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RxINFORMER

CURRENT AND EMERGING ISSUES IMPACTING WORKERS' COMP

FALL 2014

MISSING THE BIG PICTURE?

HOLISTIC PATIENT MANAGEMENT MEANS WORKING SMARTER, NOT HARDER, TO IMPROVE OUTCOMES

BREAKING THE OPIOID CYCLE: PREVENTION STRATEGIES

MEDICATION NONADHERENCE:

THE MOST COSTLY DRUG IS THE ONE THEY ARE NOT TAKING

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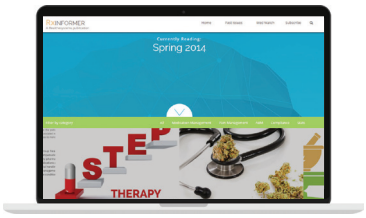

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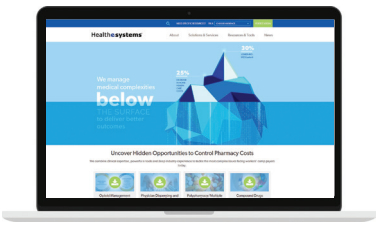

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MEDICATION MANAGEMENT: WHO'S DRIVING?

SHARED RESPONSIBILITY AND INTEGRATED STRATEGIES ARE THE KEYS TO SUCCESS

As the burden of prescription drug abuse continues to dramatically impact clinical outcomes and costs in workers' compensation, a variety of individual efforts are being made to combat the epidemic. Federal and state governments, healthcare organizations, pharmacy benefit managers, physicians, and payers have all implemented measures intended to curb inappropriate prescribing and resultant drug misuse — measures that span policy changes to increased use of electronic data sharing. But as patients continue to fall through the cracks, there must be an effort to not only continue executing these strategies, but to work towards improving their collective integration. Successful patient management is not an individual endeavor, but rather a concerted effort orchestrated by key stakeholders through a system of checks and balances. Policy is only impactful when followed; the right medication is only effective when it is adhered to; information is only meaningful when it becomes part of the decision.

In this issue, we continue to tackle the challenge of opioid management with an eye on inclusivity and integration. The selection of articles provides insights and guidance that span the continuum of patient management, from prevention at initial point of care to late-stage interventions for patients who have already become dependent or addicted. We also take a look at underlying complexities within the injured worker population that remind us why, although opioid abuse is prevalent throughout healthcare, it remains a particularly challenging battle within our industry.

PRESCRIPTION FOR PREVENTION

The earliest intervention for drug abuse is at the point of care, and even at this early stage the responsibility extends beyond the prescriber. In the article *Breaking the Opioid Cycle*, we examine the different strategies and roles for combating abuse in the most proactive sense — prevention through the elimination or restriction of scenarios that can potentially foster abuse. The outlined strategies address the problem from the broadest and most far-reaching levels, down to the most individual interactions. But whether they are implemented on a federal or state level via controlled substance schedules that provide prescribing and dispensing guidance, or on a physician level through screening and risk factor assessment, each strategy is a critical component of proactive abuse management.

ABOUT THE AUTHOR

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IDENTIFICATION AND TREATMENT OF ABUSE

While efforts continue to prevent drug abuse, there remains a significantly large population of patients who will require later-stage intervention. An alarming number of patients display aberrant drug behavior, ranging from nonadherence to medication to compulsive, daily abuse stemming from addiction. This broad range of behaviors can make detection a moving target, and the warning signs can often appear in unexpected areas of a claimant's medical history. We provide some key recommendations on multiple monitoring strategies that go beyond a cursory medication review and dig deeper to uncover potential drivers of nonadherence or other aberrant drug behaviors such as selective adherence, chemical coping, dependence, and addiction that claims professionals should be aware of when evaluating data within their population. Recognizing and interpreting these data are just the first step, however. The article *Getting Unhooked* provides a walk-through of the opioid detoxification process in patients who have been identified as dependent or addicted, including detailed recommendations regarding pharmacologic detox and adjunctive psychosocial interventions — both critically important to a successful detoxification program. Our hope is that these articles provide valuable information that will help payers to identify patients at risk for aberrant drug behavior and determine appropriate next steps in managing these injured workers.

SPECIALTY PHARMACY WEIGHS IN

Although the complexities of opioid management continue to require heavy attention, the growing presence of specialty medications within the workers' compensation space demands consideration in overall medication management. While some parallels with opioid management may be drawn, the prescribing and dispensing of specialty medications brings a new set of complexities that will require thoughtful analysis when making treatment recommendations. There exists a need to implement strategies that encourage cost-containment through appropriate patient selection for specialty medications. However, the novelty of these products can make it challenging to determine what the guideposts for prescribing should be. While specialty drugs may potentially offer unmatched success in difficult-to-treat conditions, they also have a limited track record in the clinical setting, making it difficult to confidently weigh the benefits and risks versus cost.

Coupled together, the continued efforts against opioid misuse and the emergence of specialty pharmacy within workers' compensation further underscores the need for a comprehensive and concerted approach to medication management. Even as the industry works to address the complexities of the injured worker population, these complexities change and evolve with the introduction of new challenges. A global approach to medication management will ensure that no complexity, whether existing or emerging, is overlooked.

MED WATCH

WORKERS' COMP PROFESSIONALS SHOULD KEEP AN EYE ON THESE MEDICATIONS

The 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
- ▪ GENERIC
- ♦ NEW DOSAGE/FORMULATION
- ✱ SPECIALTY

2014

MAY

Celebrex® (celecoxib) 50mg, 100mg, 200mg, 400mg ▪
PAIN
NSAID for rheumatoid and osteoarthritis, acute pain

Pennsaid® (diclofenac) 1.5% ▪
ARTHRITIC PAIN
Topical NSAID for osteoarthritis pain of the knee

Exalgo® (hydromorphone HCl extended release) 8mg, 12mg, 16mg ▪
PAIN
Opioid analgesic for moderate to severe pain

Dalvance® (dalbavancin) ✦ ✱
ANTI-INFECTIVE
IV infusion antibiotic for acute bacterial skin and skin structure infections

JUNE

Bunavail™ (buprenorphine/naloxone) ✦
PAIN
Naloxone buccal film for treatment of opioid dependence

Afrezza® (insulin human) ✦
DIABETES
Rapid-acting inhaled insulin for Type 1 or 2 diabetes

JULY

Targiniq® (oxycodone HCl/ naloxone HCl extended release) ✦
PAIN
Abuse-deterrent opioid analgesic for moderate to severe pain

Sivextro™ (tedizolid phosphate) ✦
ANTI-INFECTIVE
Antibiotic for acute bacterial skin and skin structure infections

Zydelig™ (idelalisib) ✦ ✱
ONCOLOGY
Oral agent for relapsed chronic lymphocytic leukemia (CLL), relapsed follicular B-cell non-Hodgkin lymphoma (FL), relapsed small lymphocytic lymphoma (SLL)

Beleodaq® (belinostat) ✦ ✱
ONCOLOGY
IV infusion for refractory peripheral T-Cell lymphoma (PTCL)

Butrans® (bupenorphine) Transdermal System 7.5mcg/hr ♦
PAIN
Partial opioid agonist for severe pain

AUGUST

Belsomra® (suvorexant) ✦
HYPNOTIC
First orexin receptor antagonist for insomnia
Note: Schedule IV controlled substance

Zorvolex® (diclofenac) ✦
PAIN
Osteoarthritis indication added for this oral NSAID

Plegridy® (peginterferon beta-1a) ✦ ✱
AUTOIMMUNE
For relapsing forms of multiple sclerosis

▶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.

SEPTEMBER

Movantik® (naloxegol) ✦
OPIOID SIDE EFFECTS
For opioid-induced constipation

Ferric Citrate ✦ ✱
RENAL
To reduce blood phosphate levels in patients with chronic kidney disease who receive dialysis

OCTOBER

Harvoni® (ledipasvir/sofosbuvir) ✦ ✱
ANTIVIRAL
Oral, fixed-dose combination therapy for chronic hepatitis C (genotype 1)

Symbicort® (budesonide/formoterol) ▪
COPD
A combination inhaler product for COPD and asthma

Taigexyn® (nemonoxacin) ✦
ANTI-INFECTIVE
An antibiotic to treat community-acquired bacterial pneumonia and skin infections (priority review granted)

NOVEMBER

AVP-825 (sumatriptan) ♦
PAIN
Fast-acting, dry-powder intranasal form of sumatriptan for treatment of migraine

Copaxone® (glatiramer) ▪ ✱
AUTOIMMUNE
For relapsing forms of multiple sclerosis

DECEMBER

ABT-450/ritonavir + Ombitasvir ✦ ✱
ANTIVIRAL
Oral, fixed-dose combination therapy for chronic hepatitis C (genotype 1) (priority review)

Peramivir ♦ ✱
ANTIVIRAL
IV infusion for treatment of influenza

Ceftolozane/Tazobactam ✦
ANTI-INFECTIVE
For the treatment of complicated urinary infections and complicated intra-abdominal infections

JANUARY 2015

Namenda® (memantine) ▪
PSYCHIATRY
Used to treat Alzheimer's disease

Note: In February 2014, Forest Laboratories announced discontinuation of the brand name 5 and 10mg tablets as of August 15, 2014. The oral liquid and newer extended release capsule will remain on the market. Manufacturer's information available at www.namenda.com

MARCH

Renagel® (sevelamer) ▪ ✱
RENAL
To reduce phosphate blood levels in patients with chronic kidney disease who receive dialysis

Sustiva® (efavirenz) ▪ ✱
ANTIVIRAL
For HIV/AIDS

APRIL

Abilify® (aripiprazole) ▪
PSYCHIATRY
An atypical antipsychotic used to treat psychoses and an add-on to antidepressant therapy for major depressive disorder

Zohydro® ER (hydrocodone bitartrate) ♦
PAIN
Opioid analgesic for severe pain

NOTE: Due to controversy, drug maker Zogenix submitted a supplemental NDA for a new, harder-to-abuse formulation with anticipated launch in Q2 2015.

MAY

PA32540/PA8140 (aspirin/omeprazole) ♦
CARDIOVASCULAR
Reduction in stroke and heart attack for patients undergoing previous events

Unfold for full timeline

DRUG ALERTS

NEW OPIOID COMBINATION PRODUCT DENIED APPROVAL

Moxduo® (morphine sulfate/oxycodone hydrochloride)

The FDA cited insufficient evidence to support the approval of this combination opioid analgesic. Moxduo had been under review for the treatment of moderate-to-severe acute pain.

RECENT SCHEDULE CHANGES

In recent months, the Drug Enforcement Administration (DEA) has federally rescheduled certain medications commonly seen in the workers' compensation space. It is important for workers' compensation professionals to be aware of these changes and the associated increase in regulatory controls and administrative, civil, and criminal sanctions for these products.

Hydrocodone Combination Products

Effective October 6, 2014, all hydrocodone combination products have been changed from Schedule III to Schedule II of the Controlled Substances Act, increasing restrictions on this group of medications.

Tramadol

The opioid analgesic tramadol has changed from non-schedule status to a Schedule IV controlled substance, effective August 2014.

PRODUCT RECALLS BY HOSPIRA, CUSTOMED INC.

Heparin Sodium – Single Lot

Hospira announced a recall of one lot of Heparin Sodium, 1000 USP Heparin Units/500mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500mL, NDC 0409-7620-03 Lot 41-046-JT with expiration date 01NOV2015. The recall is due to a customer-reported particulate in a single unit.

Sterile Convenience Surgical Packs

Customed, Inc. initiated a recall of their sterile convenience surgical packs. A defect in the product could result in loss of product sterility leading to infection. Affected products were manufactured and distributed January 2009 — May 2014.

RECENT NDAS/CLINICAL TRIALS

Many of the products below could be approved in 2015 through early 2016.

PAIN

ALO-02 (oxycodone hydrochloride/naletrexone hydrochloride*)
Extended-release opioid capsule for moderate-to-severe low back pain
Note: Abuse deterrent properties not as strong as Oxycontin. Submitted by Endo Pharmaceucticals.

Clonidine gel
For painful diabetic neuropathy
Note: Depending on cost and efficacy, this may be a new option for treatment of neuropathic pain and help curb opioid use.

Wearable Watch (OTC)
A wearable device delivers electrical stimulation to reduce chronic pain

Zalviso™
A preprogrammed, patient-controlled delivery system for sufentanil tablets

OPIOID SIDE EFFECTS

Androxal (clomiphene citrate)
A non-testosterone treatment for secondary hypogonadism

Androgel® (testosterone)
Testosterone replacement

* There is concern for drug abuse with oxycodone/naloxone and oxycodone/naltrexone combinations. The clinical significance of abuse deterrence with naloxone or naltrexone has yet to be determined.[1,2]

ARTHRITIC PAIN

Ampion™
For osteoarthritis of the knee

Baricitinib
For rheumatoid arthritis

Cimzia® (certolizumab pegol)
Pursuing a new indication in early active rheumatoid arthritis

Ravax®
Rheumatoid arthritis vaccine

Sarilumab
For rheumatoid arthritis

Sekukinumab
For rheumatoid arthritis

Sirukumab
For rheumatoid arthritis

SoluMatrix® (meloxicam)
NSAID with new formulation pending for osteoarthritis

Synvisc-One®
Pursuing a new indication in osteoarthritis of the hip; already approved in the knee

Tanezumab
For osteoarthritis

BREAKING THE OPIOID CYCLE:

PREVENTION STRATEGIES

FAST FOCUS

Prevention — the most proactive intervention for opioid abuse — often occurs at the point of care. However, the responsibility does not fall solely on the prescriber at this juncture. Each stakeholder has a role to play when it comes to ensuring appropriate prescribing and dispensing of opioid therapy.

