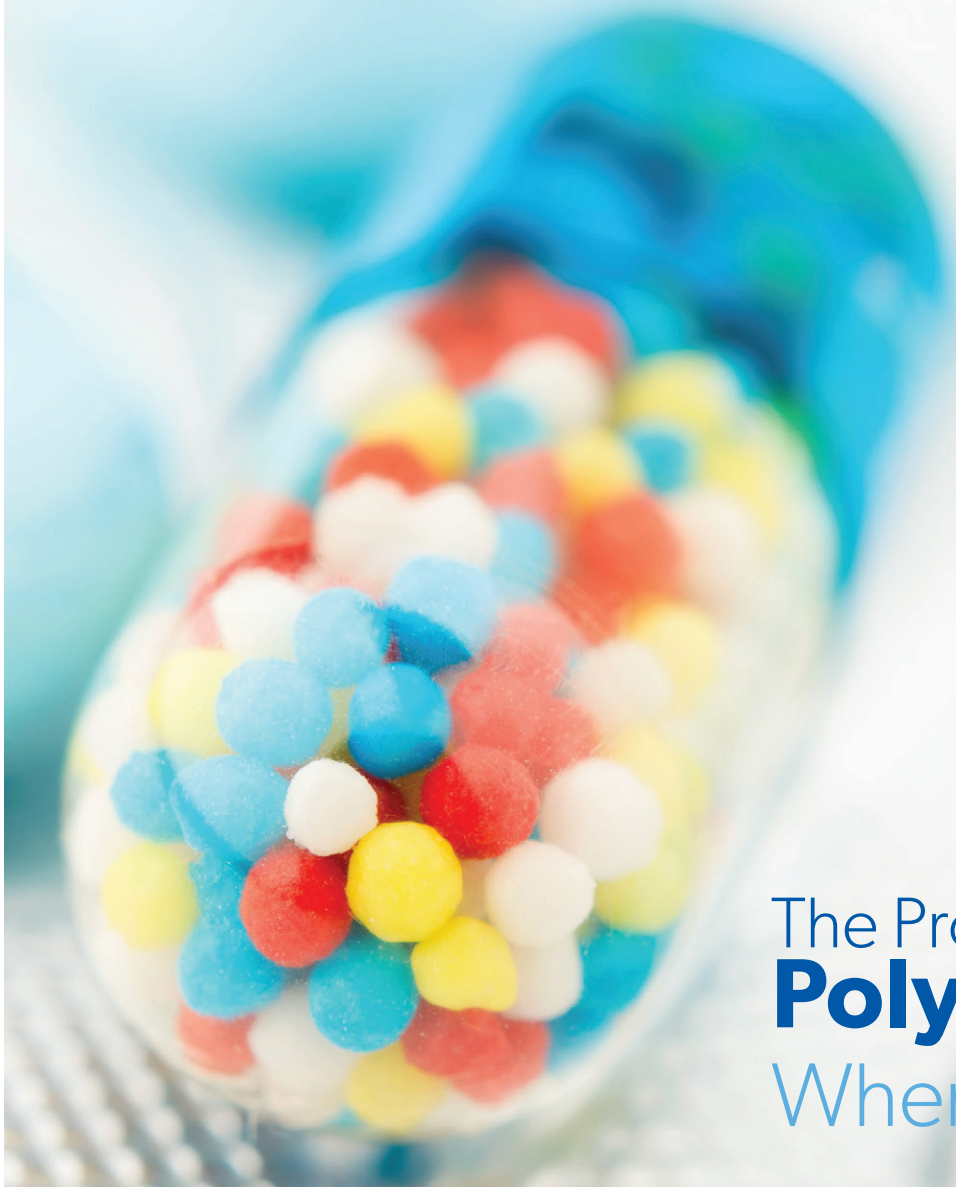
Healthesystems™

# RxInformer

*Current and emerging issues impacting workers' comp*

Spring 2013



## PDMP:
The Game Changer?

## Traumatic Brain Injury:
What Medications Are Appropriate?

## The Problem of Polypharmacy:
When More Is Less

**Other Hot Topics:**

Hydrocodone & Zohydro

Opioid Therapy

National Drug Code (NDC) Depletion

**INTERACTIVE FEATURES**

Get the *RxInformer* e-zine iPad App in the App Store for an interactive experience

## Have a Voice

Contact your Congressman to express support for these important bills.

