforts have been put aside pending future rulemaking. Recent leadership changes at the Commission may contribute to delays in rule development.

CALIFORNIA
Working Towards a Closed Formulary

The Division of Workers' Compensation (DWC) has been very active in recent months, with Home Health and Interpreter Fee Schedule drafts and Medical Treatment Utilization Schedule updates that would impact how physicians treat chronic pain patients. The DWC also adopted its Implementation Guide for Medical Bill Payment Records version 2.0, which become effective date on April 6, 2016.

In addition, the DWC has been preparing to implement a closed formulary under the mandate created by 2015 Assembly Bill 1124. Regulators have begun to outline a plan for implementation of a drug formulary that would include regular updates and involve a committee of medical professionals who would oversee the update process. A stakeholder meeting in early September drew a large crowd, many of whom were vocal as to the benefits and potential pitfalls of formularies. Healthesystems Regulatory Affairs and Clinical staff have been directly engaged in these efforts and are advocating for rules that would deliver the most appropriate and timely medical care to the injured worker. A formulary is expected to be implemented by June 2017.

COLORADO
Coverage Required for Opioid Antagonists

The Department of Labor and Employment, Division of Workers' Compensation has adopted amendments to Rule 16 & 18 dealing with Utilizations Standards and Medical Billing. The new rules require carriers to provide coverage for opioid antagonist products when a worker is at risk for accidental overdose, in accordance with recent statewide health policy changes. The Rules also incorporate updates to opioid prescribing guidance and clarification of billing requirements for compounded drugs and repackaged drugs. The new rules are effective on January 1, 2016.

CONNECTICUT
Fee Schedule Changes

Connecticut Workers' Compensation Agency (WCA) adopted changes to its Official Connecticut Practitioner Fee Schedule effective for medical services rendered on or after July 15, 2015. The fees payable to healthcare providers authorized or permitted to render care under Connecticut Workers' Compensation Act are effective on this date regardless of the date of injury. The 2015 Fee Schedule includes revisions of reimbursement rules for durable medical equipment (DME) and radiology services, among others, and became effective April 1, 2015.

FLORIDA
Clarifying the "Controlled Substance Provider" Designation

The Florida Department of Health recently released a clarification statement regarding the controlled substance prescriber designation on its website list of practitioner's profiles. The "controlled substance provider" designation is not required in order for pharmacists to fill the practitioner's controlled substance prescriptions.

Because pharmacists use their professional judgement in deciding to fill or not fill a prescription, some consumers have complained they been turned away when they presented a prescription from a physician who did not have a controlled substance designation on their Department of Health Physician Profile. This special designation is reserved for practitioners who specialize in the treatment of chronic, nonmalignant pain. The requirement, which is applicable under Florida Statute Section 456.44, has been incorrectly interpreted by some pharmacies that have declined to fill controlled substance prescriptions from doctors who do not have the designation. The Board of Health statement was intended to stop pharmacists from turning patients away when there is a legitimate need for pain medications.

LOUISIANA
Closed Formulary Bill Does Not Advance

Earlier this year SB256 was proposed, which would have required the Director of the Office of Workers' Compensation (OWC) to develop, oversee, and update a closed formulary. The Director would appoint a panel by September 1, 2015 to develop a formulary, which would include Y or N drugs. Due to a lack of consensus from the stakeholder community, the bill failed to advance, but the Director has begun the process of developing rules that would implement the same concept by rule. The OWC is also in the process of updating three chapters of its medical treatment guidelines, including the chapter on chronic pain.

MINNESOTA
New E-billing Protocols

In May, the Minnesota governor signed HF 2193 into law, enacting new electronic billing (e-billing) protocols for workers' compensation under Minn. Stat. § 176.135 7A. The new requirements are for carriers and self-insured payers to post clearinghouse information on their websites. The law change was the result of feedback by providers who complained that they were unable to adhere to mandatory e-billing requirements without knowing which clearinghouse each insurer was using to accept e-bills on their behalf. In other news, the Department of Labor updated their Chronic Pain Guidelines, with an effective date of July 1, 2015. The updated guidance has information for prescribers as to how they shall screen patients for chronic pain and perform random drug testing, as well as a plan for weaning when trials of pain medication do not deliver functional gains as expected.

NEVADA
Tightening Controls on Physician Dispensing

Senate Bill 231 revised the payment timeframes for medical bills and established controls for physician-dispensed drugs. The bill limits the day supply that physicians can dispense for Schedule II and III controlled substance to 15 days. Senate Bill 231 was signed by the governor on May 27, 2015, and becomes effective on January 1, 2016.