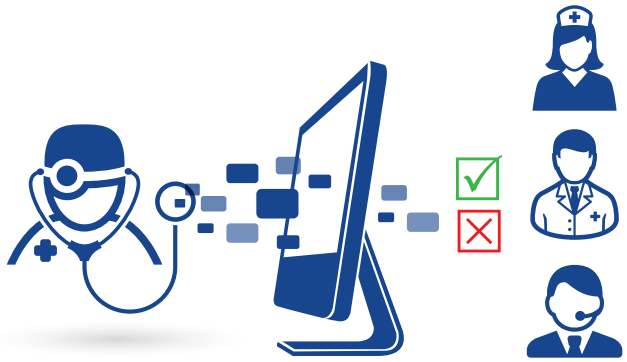
Pain is the unfortunate result of many workplace injuries. And as many payers are aware, pain is often managed through the prescribing of opioids. Too often, however, an opioid prescription that was originally intended to manage acute short-term pain following a severe injury or surgery leads to long-term use, a practice not recommended by medical guidelines. Chronic use may lead to undesirable consequences such as misuse, abuse, dependence, and addiction.

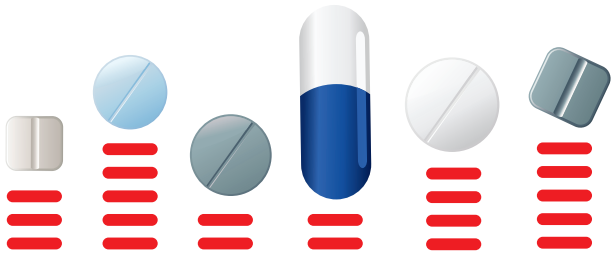
The price of opioid abuse is high, from any perspective.

55% of drug overdose deaths in the U.S. in 2011 were related to pharmaceuticals; of those, 74% were related to opioids.[1]

There are many drivers of opioid abuse in workers' compensation. The inherent need to manage pain, inappropriate prescribing practices, uncoordinated care, and the lack of financial responsibility on the part of the injured workers all contribute. In most states injured workers receive their work-related prescriptions with no out-of-pocket cost, removing the financial barrier to medication misuse.

With prescription drug abuse a national epidemic impacting over 12 million people in the U.S., and opioid abuse playing a major role in workers' compensation, many stakeholders are playing a key role in curbing abuse. The federal government, individual states, healthcare organizations, pharmacy benefit managers, physicians, and payers have all implemented strategies to address preventing drug abuse. From federal and state drug scheduling changes to Prescription Drug Monitoring Programs (PDMPs), each strategy is a step forward in reducing our nation's prescription for abuse.





STRATEGY: HEALTHCARE MANAGEMENT AND AUTOMATION

The most logical approach to curbing drug abuse would be to ensure that powerful opioids do not even make it into the hands of patients who will abuse and misuse them. This problem is not easily solved because often the signs of drug abuse, misuse, and diversion are subtle and require close collaboration and information sharing in order to uncover.

Pharmacy benefit managers are the first line of defense in this automated process — a specific medication plan anchoring a stringent prior authorization process. At a basic level, requiring authorization for an opioid prescription can help eliminate some instances of illicit drug-seeking from the onset. A more advanced approach incorporates multiple levels of authorization based on specific patient and medication factors. This approach puts complex therapy decisions in front of the appropriate decision maker in order to make a timely and informed decision.

In instances where a complex treatment regimen is in effect, **Healthesystems has demonstrated a savings of $400/script** as a result of employing a multi-tiered authorization process.

Requiring a letter of medical necessity (LOMN) from the physician detailing the medical need for prescriptions can refocus the physician on his patient's treatment plan by requiring information to support drug therapy. And when this process and valuable information is digitized and automated, accurate treatment decisions can be made in a timely manner.

STRATEGY: DRUG RESCHEDULING

Two federal agencies — the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA) have the authority to develop and maintain the federal controlled substances drug schedule. This categorizes controlled substances into five schedules based on several factors, including:

- Accepted medical use in treatment
- Relative abuse potential
- Likelihood of causing dependence, when abused

The schedule ranges from Schedule I, which indicates high potential for addiction and abuse along with no accepted medical use, to Schedule V, which indicates the least potential for abuse. The stricter schedules limit the amount of drugs to the market and require more diligence on the part of physicians when writing the prescription. On prescriptions, drug schedules are listed as CI, CII, and so forth (See table on next page).

Drug schedules are in a state of constant flux and will change based on new findings, changes to the pharmaceutical market, and legislation. Drugs can be added to a schedule, upgraded to a higher schedule, or downgraded to a lower schedule. In fact, since the Controlled Substances Act was enacted in 1970, over 200 substances have been added, removed, or transferred. [2]

Federal and state drug schedules can have inconsistencies, with the stricter classification superseding the other. In most cases, state schedules are stricter than the federal schedule. An example seen in the workers' compensation patient population is Carisoprodol (Soma®) which is a federal Schedule IV drug. Louisiana upgraded Soma to a stricter Schedule II drug.[3]

FEDERAL CONTROLLED SUBSTANCES SCHEDULE

SCEHDULE	DESCRIPTION	MEDICATION EXAMPLES
I	No currently accepted medical use in the U.S.; lacks accepted safety for use under medical supervision; has a high potential for abuse.	Heroin, LDS, marijuana, peyote, ecstasy
II	A high potential for abuse which may lead to severe psychological or physical dependence.	Hydrocodone, methadone, Demerol®, OxyContin®, Percocet®, fentanyl, morphine, codeine, hydromorphone
III	A potential for abuse lower than substances in Schedules I or II; abuse may lead to moderate or low physical dependence or high psychological dependence.	Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®), ketamine, anabolic steroids
IV	A low potential for abuse relative to substances in Schedule III.	Alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), temazepam (Restoril®), and triazolam (Halcion®).
V	A low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.	Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®) and ezogabine.

U.S. Department of Justice. Drug Enforcement Administration. Office of Division Control. Controlled Substances Schedule. http://www.deadiversion.usdoj.gov/schedules.

Drug scheduling decisions can cause controversy at times. A recent example is the rescheduling of hydrocodone combination products (HCPs) from Schedule III to Schedule II by the DEA.[4] HCPs are often used to manage pain and a common example often seen in workers' comp patients is Vicodin (combination hydrocodone and acetaminophen). The HCP schedule change occurred after 10 years of formal debate and consideration and 15 years after the initial proposal was made.

Opposition to changing HCPs from Schedule III to II came from various pharmacy, physician, and patient advocacy organizations. Those against the change wanted the re-schedule to impact only HCPs that contain hydrocodone bitartrate of 5 mg or more. Their concerns included depriving patients of access to critically needed pain medication, with a focus on patients in rural areas who have limited access to medical facilities. A schedule change would require all patients currently taking HCPs to obtain a new written prescription from their physician for each fill. The new federal schedule limits HCP prescriptions to a 90-day supply per script, but some states have stricter guidelines in place and limit prescriptions to a 30-day supply.

Advocates of the schedule change believe it will improve physician prescribing patterns and discourage pain clinics and pharmacies that offer pain medication to patients without physician oversight.

In fact, more physician visits should foster more patient/physician interaction, closer monitoring of patients on HCPs, and deliver improved treatment outcomes.

STRATEGY: PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS)

Preventing drug abuse requires a calculated balance between ensuring medications are available for patients in need while discouraging accessibility to those who are misusing. A Prescription Drug Monitoring Program (PDMP) is a statewide electronic database containing information pertaining to medications dispensed in the state. Certain individuals, such as physicians, pharmacists, or law officers are authorized under state law to access this database of patient prescription history. Its purpose is to encourage and facilitate legitimate medical use of controlled substances and to discourage drug abuse, misuse, diversion, and doctor-shopping.[5]

Forty-nine states currently have PDMPs with New Hampshire slated to begin its program soon. Drug abuse in this state is particularly problematic. Between 2000 and 2011, drug-related deaths quadrupled annually. Eighty percent of those were related to prescription drugs, usually opioids such as oxycodone and methadone.[6] Missouri is currently the only state without a prescription drug database, which may explain the influx of patients from neighboring states obtaining controlled substances.[7]

Prescription drug abuse is driven by multiple factors including inappropriate prescriber practices and patient behavior. Quite often, a small number of opioid prescribers are responsible for the majority of prescriptions. A 2012 study by the Oregon Health Authority found that 4% of prescribers were responsible for prescribing 60% of the state's Schedule II-IV controlled substance prescriptions.[8] And overall, roughly 20% of prescribers prescribe 80% of all prescription painkillers.[9] PDMPs can have a profound impact on clinical prescribing. One study found that of the prescribers who participated in a PDMP, 58% indicated a reduction in either prescriptions written or number of pills dispensed.[10]

Barriers do exist to realizing the full potential of PDMPs. These include limited funding, interstate operability and variability of data prevent states from sharing information. A handful of states have taken steps towards interstate collaboration with New Hampshire Gov. Maggie Hassan recently announcing an agreement between other New England governors to share PDMP data. Some states such as Kentucky and Ohio already have interchange of data in place.[11]

Additional integration may be on the horizon for PDMPs, which may improve their overall effectiveness. The Office of the National Coordinator for Health Information Technology (ONC) along with SAMHSA and the CDC have launched a project accurately titled "Enhancing Access to Prescription Drug Monitoring Programs Using Health Information Technology." The program aims to integrate more information and existing technologies into the PDMP such as electronic health records (EHR), health information exchanges (HIEs), and pharmacy systems. It also hopes to foster improved communication and information sharing between stakeholders through its resource center, *PDMPConnect*.[12]

Opportunities for improvement include increasing provider use of PDMPs, incorporating EHRs, and making PDMPs more accessible to providers (including incorporating them into existing systems for quick access and ease of use).

ZOHYDRO DISCOMFORT

Drug scheduling changes can also appear inconsistent at times, due to the ever-changing nature of the pharmaceutical market, changes to medical guidelines, and new research findings. While the FDA recently reclassified HCPs from Schedule III to the stricter Schedule II, it conversely approved a pure hydrocodone product that currently lacks an abuse-deterrent formulation. The approval of this pure drug, called Zohydro ER (hydrocodone bitartrate extended-release capsules) has caused discordance between the federal schedule and state-specific drug schedules.

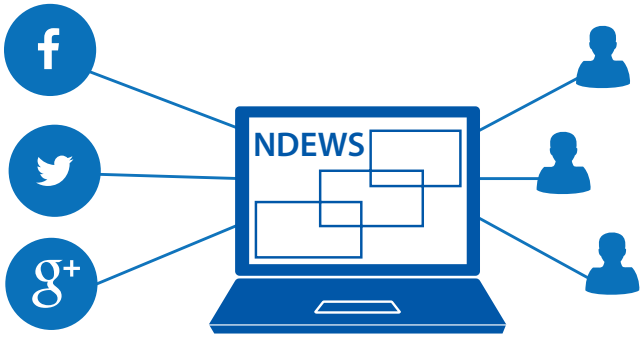
Zohydro ER is controversial for several reasons, including the fact that it does not have an abuse-deterrent formulation and therefore can be broken down for illicit intravenous and inhalation use. The FDA approved Zohydro as a Schedule II drug in 2013. It's the first FDA-approved single-entity and extended-release hydrocodone product for pain severe enough to require around-the-clock, long-term treatment.

MEDICAL MARIJUANA MAZE

A great irony exists in the fact that state drug schedules are often stricter than the federal government's drug schedule regarding opioid medications, yet nearly half of states have legalized the use of marijuana, which is currently listed as a federal Schedule I drug. As a Schedule I drug, marijuana sits alongside heroin and LSD as an illegal substance. But this could change in the future.