### HR 486 Stop Tampering of Prescription Pills Act of 2013

Incentivizes development of abuse-deterrent drugs for new and generic opioids. This bill amends the Food, Drug & Cosmetic Act. (Beta.congress.gov/bill/113th-Congress/house-bill/486)

### HR 672 Prescription Drug Abuse Prevention and Treatment Act

Provides federal oversight of prescription opioid therapy & assists states to decrease opioid abuse, diversion and deaths. (Beta.congress.gov/bill/113th-Congress/house-bill/672)


*RxInformer*

*Spring 2013*




# Interactive Exclusives

## Healthesystems Video Series on YouTube

Watch an interview series with Healthesystems President Daryl Corr as he discusses topics impacting workers' comp.

http://www.youtube.com/user/Healthesystems


## Healthesystems App

Download the Healthesystems App from the App Store or Google Play Store to look up medication information and get drug and compliance alerts on your mobile device.

## *RxInformer* iPad App

Experience an interactive version of this *RxInformer*. Download our e-zine App to your iPad Newsstand and be the first to get each issue.

INTERACTIVE FEATURES

Get the *RxInformer* e-zine iPad App in the App Store for an interactive experience

## e-Newsletters

Sign up for our *Rx Postscript* and *Compliance Quarterly* email newsletters and get timely workers' comp info delivered to your in box.

www.healthesystems.com/newsletters

# Table of **Contents**

## Medication Management



## Prevention Tools



## Compliance



## Stats

# Stemming The Tide
## on the Opioid Epidemic

*By Robert Goldberg, MD, FACOEM*

There can be little doubt that we are experiencing an epidemic of opioid use, dependency, and abuse. Prescription drug abuse is the fastest growing drug problem in the United States. The increase in unintentional drug overdose death rates in recent years has been driven by increased use of opioid analgesics.[1] The Centers for Disease Control and Prevention (CDC) charts the rise of opioid prescription overdose deaths on a curve that corresponds with the increase in opioid sales in the U.S.

Prescription medication overdose is now a leading cause of accidental death in the United States.[1] The numbers are sobering. In 2008, more than 36,000 people died from drug overdoses. Most of these deaths were caused by prescription drugs.[2]

### How Did This Happen? What Can We Do?

First, there is an increase in the volume of opioid prescriptions and number of opioid products that are now available. New products are being released with greater potency, varying speed of absorption and onset, and a variety of delivery mechanisms. 'Big Pharma' would have physicians and patients believe that the latest is the greatest. I spent many years directing evidenced-based care for insurance carriers, TPAs and employers and found little evidence that the newer, more costly medications were any more effective in improving treatment outcomes, restoring function, and returning injured workers to productive employment.

Still, we are documenting an escalation of opioid doses, more polypharmacy, more overdoses and deaths, greater side effects, and increased pharmacy costs to insurers and employers. If the number of workplace injuries in the U.S. is not increasing, why then is the number and costs of opioid and other prescriptions continuing to rise? It would seem that outside influences are impacting opioid prescribing decisions. That should not be the case.

### Shifting the Focus of Treatment

There are heightened expectations by patients that physicians have the tools to markedly reduce, if not eliminate pain from their injuries. Short-acting opioids are effective for acute pain in most patients, but not for all and not for pain that persists in the subacute and chronic phases of injuries. This is where physicians must educate their patients about the role and limitations of opioids and temper expectations around pain relief.