NEW MEXICO
Reimbursement Required for Medical Marijuana

A recent fee schedule proposal published by the state requires insurers to reimburse injured workers for medical marijuana when used for treatment of their workers' compensation claims when prescribed for an approved condition. This is the first state to recommend medical marijuana as an approved treatment based on a court decision earlier this year. However, there are many issues with this proposal and it is undetermined if the language will be approved in the final version of the fee schedule, since there are many regulatory and political hurdles that need to be overcome prior to this rule being implemented. The new fee schedule is expected to be published and become effective by January 1, 2016.

NORTH CAROLINA
Bill Provisions to Reduce Pharmaceutical Costs, Preserve Access

The state's budget bill contained provisions that will require the Industrial Commission to study how a drug formulary could impact the workers' compensation system. The bill also included restrictions on physician dispensing, specifically Schedule IV and V medications. These changes are expected to drive down pharmaceutical costs while preserving injured workers' ability to access appropriate medications though the pharmacy of their choice.

TENNESSEE
Upcoming ODG Implementation

The Division of Workers' Compensation has begun rule development to implement the Official Disability Guidelines (ODG) as the standard of care effective January 1, 2016. They have also proposed the implementation of the ODG closed formulary with a proposed effective date July 1, 2016 for claims with dates of accident as of January 1, 2016. A public hearing was conducted on August 25, 2015 and Healthesystems participated by providing input to Division staff along with other interested stakeholders.

VIRGINIA
New Medical Fee and E-billing Requirements

New legislation requires the state to develop medical fee schedules and prepare for electronic billing requirements. The new law will require payers and providers to exchange billing, claims, case management, health records, and all supporting documentation according to IAIABC-adopted standards. The Commission must establish a schedule for rules implementation by January 1, 2016. Fee schedule development meetings are taking place with many stakeholders presenting information to the Commission with several stakeholders proposing adoption of Medicare-based fee schedules. Healthesystems staff is participating in the process and anticipate rules proposals to be submitted prior to the end of 2015.

FEDERAL LAW
Healthesystems Is Ready for ICD-10 – Are You?

The month of October marked a significant milestone for the U.S. healthcare industry. As of October 1, 2015, all HIPAA-covered entities are required to begin using ICD-10 diagnosis coding as mandated by the U.S. Department of Health and Human Services. Because the vast majority of medical providers are subject to HIPAA, state workers' compensation systems in about half the country were already aligned with the federal mandate prior to the October 1 deadline.

More information about ICD-10 is available at http://www.cms.gov/Medicare/Coding/ICD10/Latest_News.html

BY THE NUMBERS

REGULATION

Oxycodone -related deaths dropped 25% in Florida following the adoption of a **Prescription Drug Monitoring Program**

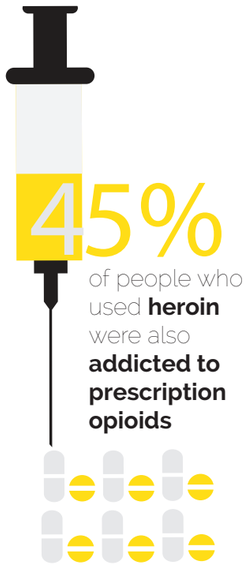
University of Florida

COST MANAGEMENT

OPIOID-INDUCED **CONSTIPATION** CAN INCUR **~$11,000 PER YEAR**

Wan Y et al. Am Health Drug Benefits 2015

OPIOIDS



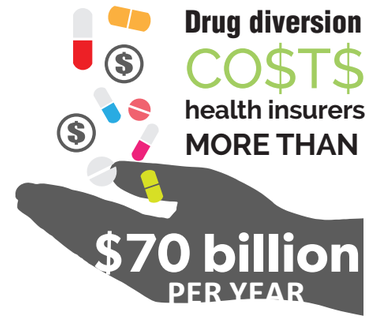
45% of people who used **heroin** were also **addicted to prescription opioids**

Centers for Disease Control and Prevention

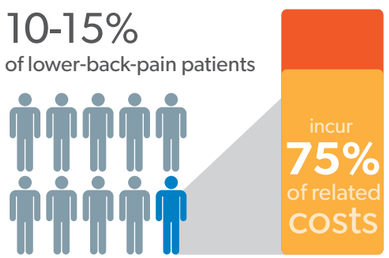
Patients with a history of substance abuse are

9x more likely to use opioids **long term**

Hooten WM et al. Mayo Clin Proc 2015.



www.insurancefraud.org



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