The FDA recently agreed to study whether marijuana should be reclassified, at the DEA's request. The agency will make a recommendation after conducting an eight-factor analysis it uses to determine the schedule classification. Factors include marijuana's abuse potential, pharmacological effect, and risk to public health. [13]

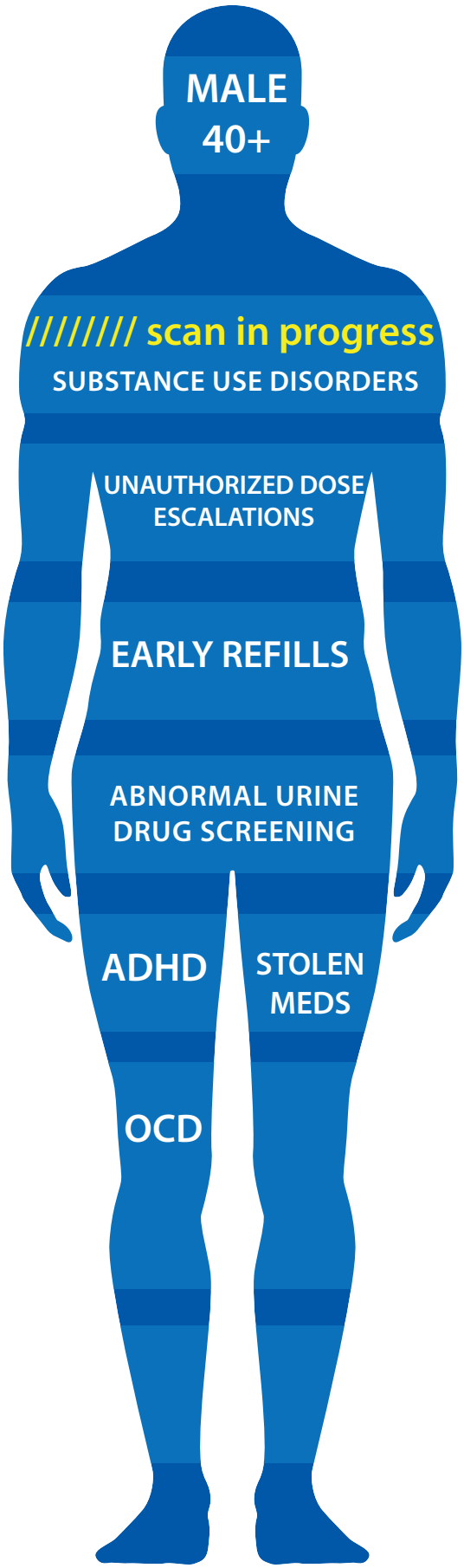
Even though marijuana use is still illegal by federal standards, 21 states and Washington D.C. have already passed legislation that varies from limited medical to recreational use to allowing medical marijuana to be used as a defense in court.[14]



STRATEGY: EMERGING TECHNOLOGY

National Institutes of Health (NIH) has started a real-time National Drug Early Warning System (NDEWS). The program is designed to monitor emerging trends that will help health experts respond quickly to potential outbreaks of illicit drugs. Additionally, NIH hopes to identify instances of increased use of so-called designer synthetic drugs. Drug trends quickly change as abusers find new ways to possess and use them — and in many cases this information is spread online. The innovative system will review data from social media and websites to quickly uncover new drug trends. It will also utilize more traditional national and local level data resources.[15] The goal is to keep up with emerging localized drug trends to keep them from spreading to surrounding areas.

As information is uncovered through NDEWS, the goal is to share information across a network of addiction experts, dispatch a team of rapid response experts to access the outbreak and collect data (including anonymous urine samples provided by criminal justice drug testing), and disseminate the information immediately to the public.



STRATEGY: RISK ASSESSMENT

Drug abuse prevention strategies address a variety of factors but perhaps one of the simplest yet often underutilized prevention methods is to screen patients for risk factors before a prescription is ever written. Quite often, risk assessments can help predict opioid abuse. Several types of screening tools are available to physicians with the most popular being DIRE (Diagnosis, Intractability, Risk, Efficacy score), ORT (Opioid Risk Tool), and SOAPP-R (Screener and Opioid Assessment for Patients with Pain — Revised).

Used in conjunction with a prescriber's clinical assessment and incorporated into a patient's treatment plan, these strategies deliver better patient outcomes. It is important to gain holistic insight into the full medical picture of the patient in order to consider comorbidities and other factors which may put the patient at risk for aberrant drug behavior. Even after screening has occurred and therapy initiated, it is important for the patient to be monitored closely by the prescriber for risks including: early refills requests, depression or anxiety, dose escalations, substance abuse, or unexpected urine drug screen results.

COLLABORATION

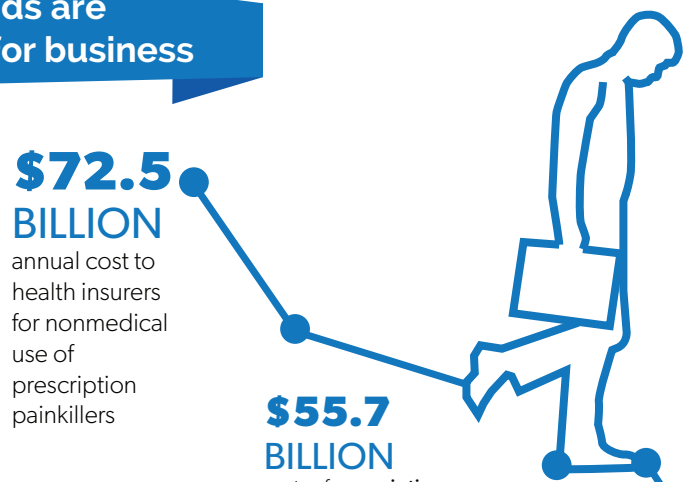
Many strategies exist to prevent opioid abuse but just as many opportunities exist for workers' compensation patients to cross the line towards abuse. From payers to PBMs: patients to physicians: states to the federal government; all stakeholders need to engage in the prevention process in order to prevent the next opioid tragedy. Prevention is not necessarily achieved with a stepwise process. Multiple strategies employed by multiple stakeholders at the appropriate time deliver the best opportunity for breaking the opioid cycle.

WHO IS AT RISK FOR OPIOID ABUSE?

Studies suggest that up to 30% of patients who use opioids become addicted.[16] Patients who are at the highest risk for opioid misuse, abuse and overdose include those who:

- possess a history of substance abuse
- doctor shop to obtain multiple prescriptions
- use high daily doses of prescription painkillers
- misuse multiple abuse-prone prescription drugs
- possess low incomes
- live in rural areas
- have a genetic predisposition for addiction
- suffer from mental illness[17]

Opioids are bad for business



$72.5 BILLION
annual cost to health insurers for nonmedical use of prescription painkillers

$55.7 BILLION
costs of **prescription opioid abuse in** the U.S. in 2007

OF THIS AMOUNT:

25.1 BILLION
healthcare costs
(e.g., abuse treatment)

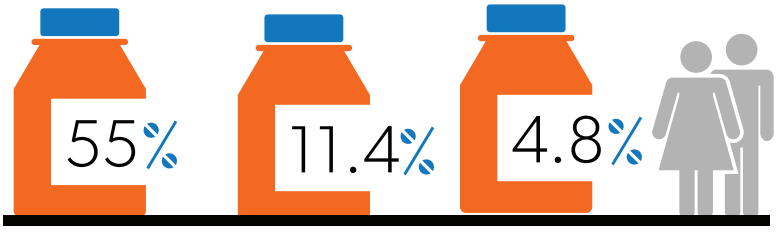
25.6 BILLION
workplace costs
(e.g., lost productivity)

5 BILLION
criminal justice costs

SOURCES: Birnbaum HG et al. Pain Med. 2001;12:657-67; Centers for Disease Control and Prevention (CDC).

The Source

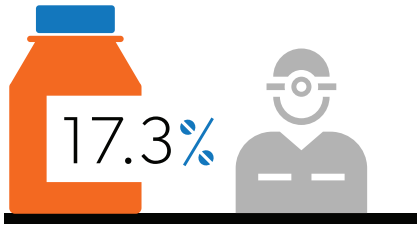
More than **THREE OUT OF FOUR** people who misuse prescription painkillers use drugs **PRESCRIBED TO SOMEONE ELSE**



OBTAINED **FREE** from **friend** or **relative**

BOUGHT FROM a **friend**

TOOK FROM A **friend or relative** without asking



PRESCRIBED BY one **doctor**

RECEIVED FROM **drug dealer** or **stranger**

OTHER

Roughly **20%** of prescribers prescribe **80% of all prescription painkillers**

SOURCES: Substance Abuse and Mental Health Services Administration (SAMHSA); Institute for Pharmaceutical Outcomes and Policy 2010; Dhalla IA et al. Can Fam Physician. 2001;57:e92-6; California Workers' Compensation Institute.

General Drug Abuse

12 MILLION
people reported using prescription painkillers non-medically in the U.S. in 2010.

- **Deaths from drug overdose** have been **rising steadily** over the past two decades and have become the **leading cause of injury death** in the United States.
- Every day in the United States, **113 people die** as a result of drug overdose, and **another 6,748** are treated in emergency departments (ED) for the **misuse or abuse** of drugs.
- Nearly **9 out of 10 poisoning deaths** are caused by drugs.
- **Benzodiazepines** are frequently found among people treated in EDs for misusing or abusing drugs.
- **People who died of drug overdoses** often had a combination of **benzodiazepines** and **opioid analgesics** in their bodies.

SOURCES: CDC; SAMHSA; Paulozzi LJ. J Safety Res. 2012;43:283-9.

Killing more than pain

53% of **drug overdose** deaths in the U.S. in 2011 were related to **pharmaceuticals.**

1.4 MILLION
EMERGENCY DEPARTMENT VISITS
involved the nonmedical use of pharmaceuticals in 2011

301,201 visits were related to ANTI-ANXIETY and INSOMNIA medications

420,040 visits were related to OPIOIDS

OF THOSE DEATHS:

INVOLVED OPIOIDS

INVOLVED BENZODIAZEPINES

SOURCES: CDC; National Center for Injury Prevention and Control.

GETTING UNHOOKED: Opioid Detoxification Is a Necessary Evil in Workers' Compensation

FAST FOCUS

The prevalence of opioid prescribing among injured workers opens the door for misuse and abuse of these narcotic analgesics. While prevention is the foremost goal, successful detoxification employing both pharmacologic and psychosocial strategies offers hope to dependent or addicted patients.

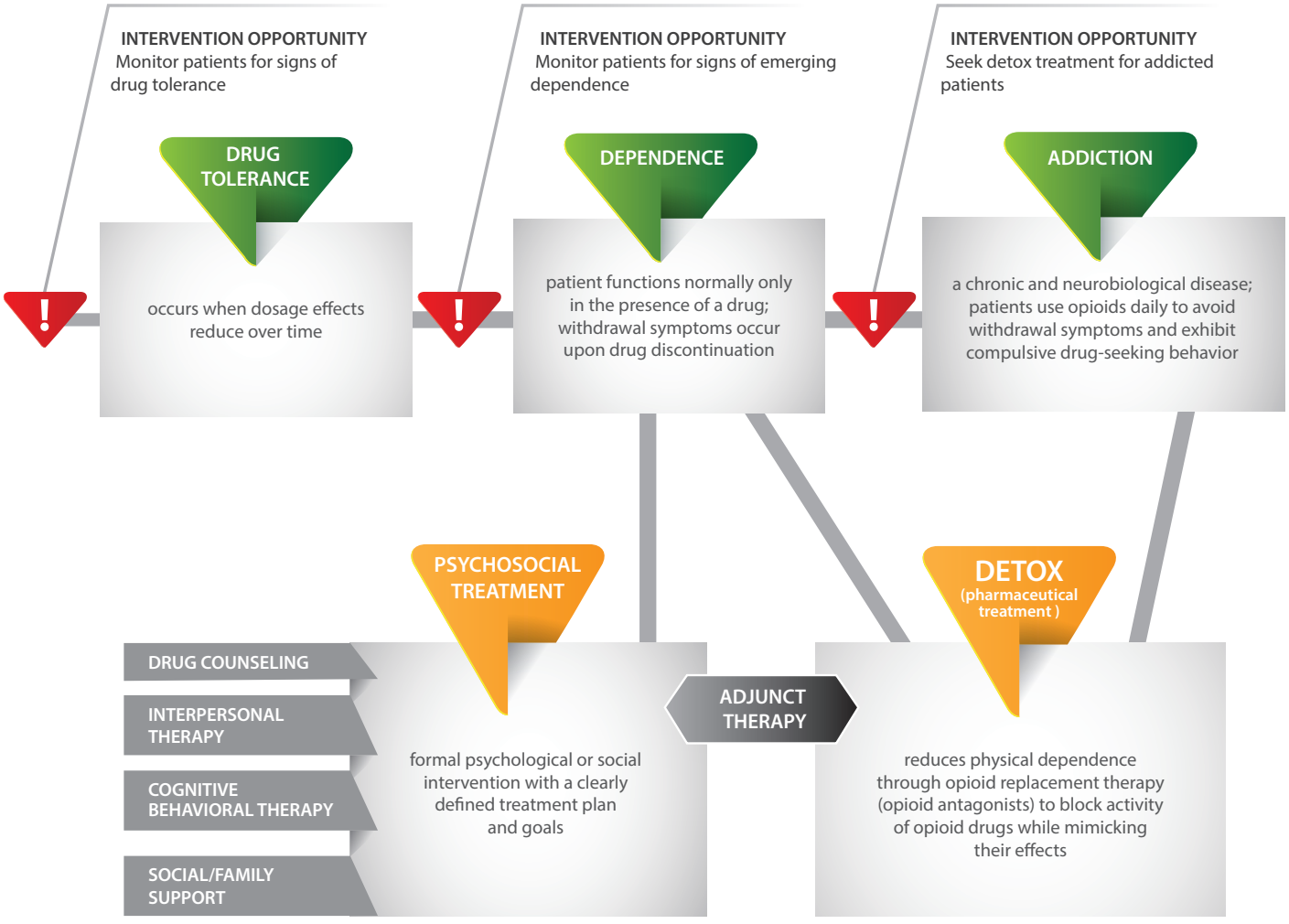
Opioids are a dual-edged sword. While they can be used to manage acute pain associated with surgical procedures, medical conditions or severe injury, medical evidence does not support long-term use.[1] Chronic use of opioids is often associated with extended disability, poor outcomes, and higher medical costs[2,3,4,5] — and yet these powerful pain killers continue to be prescribed. Opioids also offer a significant chance — as high as 30 percent according to some studies — that patients will misuse them.[6]

Opioids are often prescribed to treat pain associated with workplace injuries, and there is benefit (although limited) in short-term use to treat acute pain. However, there is a lack of evidence to support their long-term use, and workers' comp payers often see chronic use of opioids to treat injured workers. In fact, an estimated $1.4 billion is spent annually by workplace insurers on opioids.[7] With the high potential for misuse or abuse of opioids — often leading to dependent or addicted patients — and the strong prevalence of these drugs used in workers' compensation, detoxification sometimes becomes necessary.