## About the Author

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

As a primary treating physician for many years, as well as a professor and residency program director at the University of California San Francisco, I stressed to patients and occupational medicine residents that the treatment goals should be the restoration of function and a prompt return to work as opposed to a primary focus on pain relief. Focusing on pain relief can set a course for escalating doses of medications, a switch to longer acting and multiple medications, and prescribing additional medications to counter the side effects of the escalating doses.

### Tools Available

Physicians need more education about the risks of opioid medication, the limitations of their use and the best practices when prescribing. Among a growing list of tools available, best practices include risk stratification, treatment agreements, urine drug screening, attempts at dose reduction and weaning, referral for consultation, and the use of prescription drug monitoring programs (PDMPs).

The workers' compensation industry and pharmacy benefits managers can provide physicians with tools that alert them about escalating doses, multiple prescribers and multiple pharmacies. Physician-to-physician discussions and consultations with highly trained clinical pharmacists have been shown to make a positive difference in prescribing patterns. However, early intervention is key and insurance claims professionals and case managers need to have timely and appropriate alerts then act to engage prescribers, pharmacies and injured workers to reduce the numbers of medications and doses of opioids.

If we strive to work together with physicians as partners and give them the information and incentives to educate their patients about risks, benefits, and expectations of treatment, there is a high likelihood that we can achieve a positive response and reduce the size of the epidemic. It is clear that the traditional approach to the treatment of acute and chronic injury and pain is not working well. A new and sustained approach is ever evolving to reduce the human and financial costs to workers and their families, employers, insurers, and our society.

The articles that follow address in more depth some of the key pharmacy issues that I touched on. Hopefully, the more that we share information as partners, the better our chances will be of turning back the tide on this very costly problem.

# **Med** Watch

Workers' comp professionals should keep an eye on these medications

## Drug Alerts

### Zolpidem-Containing Products - Ambien®, Ambien CR®, Edluar®, Zolpimist™ and generics

The FDA recently announced that it is requiring the manufacturers of most zolpidem-containing products to lower the recommended dose.[3]

New data show that in some patients, levels of zolpidem in blood may still be high the morning after taking the medication, resulting in continued drowsiness, and may impair activities that require alertness such as driving. Women especially are at higher risk for impairment the morning after use. The highest risk for impairment occurs in patients who take the extended-release formulation of zolpidem (Ambien CR® and generics).

The FDA recommends that the bedtime dose be lowered to ensure lower levels of medication in blood in the morning and manufacturers will be required to lower the recommended dose.

Intermezzo®, a zolpidem-containing product approved for middle-of-the-night-awakenings, will have no changes to the recommended dose. Intermezzo's labeling already contains a lower dose recommendation for women than for men.

**Immediate-Release (IR) Products - Ambien, Edluar, Zolpimist, and Generics**

Manufacturers of IR zolpidem products will be required to update their labeling to reflect the recommended lower dose. The FDA requires:

- Lowering the recommended initial dose for women from 10 mg to 5 mg (taken immediately before bedtime)
- The drug labeling should recommend that health care professionals consider prescribing a lower dose of 5 mg for men. In many men, the 5 mg dose provides sufficient efficacy.
- The drug labeling should include a statement that, for both men and women, the 5 mg dose could be increased to 10 mg if needed, but the higher dose is more likely to impair next morning driving and other activities that require full alertness.

**Extended-Release (ER) Products - Ambien CR and Generics**

Manufacturers of ER zolpidem products will be required to update their labeling to reflect the recommended lower dose. The FDA requires:

- Lowering the recommended initial dose for women from 12.5 mg to 6.25 mg (taken immediately before bedtime).
- The drug labeling should recommend that health care professionals consider prescribing a lower dose of 6.25 mg in men. In many men, the 6.25 mg dose provides sufficient efficacy.
- The drug labeling should include a statement that, for both men and women, the 6.25 mg dose can be increased to 12.5 mg if needed, but the higher dose is more likely to impair next morning driving and other activities requiring full alertness.