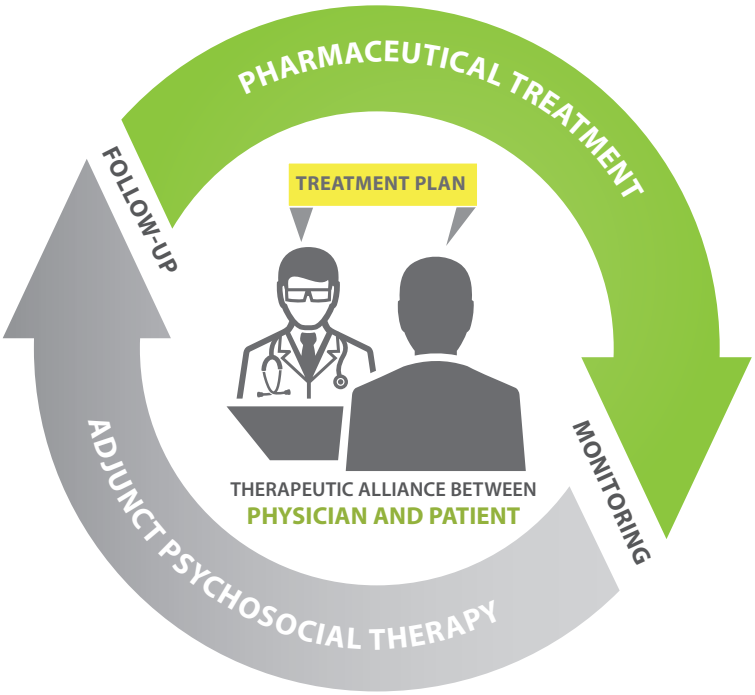
Opioid detoxification, or detox, refers to the process in which a patient who is dependent on opioids is slowly withdrawn from the effects of the drug. The process often involves the administration of medication to relieve some withdrawal symptoms given at a certain dose, and then tapered off. It can also involve psychosocial strategies applied in concert with medication.

The path to detox can be avoided altogether by identifying opportunities for early intervention. Patients who develop a tolerance to opioid therapy may be considered at risk for dose escalation, which can then potentially lead to physical dependence or addiction — resulting in the need for detox. Payers, physicians, and PBMs need to be vigilant about looking for early warning signs such as dose increases, irregular refill patterns (for example, the patient refills their opioid prescription on time, but refills their neuropathic agent late or not at all), switching physicians or pharmacies, lost prescriptions, and other behaviors.

IDENTIFICATION AND TREATMENT OF ABERRANT DRUG BEHAVIOR



THE PATH TO SUCCESSFUL DETOX TREATMENT



OPIOID TOLERANCE

Patients who use opioids for extended periods of time may develop physical tolerance to the effects of the drug, requiring a higher dose to maintain the same level of pain relief.[8] Once a patient has become tolerant to an opioid, discontinuing the drug may result in withdrawal symptoms. These symptoms vary in intensity depending on several factors and can include: insomnia, anxiety, abdominal pains, sweating, shivering, and craving.[9] While unpleasant, opioid withdrawal is not life-threatening. Opioid tolerance is different than dependence and/or addiction. Dependence does not necessarily indicate addiction, however, opioids do have a high potential for addiction.[10]

OPIOID DEPENDENCE

A patient may become dependent on opioids with chronic use. Dependence refers to a state in which a patient functions normally only in the presence of a drug and when the drug is discontinued, withdrawal symptoms occur.[11] Dependence occurs as patients continue taking opioids in an effort to combat the withdrawal symptoms.

OPIOID ADDICTION

Addiction is a chronic and neurobiological disease in which patients sustain long-lasting changes in the brain. Addicted patients use opioids daily to avoid withdrawal symptoms and exhibit compulsive drug-seeking behavior, despite harmful consequences.[12, 13]

In order to safely remove a dependent or addicted patient from opioid use, detoxification can be employed. For patients who are addicted to opioids, detox may be the first stage of a multi-pronged approach to addiction treatment.

Methadone:	**Buprenorphine:**
Methodose and Dolophine®	Suboxone® and Subutex®
Opioid agonist	Partial agonist
Interacts with other respiratory depressants	Interacts with other respiratory depressants
Detox length: Rapid regimens may last seven to 21 days. Slow tapering can last up to six months or longer.	Detox length: May be completed within one week through 14 days, or up to several weeks in some cases.
Lower cost than buprenorphine	Higher cost than methadone

DETOX

Detoxification can safely manage the acute withdrawal symptoms of addiction and can increase the chance for long-term addiction treatment success.[14] Treatment does not end with detox. In fact, detox itself can include many facets including pharmacological, adjunctive psychosocial, and relapse prevention. In addition, many factors influence the success of a multi-faceted detox program, including the therapeutic alliance between a physician and patient and the establishment of a strong social support network.[15]

PHARMACOLOGIC DETOX

The Food and Drug Administration (FDA) has approved the use of pharmacotherapy to treat opioid dependence.[16] This involves the use of opioid agonists and partial agonists such as methadone or buprenorphine. Determining which medication to use depends on a number of factors such as: severity of dependence; current medication use (including illicit drug or alcohol use); comorbid conditions; and other patient-specific concerns. **Methadone**, an opioid agonist, produces minimal tolerance and alleviates cravings; it tends to be a better medication to treat patients who are dependent on high doses of opioids.[17] **Buprenorphine**, a partial opioid agonist, activates receptors in the brain to a lesser degree than a full agonist. It also partially works as an antagonist, allowing for a slight opioid effect, which suppresses withdrawal symptoms and cravings. Both of these drugs carry potential for drug-drug interactions, so coordination of patient care is important. Guidelines suggest that when additional medications are necessary, only the minimum effective dose is given.[18] Methadone and buprenorphine are both Schedule II controlled substances and patients are typically monitored and guided through detoxification closely.

Duration of detoxification with opioid agonists depends on a number of factors and the medication used; it can take several days to several months, or even years. It is also depends on whether detox occurs in an in-patient or out-patient setting. Patients being treated with methadone can typically remain on the drug therapy for several weeks to three years or longer.[19] Using buprenorphine for detoxification is typically faster than methadone and can take days to several weeks.[20] With both drugs, patient adherence is crucial in order to achieve success.

Workers' compensation payers should look for early indicators of drug tolerance and dependence on opioids in order to avoid the hard costs of addiction, such as detoxification, which could involve years of pharmacologic therapy. In addition, early intervention helps payers avoid downstream medical costs that may arise from detox, including the costs to treat symptoms and comorbidities — such as liver damage and respiratory failure.

An integral component to successful detox is the therapeutic alliance between the physician and the patient. The relationship should be positive and supportive so that the prescriber can help motivate the patient to change behavior, as well as gain insight into the social or relationship problems that may be contributing to drug use. Physicians should help patients identify circumstances when they are susceptible to drug misuse and develop healthy coping strategies for the patient to use.[21] Since adherence to pharmacologic therapy is crucial, a strong physician/patient alliance can help foster patient "motivation" to engage in therapy and avoid opioid misuse.

ADJUNCT PSYCHOSOCIAL STRATEGIES

Pharmacologic treatment alone can lead to relapse[22], so detox should be supplemented with psychosocial strategies in order to ensure the highest chances for overcoming opioid dependence or addiction. It is important for workers' compensation payers and physicians to take a holistic and patient-centric approach to analyzing each patient and fully understanding all issues, concerns, and possible comorbidities. For example, a psychiatric comorbidity is common in patients who are addicted and if not understood and treated, this can present a barrier to successful detox treatment.[23] The goal of psychosocial therapy is to:

- Modify behaviors that support addictive behavior
- Encourage adherence to pharmacologic therapy
- Treat psychological comorbidity that may act as a trigger for addictive behavior[24]

The level of intensity in which physicians approach individual goals will vary by patient and the ability to modify patient behavior varies as well.

Some of the more common adjunct psychosocial components added to pharmacologic therapy for the treatment of addiction include:

Cognitive behavior therapy (CBT). The Fall 2013 issue of *RxInformer* refers to CBT as an alternative pain management strategy, and in the case of opioid addiction it attempts to change addictive behavior through changes in a patient's beliefs that serve to support the addiction or by positive motivation to change behavior.[25]

Drug counseling. Counseling aims to support the treatment plan and address psychological issues that may have contributed to or support opioid addiction. It often applies strategies such as patient drug diaries and motivation to encourage successful detox.

Interpersonal therapy. A type of psychological intervention, interpersonal therapy aims to help the patient identify and cope with interpersonal conflicts, grief, loss, and social issues in order to eliminate drug use.[26]

Social support network. There is anecdotal evidence to suggest that patients who positively engage in social support, such as a peer support group or a 12-step program, experience more success in the detox process.

Family support. Family support helps patients understand the effects that their addiction can have on their relationships. The goal of family support is to foster supportive interactions and reduce conflict.[27]

While detoxification is not the end goal for any workers' compensation case, it is, unfortunately, a strategy that occasionally needs to be applied. The nature of workers' compensation injuries often leads to the first prescription of Vicodin, OxyContin or rapid-release fentanyl products (e.g., Fentora, Subsys) — all opioid formulations with a strong potential for causing abuse or addiction. And in many cases that first prescription turns into refill after refill, most times at escalating doses. Physician education into the appropriate use of opioid therapy to treat short-term acute pain should be ongoing, so that these powerful and addictive drugs are not used incorrectly and prescribed chronically. In cases where drug dependence and addiction develop as a result of long-term use, detoxification remains the answer. The ultimate goal for the welfare of the injured worker and the benefit of the payer and employer is return to work, and successful detoxification employing both pharmacologic and psychosocial strategies can deliver this result.

A Tale of Two Chronic Opioid Users

Cindy K., 35 year old female,
physically dependent on opioids

Cindy K. is a 35-year-old factory employee with chronic neck pain due to the repetitive nature of her manufacturing job. Her physician prescribed hydrocodone to help control pain associated with her musculoskeletal disorder while she underwent physical therapy. Unfortunately, well after her six weeks of physical therapy had ended, Cindy was still being prescribed the opioid painkiller. She didn't like the mental "fuzziness" that accompanied the use of the medication and tried to quit taking the hydrocodone on her own. She began to experience insomnia and anxiety, and spoke to her physician about these symptoms.

Cindy had become physically dependent on the opioids and was experiencing withdrawal symptoms. Her physician identified the issue and deployed a detoxification strategy in order to wean Cindy from her dependence on hydrocodone by using buprenorphine to taper her opioid dose. The physician developed a treatment plan for Cindy to address her musculoskeletal disorder and included physical therapy and anti-inflammatories.

Paul H., 42 year old male,
addicted to opioids

Paul H. is a 42-year-old postal employee suffering from lower back pain due to an injury he sustained in the workplace. His physician prescribed Percocet to relieve his pain and scheduled an MRI. Based on the results of the scan, his physician prescribed 12 weeks of physical therapy to address a lower-back muscle strain and renewed his prescription for Percocet. Six months later, Paul was still taking Percocet, but he began to notice that the dose was not managing his pain as well as it had been. He began to increase the number of pills he was taking, and eventually ran out of his prescription early. Paul claimed he had lost his pills while traveling and requested an early refill.

During his next office visit, Paul's physician questioned the early refill request and Paul became agitated and defensive, stating he would find a new doctor who better understood his chronic pain. His physician identified warning signs that Paul may have become addicted to the opioid and recommended detoxification using methadone, CBT, and drug counseling.

ABOUT THE ADDICTED

Americans aged **50 to 69 years**
are the fastest growing population of opioid addicts.

The number of people aged **65 years and over**
who have at some point abused opioids **increased by 34%**
from 2011 to 2012.

About **24 million** Americans — **9.2%** of the population
— used an illicit drug in 2012, up from **8.1%** in 2008.

45% of prescription drug abusers are high school graduates
and **30%** completed some college.

SOURCE: The Changing Face of Opioid Addiction. Medscape.

ONE TOO MANY

A personal perspective

By Deborah Conlon, PharmD, BS Pharm, CPh

As a clinical pharmacist, I am well-versed in the hazards of opioid therapy. There are countless statistics relating to adverse events, opioid overdoses and deaths. In fact, I have recited these figures many times when presenting to colleagues regarding the dangers and the hazards of opioid use. However, statistics are just numbers, until one of those numbers becomes the one that is too many. It became very personal the day one of those numbers belonged to me; when it wasn't just a number, but my loved one. Suddenly, only that one statistic mattered, THE ONE that was one too many for me.

My loved one's injury, like many of the patients we see, started with a lower back strain at work. After one too many times bending over and she sprained her back. This is where the slippery slope began.

Despite the warning signs and red flags that were present that indicated opioids would be hard for her to withdraw from, the opioid prescribing began. Despite conversations about finding alternatives, the doctors continued to prescribe and even increased the doses. Despite the fact that one prescriber started the medications and a new prescriber entered, they were continued. It became another case of "I didn't start them, I inherited this patient."

As the years passed, the doses increased and the side effects increased, but the pain remained and the opioids continued. She was in pain both mentally and physically and chased what she thought was the answer into the bottom of an opioid bottle. Once a vibrant, active, fun-loving woman, she had turned into a depressed, reclusive shell of her former self.

A wake-up call to the severity of the situation came when we received a call about a year ago to report she had been taken by ambulance to the hospital. She was admitted for respiratory failure related to her opioid use. This was when the physician first talked about the need to back down on the opioids because she was having side effects. She had been having multiple side effects for years, signs of hyperalgesia, worsening depression, respiratory difficulties, weight gain, lethargy, difficulty concentrating … but the opioids continued. After the hospitalization for respiratory failure, there was a decrease in dose; however, opioids were continued and eventually the dose surpassed the previous morphine equivalent dose following a joint replacement surgery just six months after her hospitalization.

Detoxification was requested during both hospitalizations, but in California the waiting list is long and difficult to get on, or so we were told. The opioid prescribing continued … we were told they would work on this once she was discharged from the hospital. She never entered a detoxification program.

I was sitting at my desk writing about patient safety concerns related to continued high dose opioid therapy for a back sprain when my phone rang. The call was from a police officer in my loved one's California town. He stated he was sorry have to tell me this way but he was calling to tell me they had found my family member dead in her home. Her cause of death was ruled accidental opioid overdose. Was it accidental? We will never know. All I know is that she had been given a "loaded gun" of opioids for many years and whether she pulled the "trigger" or it was accidental remains unknown.

For me, the battle against reckless opioid prescribing has become very personal. I am no longer just reciting statistics of opioid deaths; I am living with the anger, pain, and grief involved with one of those statistics. To the local coroner, she is just one of the many faces of countless opioid deaths. For me, it was the face of MY loved one, THE ONE that was ONE TOO MANY.

MEDICATION NONADHERENCE:
THE MOST COSTLY DRUG IS THE ONE THEY ARE NOT TAKING

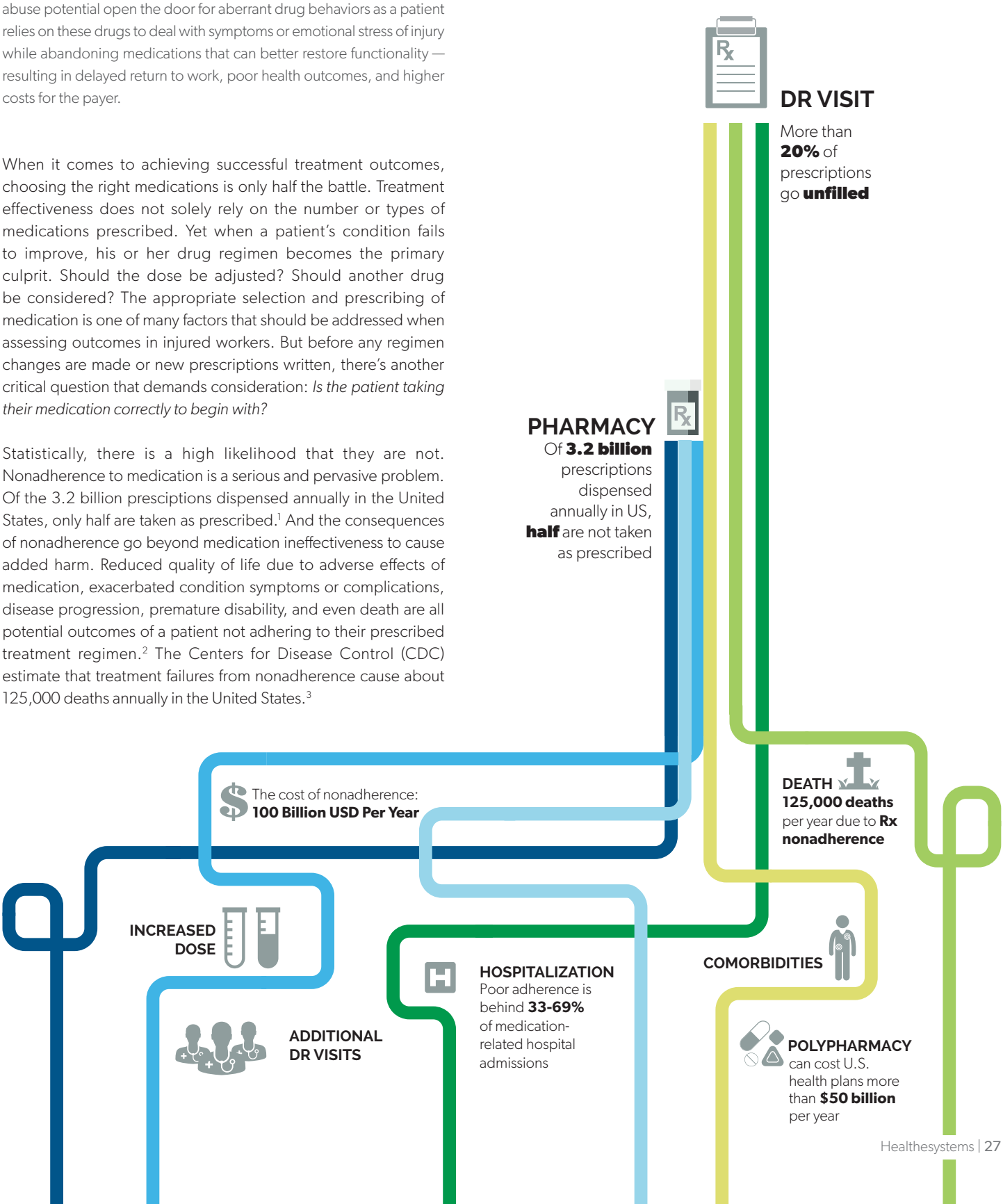
FAST FOCUS

Nonadherence to medication is pervasive across healthcare, and the backdrop of workers' compensation presents unique challenges to consider when managing treatment. Opioids and other products with abuse potential open the door for aberrant drug behaviors as a patient relies on these drugs to deal with symptoms or emotional stress of injury while abandoning medications that can better restore functionality — resulting in delayed return to work, poor health outcomes, and higher costs for the payer.

When it comes to achieving successful treatment outcomes, choosing the right medications is only half the battle. Treatment effectiveness does not solely rely on the number or types of medications prescribed. Yet when a patient's condition fails to improve, his or her drug regimen becomes the primary culprit. Should the dose be adjusted? Should another drug be considered? The appropriate selection and prescribing of medication is one of many factors that should be addressed when assessing outcomes in injured workers. But before any regimen changes are made or new prescriptions written, there's another critical question that demands consideration: *Is the patient taking their medication correctly to begin with?*

Statistically, there is a high likelihood that they are not. Nonadherence to medication is a serious and pervasive problem. Of the 3.2 billion presciptions dispensed annually in the United States, only half are taken as prescribed.[1] And the consequences of nonadherence go beyond medication ineffectiveness to cause added harm. Reduced quality of life due to adverse effects of medication, exacerbated condition symptoms or complications, disease progression, premature disability, and even death are all potential outcomes of a patient not adhering to their prescribed treatment regimen.[2] The Centers for Disease Control (CDC) estimate that treatment failures from nonadherence cause about 125,000 deaths annually in the United States.[3]

COMPOUNDING EFFECTS OF MEDICATION NONADHERENCE[1,4,5]



While patients are suffering, so are payers' pockets. The negative health consequences of missing doses or taking medication inappropriately translates into higher medical costs for payers in the form of excess hospitalizations, extra physician office visits, wasted pharmacy costs and polypharmacy.[2] Beyond workers' compensation, the numbers are staggering: medication nonadherence is estimated to cost the overall health care system and society upwards of $100 billion per year.[1,4]

Simply put, the cost of not following "doctor's orders" is high — both in lives and dollars. However, the reasons for nonadherence are myriad and complex.[4] This holds true across the healthcare spectrum, but workers' compensation presents some additional and unique challenges when it comes to the overall management of drug therapy.

NONADHERENCE IN WORKERS' COMP

Workers' compensation programs are designed to promote functional restoration and return to work by eliminating direct financial barriers to treatment. However, this construct — while altruistic in nature — may give rise to new and different drivers of nonadherence not typically seen in the group health setting.

The lack of financial responsibility for the injured worker can translate to a reduction in self-responsibility. Without the burden of out-of-pocket costs, a patient may become less motivated to follow the treatment plan that best expedites functional restoration and return to work. Instead, the focus of the injured worker becomes palliation, opening the door for selective adherence. The potential for this behavior is strengthened by the very nature of workplace injuries and their associated treatments. Opioids and other medications commonly prescribed under workers' compensation are designed to address symptoms rather than underlying disease conditions. So it is not surprising that a proportion of patients elect to take the medications in their regimen that mask pain, while disregarding therapies that more effectively address healing over the long term (see adjacent sidebar on chemical coping).

Strategies for combating nonadherence in the injured worker population must address psychosocial factors that are unique to the population. Absence of a financial stake in the treatment process poses the risk that a patient will have a lower emotional investment in treatment-related decisions, but there are also non-financial barriers to consider. Injured workers are more likely to suffer depression than their noninjured counterparts — 45% more likely, according to a post-analysis of nearly 368,000 injured and noninjured workers.[6] The feelings of hopelessness that come with depression may contribute to a "why bother?" mindset that deters adherence. This may explain why depression as been shown to impact time to recovery and/or return to work, even in the case of minor injury, as well as increase cost of treatment.[6,7]

Chemical Coping: Too Much of a "Good" Thing

Successful application of adherence monitoring strategies means knowing what to look for. But evaluation of opioid use or misuse is rarely black and white. The population of patients taking opioids is not conveniently split into two groups — those exercising appropriate usage and those who are dependent or addicted.

Chemical coping is a broad term used to describe the expansive gray area between proper, nonaddictive opioid use and addictive behavior.[9,10] Most chemical copers fall somewhere in the middle and take opioids — drugs designed for physical pain — to cope with negative emotions, such as the stress surrounding an injury or life-related challenges.[10,11] Oftentimes, these patients incorrectly perceive their emotional pain as being physical.[12] Chemical copers typically practice selective adherence, relying on opioids as their sole form of treatment. In fact, the most prominent indication of chemical coping is the patient's unwillingness to include nonpharmacologic approaches to care in their treatment.[13]

While chemical copers can include addicts, the two terms are not synonymous. In fact, most chemical copers are not addicted.[12] Addiction is a chronic and neurobiologic disease in which patients sustain long-lasting changes in the brain. Addicted patients exhibit compulsive drug-seeking behavior and use opioids daily to avoid

See *Getting Unhooked* on page 20

withdrawal symptoms, despite harmful consequences.[14,15]

There are some traits that put patients at higher risk for chemical coping, including a history of alcoholism or substance abuse, presence of mental or psychiatric disorder, high emotional expression, or limited coping mechanisms.[13] However, given that chemical coping covers such a large middle ground, there is a need for comprehensive monitoring strategies that can take a variety of factors into consideration.

If chemical coping is determined to be in play, opioid use should be closely monitored, especially during periods of emotional stress. Shorter-term management of chemical coping may include rehabilitative and psychological interventions for providing alternative forms of coping, and simplification of drug regimens that rely primarily on long-acting opioids to avoid "pill popping" with short-acting agents.[11] A multi-disciplinary approach incorporating psychotherapeutic intervention will provide long-term benefits for chemical copers.[13]

DRIVERS OF NON- OR SELECTIVE ADHERENCE IN WORKERS' COMP

- Lack of financial responsibility to injured worker
- Nature of injury (acute, chronic pain)
- A focus on symptoms vs functional restoration
- High-risk medications (opioids, sleep aids)
- Depression or other comorbidities
- Polypharmacy

THE ROLE OF MONITORING IN ADHERENCE

Appropriate medication prescribing and adherence work hand-in-hand to drive successful outcomes. But the two components differ in one crucial aspect: medication regimens may change, but adherence is a constant endeavor. An injured worker may experience medication switches, dose modifications, changes in health condition or quality of life, battles with drug dependence — the potential drivers of nonadherence are numerous. Despite the changes, there remains the need and the expectation for sticking with the treatment plan.

This is a tall order, especially for an injured worker who is facing other challenges such as disruptive changes in lifestyle due to sudden injury and/or loss of function, or the stresses that come with potential loss of income. The World Health Organization (WHO) asserts the position that responsibility for maintaining adherence should not fall fully on the shoulders of any patient.[8] Arguably, this positioning is especially relevant within the injured workers population, which already struggles with inherent barriers to adherence.

Ideally, a strong foundation for successful treatment may be established through the physician-patient relationship. While it is the physician's role to prescribe, adherence to these medications is best achieved through a collaborative approach in which there is shared responsibility; meaning that patient and physican are equally accountable for ensuring that the treatment plan is being followed.

This sharing of responsibility, however, should not be limited to physician and patient. Other stakeholders, such as a pharmacist or a pharmacy benefits manager — can and should play a role in monitoring and managing adherence. **The unique challenges of workers' compensation and the risks these challenges pose to adherence further underscore the critical role of an ongoing and inclusive approach to monitoring**.