**Clinical Recommendation**

Healthesystems clinical pharmacist staff does not recommend long-term use of sleep aid medications such as zolpidem, as the safety of long-term use of sleep aids has not been studied.[4] Without evidence-based research, we remain cautious about the long-term use of this drug. This product should not be used when another sleep aid has been prescribed because duplication of this class of drug may result in significant adverse events.

**Patient Alert:**
Patients should contact their health care provider to determine how current therapy doses should be changed to ensure safety.

## Drug Alerts

### OxyContin® Patent Set to Expire — Non-Abuse Deterrent Generics Are Cause for Concern

There is concern among all stakeholders in pain management and drug addiction therapy that a generic version of the non-abuse deterrent Oxycontin (oxycodone ER) could be coming soon to pharmacy shelves near you. On April 16, 2013, the patent for the original formulation of Oxycontin expires. If the patent expires, generic versions of this opioid will be available which will not be abuse deterrent, and abuse of this potent drug will skyrocket.

It is possible that a lawsuit filed this January by the manufacturer of Oxycontin, Purdue Pharma, will avoid this situation. At the recent National Rx Drug Abuse Summit, speakers supported two bills: HR 672, the Prescription Drug Abuse Prevention and Treatment Act, and HR 486, the Stop Tampering of Prescription Pills Act of 2013.

HR 486 would amend the Food, Drug and Cosmetic Act (FDCA) to provide incentives to drug manufacturers to develop abuse deterrent formulations of recognized drugs of abuse. The bill addresses both new products and generic versions of existing drugs. HR 672 would increase Federal oversight of prescription opioid treatment and provide assistance to states to decrease opioid abuse, diversion and deaths.

## New Drugs

### Zecuity™ (sumatriptan iontophoretic transdermal system)

*For migraine treatment*

***Status: Available fourth quarter of 2013***

This is the first transdermal patch approved for migraine treatment. This patch, a non-oral route of administration, may be beneficial for individuals who experience significant nausea and vomiting as migraine symptoms, and who do not wish to use needles.

**FDA-approved Indications:**

Acute treatment of migraine with or without aura (sensory warning signs or symptoms of migraine such as flashes of light, blind spots) in adults.

**Limitations of Use:**

- Use only after a clear diagnosis of migraine has been established
- Not indicated for the prevention of migraine attacks

**Concerns:**

Zecuity is expected to be higher in cost than other generically available formulations.

**Comparable Products:**

Other sumatriptan formulations (nasal spray, tablet, injection) are comparable and less costly.

**Clinical Recommendation:**

Establishing prior authorization for this product to treat workers' compensation patients is recommended. Claims professionals should request documentation of medical necessity from the prescriber.

### Quillivant XR™ (methylphenidate HCL extended-release oral suspension)

*For attention deficit hyperactivity disorder (ADHD)*

***Status: Currently available***

This medication is available as 25 mg/5 ml dry powder for reconstitution/mix in the pharmacy prior to dispensing. It is the first liquid formulation that is a once-daily, extended-release product.

**FDA-approved Indications:**

The treatment of attention deficit hyperactivity disorder (ADHD)

**Concerns:**

Quillivant XR is expected to be higher in cost than other comparable products.

**Clinical Recommendation:**

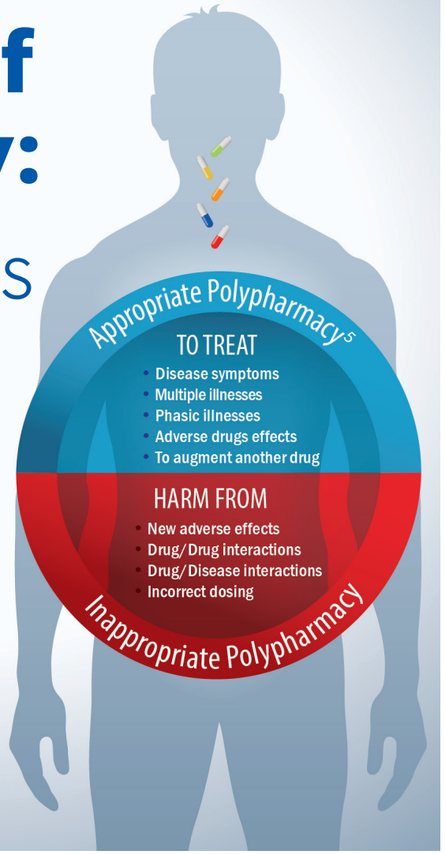
Treatment for ADHD has a limited role in the workers' compensation population, so this medication should have limited use. It is recommended that Quillivant be excluded from both the acute and chronic medication plans for workers' compensation payers. Occasionally, off label use of a CNS stimulant such as Quillivant in the workers' compensation population may occur for treatment in post-traumatic brain injury cases.