Singular monitoring practices, such as reviewing prescribing history, provide only a narrow view of a patient's case. Pharmacy records provide refill patterns, which can help identify early or late refills that may suggest inappropriate adherence patterns. Drug screenings can indicate the presence of prescribed drugs with abuse potential, as well as non-prescribed or recreational substances that may detract from adherence to the prescribed treatment plan. While these are valuable pieces of information, on their own they are just that — pieces. The best approach is to use a combination of monitoring practices in order to form a more complete picture of patient adherence.

TURNING INFORMATION INTO ACTION

Comprehensive data exist, but become meaningful only with the proper analysis and follow-through. Therefore, it comes as no suprise that the most effective evaluations are rooted in cross-functional review and communication. A conversation between physician and payer can uncover concerns that may be undocumented or unclear in the paper trail. A clinical pharmacist can lend their expertise through a regimen review to identify unnecessary polypharmacy or other complexities in drug regimen, providing guidance to the prescriber.

Above all, every patient is unique. There is no one-size-fits-all approach to drug adherence monitoring or overall treatment management. The most appropriate combination of monitoring practices should be applied to a given case in order to obtain relevant and actionable information.

Turn to page 30 for a more in-depth look at holistic patient management.

Drug adherence monitoring is just one aspect of managing overall treatment for injured workers.

MISSING THE BIG PICTURE?

HOLISTIC PATIENT MANAGEMENT MEANS ...

WORKING **SMARTER**, NOT HARDER, TO IMPROVE OUTCOMES

FAST FOCUS

While the workers' compensation industry has made efforts toward a global or holistic approach to patient management, there remains continued opportunity for innovation and improvement. A comprehensive, integrated set of tools and strategies can effectively address the fluctuating medical needs of the injured worker while containing costs.

The goal of treatment in injured workers is straightforward — to restore function to the patient, thereby enabling return to work. But the path to getting there is often complex. The course of a patient's condition is rarely, if ever, a straight one. A step toward improvement can be countered with a setback. Complicating factors, such as comorbidities, adverse drug reactions or psychosocial influences, may cause an unexpected diversion from the treatment plan.

MANEUVERABILITY ALONG THE CONTINUUM OF CARE

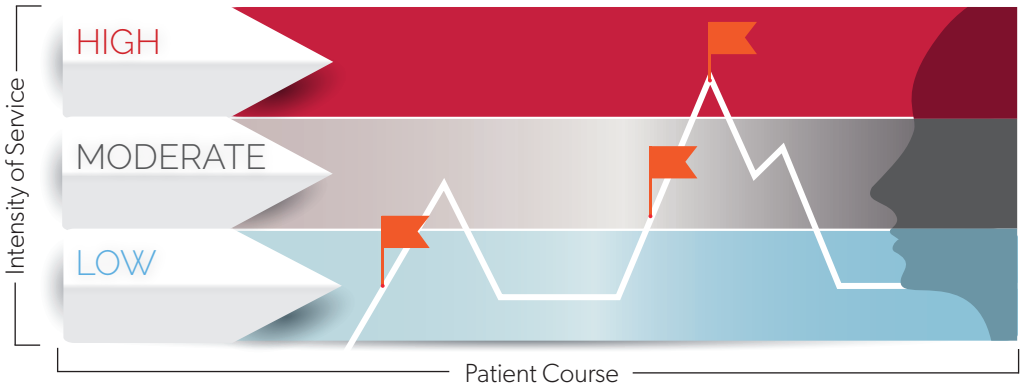
Successful outcomes rely on a treatment approach that can course-correct with equal flexibility. The ability to maintain synchronicity with the needs of an injured worker by delivering the appropriate treatment at any given point of the care continuum is the key to success.

This means recognizing when to intervene, and applying the appropriate level of intervention. The right information is needed in order to make the best treatment decision, and the complexity of the case determines the intensity of service required to uncover this information. No two patients are alike, and each will require different levels of intervention over the course of their condition. The ability to adjust accordingly, to focus the highest intensity of service on the most complex claims and tailor back for less complex ones, enables the highest level of quality care across the spectrum.

ADOPTING A HOLISTIC APPROACH

The ability to deliver a flexible and customizable approach to patient care requires a more holistic view than historically has been performed. For example, too often, clinical analysis and recommendations are based on a single aspect of a patient's medical profile — such as their medication history. But applying a one-dimensional measure of evaluation simply leaves too much ground uncovered to make the most informed treatment recommendation at a given time. There are many variables within a patient's history, aside from drug regimen, that a prescriber may be overlooking or even unaware of that can impact safety and effectiveness of the treatment regimen. Consider a patient successfully managed on Vicodin — until it's discovered that their liver enzymes are dangerously high. A review of their drug therapy may uncover if any other acetaminophen-containing products are part of the mix. But it won't

CONTINUUM OF CARE: INTENSITY OF SERVICE CORRESPONDS TO FLUCTUATING RISK LEVEL



EXAMPLES OF FLUCTUATING RISK may include:

MED increase

Comorbidity identified

Non-adherence

Inappropriate prescribing

uncover the bout of Lyme disease the patient had six years prior that contributed to underlying liver damage. This type of critical data can only be found by digging deeper. Therefore, additional evaluation strategies are needed to obtain a more complete picture of the patient in order to understand the full context of any clinical decisions.

However, improvement in care doesn't just mean doing more. It means doing *better*. Application of these multiple strategies is only effective when part of an integrated approach. Collectively, the information is out there, but fragmentation of knowledge among stakeholders renders it useless, as no one party has consistent visibility into the overall patient. This becomes dangerous as medication decisions are being made based on assumptions or partial information. The absence of key information, even just one piece — a comorbidity, a potentially fatal drug-drug interaction — can lead to negative consequences. At best, treatment ineffectiveness. At worst, hospitalization or even death. The left hand must know what the right hand is doing in order to ensure the safety and well-being of the patient.

INTEGRATING CLINICAL KNOWLEDGE WITH TECHNOLOGY

Healthesystems' comprehensive suite of clinical and analytics services supports a holistic approach to patient management by providing solutions across the continuum of care, from automated interventions, including prior authorizations, medication plans and alerts, to enhanced clinical decision support.

Based on program outcome results, Healthesystems identifies that approximately 8 to 9 out of 10 claims are lower severity and can be efficiently and effectively managed through lower-intensity services offered by Healthesystems' innovative technology solutions and analytics tools.[1] The remaining population represents highly complex claims that drive the majority of spend, although they represent a small portion of patients. For this reason, these patients are recommended for a more customized, comprehensive clinical assessment to uncover potential complicating factors such as the presence of comorbidities or psychosocial and behavioral concerns, indicators of nonadherence, or prescribed drug therapies that may be inappropriate for their medical needs. While an initial review of their medication profile may prove valuable in identifying these potentially high-risk patients by uncovering the presence of high opioid use or dangerous drug combinations, this information is just the tip of the iceberg. An analysis of full healthcare records reveals a much larger picture, and often uncovers underlying concerns that impact the medication regimen and overall treatment plan:

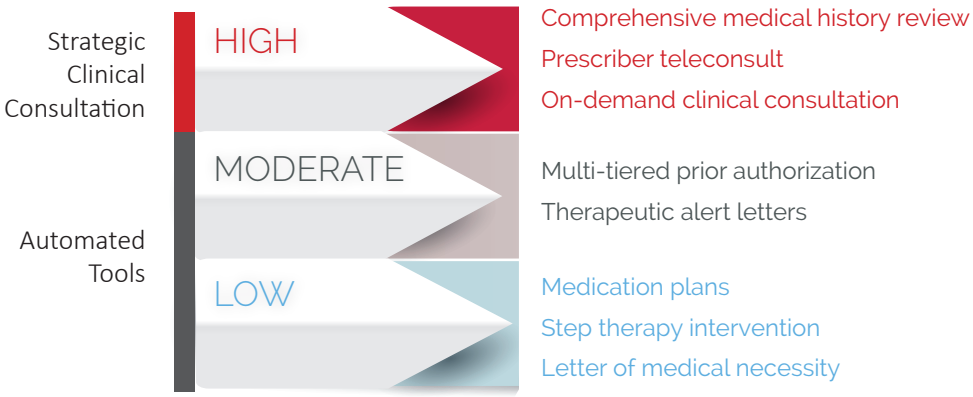
Is the patient showing signs of nonadherence to therapy?

Did the doctor note lack of improvement based on the current treatment regimen?

Was a urine drug screen conducted?

More often than not, the answer to these questions is YES.

SERVICES ALONG THE CARE CONTINUUM



In fact, approximately **3 out of 4 claims** evaluated through Healthesystems' enhanced clinical decision support services **revealed a complicating factor** beyond the original prescription concern.

Complicating factors most commonly identified during medical history review:

URINE DRUG SCREEN CONDUCTED 48-75%

COMORBIDITY 50-58%

INAPPROPRIATE MEDICATIONS 25-33%

Psychosocial/behavior concerns 35-58%

Nonadherence 25-33%

The presence of each of these may pose a direct or indirect threat to treatment outcomes — threats that would not have been uncovered in a review of prescription history alone. For example, a urine drug screen — which was identified in a least half of reviewed cases — may indicate potential abuse. A next step would be to evaluate the results of this test, and determine what actions should be taken based upon those results.

Comprehensive clinical analysis offers critical insights that can help change the trajectory of a claim. In approximately 70% of claims reviewed, more than one complicating factor was present within an individual claim, further compounding the complexity and subsequent risk.[1] Now that these complications have been brought to light, action can be taken:

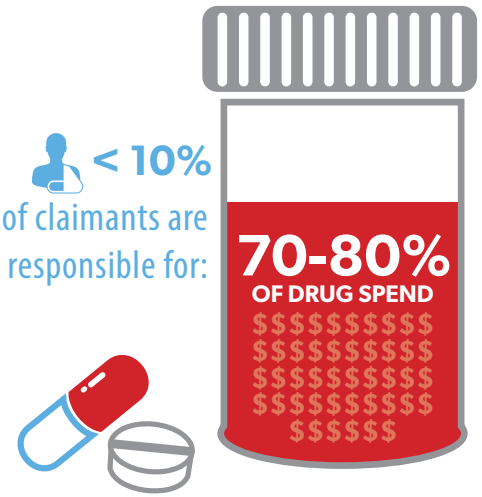
- an unnecessary and potentially dangerous medication is removed from the regimen;
- psychosocial therapy is included to address non- or selective adherence;
- the medication regimen is modified to address drug-disease interactions regarding an existing comorbidity.

MORE INFO

To learn more about how Healthesystems' enhanced clinical decision support is changing the way clinical intervention has historically been conducted and delivered, visit www.healthesystems.com.

QUALITY CARE LEADS TO QUANTIFIABLE OUTCOMES

A customized and patient-centric approach to care that prioritizes safety and appropriateness of treatment will positively influence health- and cost-related outcomes over the long term. Identifying opportunities for intervention early in the course of a patient's condition and taking action to address potential threats can help manage snowballing costs resulting from symptom progression, new or existing comorbidities, unnecessary or potentially dangerous medications, and increased number of physician office visits and hospitalizations. It is these factors — factors that can often be prevented or proactively addressed — that can drive costs across an entire population; typically less than 10% of injured worker claimants are responsible for 70-80% of drug spend. Even just one complicating factor can have a significant impact. Consider the effect of comorbidity on outcomes; a study of injured patients with comorbid depression were less likely to return to pre-injury function and/or work status when compared with their non-depressed counterparts.[2] Proactive management of complicating factors such as comorbidities, psychosocial issues, or nonadherence can have a measurable impact on cost; and for this smaller but very complex population, the effort and resources put into comprehensive evaluation and subsequent clinical decision-making can translate into exponential payoff.



COMPOUNDING TRENDS
ARE CAUSE FOR CONCERN

FAST FOCUS

Emerging trends in compounding ingredients bring unwarranted costs and new potential for risk.

The safety concerns surrounding compound medications are well reported in the media — from a 2012 fungal meningitis outbreak caused by an injectable steroid made at a compounding pharmacy to the tragic death of an infant in 2014 due to exposure to a topical medication. Healthesystems has often reported the serious safety concerns associated with compounds including questionable quality control measures, adverse systemic events related to absorption, and lack of proven efficacy.

See past Healthesystems articles: *Compounds: The Topical, Transdermal and Oral Debate*, *RxInformer* Fall 2012; *Topical Analgesics: Expensive and Avoidable*, *RxInformer* Fall 2013; *Topical Compounds and Safety Concerns*, *RxPostscript* September 2014.

CORTICOSTEROID POWDER INGREDIENT TRENDS

Less examined are fluctuating ingredient trends found in compound medications that can have a profound impact on cost. A recent Healthesystems clinical analysis uncovered the increased use of certain corticosteroid powders that are quite expensive. Corticosteroid fluticasone powder has recently seen increased use in compound medications with an Average Wholesale Price (AWP) of $3,000 to $4,200 per gram, depending on the National Drug Code (NDC) submitted. A comparable ingredient with a significantly lower cost is triamcinolone with an AWP of $20 to $95 per gram, depending on the NDC submitted. Another comparable corticosteroid powder with a slightly higher cost than triamcinolone is Clobetasol powder with an AWP of $150 to $600 per gram. All of these corticosteroid powders are similar with the major differentiating factor being their cost.

COMPARABLE CORTICOSTEROID POWDERS

FLUTICASONE

AWP
$3,000 - $4,200/g

TRIAMCINOLONE

AWP
$20-$95/g

CLOBETASOL

AWP
$150 - $600/g

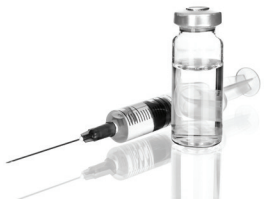
NSAID INGREDIENT TRENDS

Our clinical analysis also revealed the recent emerging use of a non-steroidal anti-inflammatory (NSAID) ingredient, ketorolac. Toradol, the brand name medication containing this NSAID ingredient, has been billed using varying NDCs, with a vast discrepancy in price from an AWP of $150 per gram to $3,000 per gram. Compared to Voltaren 1% gel billed at an AWP of 50 cents per gram or diclofenac bulk powder with an AWP of approximately $15 per gram, a compound medication containing Toradol can cost upwards of 200 times more than equivalents.

The practice of inflating the costs of compound ingredients is not new to workers' compensation, yet trends pertaining to the continued use of specific ingredients continue to evolve. In all instances, due to safety concerns, lack of proven efficacy, and inflated costs, compound medications should only be used when medically necessary.

COMPARABLE NSAID PRODUCTS

TORADOL



AWP
$150-$3,000/g

VOLTAREN 1% GEL

AWP
$.50/g

DICLOFENAC BULK

AWP
~$15/g

SPECIALTY PHARMACY MEDICATIONS:

DRUG INNOVATIONS OFFER GREAT PROMISE AT HIGH COST

FAST FOCUS

The growing presence of specialty medications within workers' compensation introduces a new set of complexities to medication management. Careful patient selection will contain costs while ensuring appropriate care; however, the limited clinical experience surrounding these novel agents will make it difficult to weigh potential benefits against cost.

The workers' compensation industry is already seeing some instances of specialty pharmacy treatments in limited patient populations. As this segment of the pharmaceutical industry continues to evolve, it is becoming even more important for payers to develop proactive strategies to monitor the appropriate use of these costly medications. A precautionary yet strategic effort to address specialty medications can better equip workers' comp payers to manage future and ongoing research and development, as evidenced by the large number of specialty drugs in the medication pipeline.

Similar to the manner by which other medical trends in workers' compensation began, such as compounds and opioid prescribing, specialty pharmacy represents a small yet growing portion of todays injured worker population. This area of innovative pharmaceuticals is focused on the treatment of complex conditions that previously had fewer, if any optimal therapeutic options. However, they also have the potential to significantly raise overall workers' compensation prescription costs. Discussed in depth in the Spring 2014 issue of Healthesystems' *RxInformer* journal, specialty medications are one of the biggest cost concerns for the healthcare system today, as costs can top several hundred thousand dollars annually for a single patient.[1]

Signs of this burgeoning segment of the pharma industry are evident in group health. Spending on specialty medications has grown to represent 15 to 20 percent of overall prescription expenses, with a small percentage of patients driving nearly 20 percent of overall costs. This is expected to increase 30 percent over the next five years as new and innovative products enter the market.[2]

Cumulative specialty drug spend in 2012 in the United States was approximately $87 billion. Some pharmacy experts suggest it could quadruple by 2020 reaching $400 billion.[3]

The U.S. Food and Drug Administration's (FDA) approval of specialty pharmaceuticals has outnumbered those for traditional medications in the last two years. Currently, more than 5,000 new specialty medications are in the global pipeline.[4] Another factor which may expedite specialty medications into the market is the FDA's new Breakthrough Therapy Designation intended to fast track new medications for serious or life threatening conditions by speeding up approval from ten years to only two. [5]

COST COMPLEXITIES

Typically, new medications entering the market tend to be expensive. Often, traditionally developed medications eventually become less costly when a generic is available. The trajectory for specialty medications, however, is different. Their cost is significantly higher for several reasons, most notably because of the complex manner in which they are manufactured. In addition, compared to traditional drugs, there often are no alternatives to specialty medications, and currently no biosimilars exist for these agents. Specialty medication often requires different routes of administration which also add to the cost of the total treatment. And, because the conditions treated with these medications are complex, so is the corresponding medication regimen which may involve multiple medications and more diverse dosage forms, increasing cost.

An example of the cost complexities of specialty medication is found with the drugs Sovaldi and Olysio. These medications are 90 percent curative for hepatitis C, which gradually damages the liver and affects three to four million Americans. A treatment regimen using Sovaldi can cost $84,000 to $168,000 per patient.[6] Sales of Sovaldi have reached nearly $6 billion for its first two quarters on the market — breaking pharma industry records for a new medicine.[7]

To illustrate the cost impact of this treatment, consider an employer treating six employees who contracted hepatitis C as of a result of work-related incidents; the treatment regimen costs could be as high as $1 million using Sovaldi or Olysio. However, the benefit of these medications are quite promising for saving lives and preventing liver transplants, which has led some experts to predict that hepatitis C will be rare by 2036.[8]

In the case of hepatitis C where early treatment can significantly improve outcomes, some cost relief may be on the way. In October of 2014 the FDA approved a new specialty combination drug called Harvoni to treat this condition. It is the first and only hepatitis C treatment to provide a complete regimen in a single tablet. The recommended treatment is one orally administered tablet taken daily for a duration of 12 or 24 weeks.[9] The medication itself is more expensive than Sovaldi but some patients have only required a shorter duration of eight weeks, at a cost of approximately $63,000.[10]

INFUSION & INJECTABLE THERAPIES

In workers' compensation, infusion therapy, or medication administered through a needle or catheter, may play a role in treating various complex conditions such as rheumatoid arthritis, osteoarthritis, hepatitis C, and other conditions. Infused medication is typically administered intravenously, but it can also refer to intramuscular injection and epidural injection. The types of infusible medications vary and can include corticosteroids, antibiotics, chemotherapy, pain management, and newer biologics such as immunoglobulin.

Infusion therapy can be performed at home, at an infusion center, in a physician's office, or in a hospital setting. However, according to one study, infusions are increasingly occurring in the hospital setting, where costs are the highest.[11]

Injectable specialty medications can be self-administered or administered by a healthcare professional. Medications such as Synvisc®, Orthovisc® and Euflexxa® occasionally are seen within the workers' compensation patient population. All of these aforementioned drugs are indicated for the treatment of pain in osteoarthritis (OA) of the knee. These injections can exceed $1,000 per single joint treatment.[12]

Self-injectable biological agents such as Humira® or Enbrel® are also occasionally seen in workers' compensation and these drugs are indicated for treating moderate to severe rheumatoid arthritis (RA) symptoms. Costs associated with these treatments can be over $2,000 per patient per month.[13]

Other drugs to manage this condition, which are close to approval by the U.S. Food and Drug Administration (FDA) include the RA vaccine Ravax®, sarilumab and secukinumab, a IL-17 inhibitor.[14] In total, there are currently 92 medicines in development for arthritis, including 55 for RA and 10 for OA. See RA/OA Medication in Development by Phase graphic below.

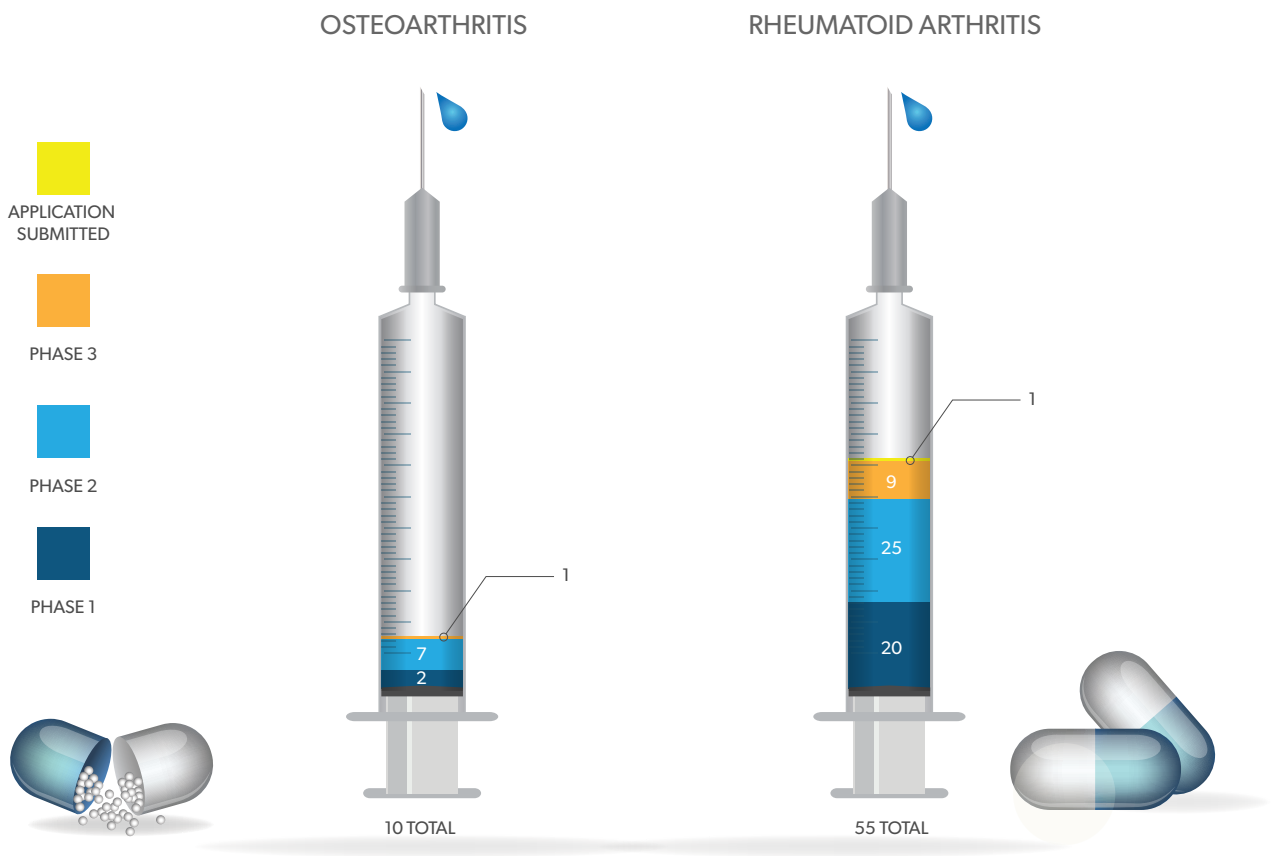
Proactive clinical intervention is most effective toward achieving optimal outcomes resulting in appropriate cost containment.

TOOLS AND STRATEGIES

Specialty medications offer new opportunities for treating injured workers with complex conditions. Payers need to consider a balanced approach, weighing the potential patient benefits with the high costs often associated with these products, and proactively develop strategies to manage this evolving trend.

Some group health drug benefit companies are excluding coverage of these drugs in order to manage costs, but wholesale refusals are not possible in the workers' compensation system. Therefore, it is critical to ensure specialty medication therapies are medically appropriate and adhered to from the onset.

MEDICATION IN DEVELOPMENT BY DISEASE AND PHASE



NOTE: Not all OA and RA medications in development are injectable.

Healthesystems applies its Specialized Transaction & Alternative Therapy (STAT) approach to ensure that appropriate therapy is balanced with cost. Timely clinical analysis of pharmacy transaction and billing data are conducted to identify concerns such as the selection of the most effective, evidence-based drug, as well as the correct dose, medication adherence, and treatment outcomes. Specialty medications can be identified and addressed according to each payer's unique needs.

ADHERENCE PLAYS A ROLE

Specialty medications, similar to all other medications, need to be prescribed appropriately and close clinical evaluation can ensure evidence-based guidelines are followed. Adherence to therapy is especially critical for many specialty medications.

It is important to understand that not only are specialty medications different than their traditional counterparts, but patients taking specialty medications are different, too. Their complex conditions often involve medications with different routes of administration and their medical treatment may involve more specialist visits, more hospital admissions, as well as more lab tests; in addition, these patients are often faced with more severe side effects resulting from their treatment regimen with specialty medications. Ensuring that the injured worker adheres to treatment is important to fostering successful outcomes.

Nonadherence can certainly add to medical costs with researchers estimating the cost to the overall healthcare system and society at upwards of $100 billion per year.[15]

For more information on medication adherence, see page 26

With some specialty medication regimens, patients who do not adhere and complete therapy can develop resistance, rendering treatment reintroduction to be potentially ineffective. For example, nonadherence to a particular HIV medication therapy is closely associated with incomplete viral suppression and disease progression and is thought to be a risk factor for the development of drug resistance.[16] In other cases, where reinitiating treatment is possible, it becomes more costly to pay for subsequent treatments.

Nonadherence compounds an already costly medication regimen. While specialty pharmacy medications continue to show promise in treating and curing illnesses, they are quite complex and costly. Ensuring appropriate prescribing and carefully applying proven medical cost containment strategies will help ensure both patient safety and effective cost containment for payers.

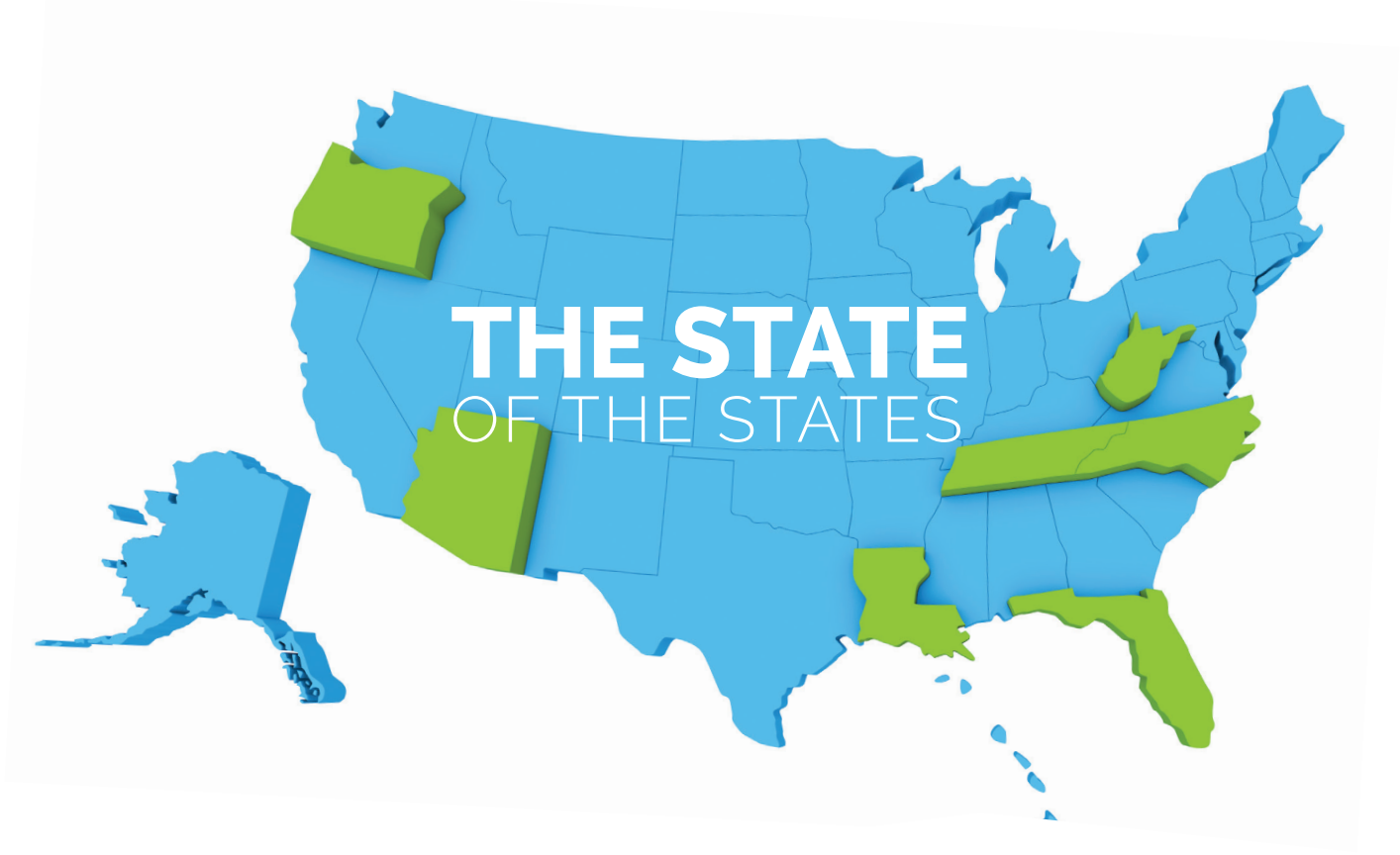
For patients already faced with a complex medical condition, nonadherence can lead to:

Additional physician visits

Additional hospital admissions

Additional prescriptions

Emergency department visits



NORTH CAROLINA
Pharmacy Fee Schedule Enacted

On August 7, Governor Pat McCrory signed Senate Bill 744, changing the workers' compensation landscape in North Carolina by implementing the state's first workers' compensation pharmacy fee schedule. The pharmacy fee schedule language was added to the state's budget bill (Senate Bill 744) as a late amendment on July 30, shortly before the bill's passage on August 2. The fee schedule caps payment for prescription drugs dispensed to injured workers at 95% of the Average Wholesale Price (AWP), calculated on a per-unit basis as of the date of dispensing. Payment for physician-dispensed drugs is also capped at 95% of the AWP set by the original manufacturer of the drug, as identified by its National Drug Code (NDC). Claims for physician-dispensed drugs that do not include the original manufacturer's NDC are limited to 100% of the AWP of the least expensive clinically equivalent drug. In addition, the bill limits reimbursement for physician-dispensed Schedule II and Schedule III controlled substances to an initial five-day supply for each physician who treats the injured worker, beginning with the worker's initial treatment following injury. The pharmacy fee schedule became effective on August 7, 2014.

The North Carolina Industrial Commission is working toward adopting rules that will make some clarifications regarding the fee schedule. Healthesystems has provided input for that process.

The full text of Senate Bill 744 may be viewed at www.ncga.state.nc.us/Sessions/2013/Bills/Senate/PDF/S744v9.pdf (see page 148 for the pharmacy fee schedule language).

ARIZONA
Industrial Commission Drafting Medical Treatment Guidelines

In July, the Industrial Commission of Arizona (ICA) released for public comment a first draft of a rule outlining a process for utilizing medical treatment guidelines. The ICA is required to develop state-specific, evidence-based treatment guidelines by the end of 2014 in accordance with Arizona Revised Statute § 23-1062.03. The ICA has indicated that new treatment guidelines would be mandatory for treating chronic pain or using opioids and would otherwise identify care that is generally considered reasonable. Carriers and self-insured employers would be required to pay for treatment and services defined as reasonable under the treatment guidelines, and no preauthorization would be required to ensure payment for such treatment and services. Providers could seek preauthorization in cases where treatment or services deviate from or are not addressed in the adopted guidelines.

While the draft rule focused on process, the work is ongoing with the understanding that rulemaking will ultimately specify ODG treatment guidelines.

The ICA accepted public comments on the proposed treatment guidelines at a July 28, 2014 meeting, and on September 29, 2014, the Director's Advisory Committee for Evidence Based Medical Treatment Guidelines met to discuss the guidelines, as well. This committee was established in 2012 to make recommendations to the ICA with respect to the statutory requirements to establish evidence-based treatment guidelines for injured workers.

Healthesystems has been actively involved in discussions on the proposed guidelines and has provided comments to the ICA regarding potential impacts the treatment guidelines may have on injured worker treatment and pharmaceutical billing.

FLORIDA

Proposed Revisions to Medical Billing and Reporting Rule

In early June, the Florida Division of Workers' Compensation (DWC) proposed revisions to the workers' compensation medical services billing, filing, and reporting rule, 69L-7.710 F.A.C. The proposal rewrites and reorganizes the rule into five separate rules. The proposal includes specific billing instructions for repackaged drugs, clarifying the use and placement on billing forms of original and repackaged National Drug Codes (NDCs). It also adds new, and modifies existing Explanation of Bill Review Codes for use in describing reimbursement decisions involving repackaged drugs. Additional provisions of the proposed rule adopt the CMS-1500 version 02/12 billing form and the 2014 Medical EDI Implementation Guide, Revision F. The proposed Revision F retains and updates the DWC's proprietary (non-standard) format for state reporting.

The DWC conducted a public rule development workshop on June 18, 2014; however, at present, no estimated timeframe for adoption of the revised rule is available.

The Notice of Development of Rulemaking and the proposed text may be viewed at https://www.flrules.org/gateway/View_Notice.asp?id=14637608.

LOUISIANA AND WEST VIRGINIA

Legislative Action to Limit Opioid Use

With prescription drug abuse and overdose deaths on the rise, several states are trying to take control of the epidemic. West Virginia and Louisiana have taken legislative steps this year to reschedule certain opioids in order to help curb their use. West Virginia House Bill 4208 went into effect June 6, 2014, and moved hydrocodone from a Schedule III controlled substance to a Schedule II and tramadol from unscheduled status to a Schedule IV controlled substance. Louisiana's Senate Bill 618, effective August 1, 2014, moved carisoprodol from a Schedule III controlled substance to a Schedule II. Both bills passed their respective legislatures without a single nay vote and were quickly signed by the states' governors. The reclassification will provide tighter controls on hydrocodone and carisoprodol, as they are now required to adhere to federal and state-specific Schedule II restrictions that include a 30-day supply limit with no refills.

Tramadol's entry into a low-tiered schedule means patients will be limited to five refills in a six-month prescription, and prescribers in West Virginia now are responsible for reporting prescribing and dispensing information for this drug to the state's Prescription Drug Monitoring Program (PDMP).

In Louisiana, a prescriber is required to access the PDMP prior to initially prescribing any Schedule II controlled dangerous substance to a patient. The recent legislative action means that this requirement will now apply to carisoprodol.

TENNESSEE

Governor Introduces Statewide Plan to Reduce Prescription Drug Abuse

Prescription drug abuse — specifically, abuse involving opioids — is a pervasive, multi-dimensional issue impacting individuals, families, and communities, and it has become an epidemic in Tennessee. In order to combat this epidemic, Governor Bill Haslam introduced a plan this year to prevent and treat prescription drug abuse in the state. Referred to as "Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee," this program involves a number of different state agencies working together to reduce the misuse and abuse of prescription drugs. The strategic plan was developed by the Tennessee Department of Mental Health and Substance Abuse Services in collaboration with sister agencies impacted by the prescription drug epidemic. Numerous recommendations are provided in the plan, including the development and adoption of opioid treatment guidelines by the Department of Health, improved use of the state's Controlled Substance Monitoring Database, and the passage of legislation enhancing laws governing pain management clinics. Other efforts to help curtail prescription drug abuse include prescriber and dispenser information sharing across state lines. The Department of Health is currently working with other states to create a prescription drug alliance in order to share prescriber and dispenser information from each state's PDMP. Without information from other states' PDMPs, it is impossible to get a full picture of the types of drugs that individuals are being prescribed.

Details can be viewed on the Tennessee Department of Mental Services and Substance Abuse Services website at http://tn.gov/mental/prescriptionforsuccess/Prescription%20For%20Success.pdf.

OREGON

Healthesystems Goes Live with EDI Release 2.0 Reporting for Medical Bill Payment Records

On June 10, 2014, the Oregon Workers' Compensation Division (WCD) announced that it was pushing the July 1, 2014 effective date for the use of release 2.0 of the International Association of Industrial Accident Boards and Commissions (IAIABC) EDI rules for reporting medical bill payment records out to October 1, 2014. This was followed by a WCD announcement on August 4, 2014 that insurers would be required to report under EDI release 2.0 no later than January 1, 2015, and that the WCD would not impose civil penalties against insurers who did not meet the October 1 deadline until March 2015. Each of the changes in effective dates for the EDI Release 2.0 rules, as well as the postponement of penalties against insurers, were made to accommodate carriers who were still in the process of programming and testing their systems to use the new release.

Healthesystems' efforts to implement EDI release 2.0 for Oregon medical bill payment reporting began in early 2013 and culminated on October 1, 2014, with the implementation of the systems necessary to report bills using the new requirements.

BY THE NUMBERS

ADHERENCE MATTERS

Rx QTY: 3.2 BILLION
PRESCRIPTIONS DISPENSED ANNUALLY IN THE U.S.

ONLY HALF ARE TAKEN AS PRESCRIBED.

REFILLS: 0

Pharmacy

SOURCE: Osterberg L, Blaschke T. Adherence to medication. N Engl J Med. 3005;353(5):487-97.

The Centers for Disease Control estimate that **treatment failures** from **nonadherence** cause about

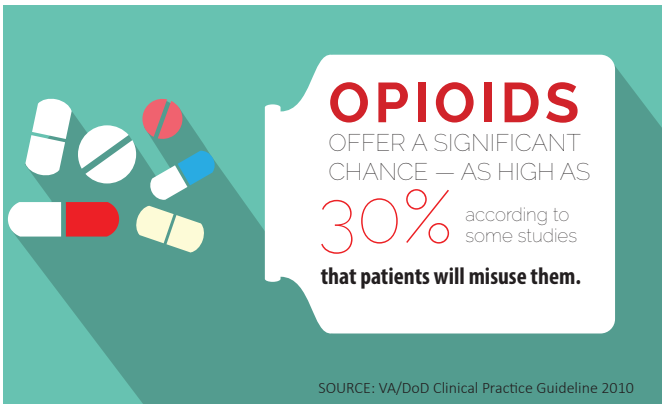
125,000 Deaths
ANNUALLY in the U.S.

SOURCE: Centers for Disease Control (CDC) 2013

OPIOIDS

ONE.4 BILLION
IS SPENT ANNUALLY BY workplace insurers on OPIOIDS

SOURCE: THE NEW YORK TIMES



SPECIALTY PHARMACY

Specialty drugs comprise **15-20%** of RX expenses, with a projected **↑30%** over the next 5 years.

Spending on specialty drugs in 2012 in the U.S.
~$87 billion
with predictions of **$400 billion by 2020.**

SOURCE: IMS Institute for Healthcare Informatics 2013; CVS CAREMARK

When a complex treatment regimen is in effect,

Healthesystems
HAS DEMONSTRATED A SAVINGS OF
$400/script
BY EMPLOYING A
MULTI-TIERED
AUTHORIZATION PROCESS

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