**Drug Info**
Need additional drug information?
Contact our clinicians
866.646.2838 or
druginfo@healthesystems.com

# The Problem of Polypharmacy:

## When More is Less

When three or more medications are prescribed at the same time, and drugs are being prescribed to treat the side effects of other drugs, the results can be potentially dangerous.




**INTERACTIVE FEATURE**

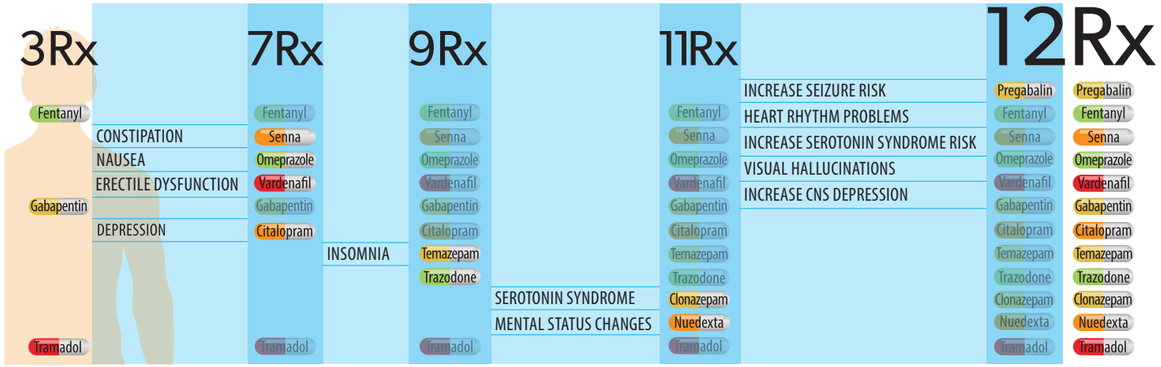
Experience an interactive polypharmacy scenario. Get the *RxInformer* iPad App

The percentage of workers' compensation claims with multiple chronic medical conditions appears to be growing.[6] With an increase in medical conditions there is an accompanying rise in medications prescribed. The use of multiple medications by an individual has been termed *polypharmacy*. Polypharmacy can be seen in many workers' compensation scenarios. While definitions vary,[7] polypharmacy has most commonly been defined as use of three to five or more different medications taken by a patient at the same time.[8] In addition to other medical conditions, another "risk factor" for polypharmacy is having workers' compensation medications in addition to medications for non-work-related conditions.[9] Often these combined treatments go undetected.

Polypharmacy is not inherently bad. Rational polypharmacy is based on the safe and appropriate use of multiple drugs. The patient may benefit from combined therapies that reduce the symptoms of disease, cure or prevent disease progression, and minimize disability. For example, five drugs are recommended for the initial treatment of tuberculosis, and four drug polypharmacy is recommended for treating stomach ulcers caused by bacteria called *H pylori*. In workers' compensation, guidelines for the treatment of nerve pain find certain antiepileptic drugs can be combined with certain antidepressants and a non-opioid analgesic to effectively reduce neuropathic pain. Another workers' compensation example is treatment of frequent migraine headaches by adding a headache prevention medication to the immediate-treatment medication to reduce headache frequency and disability.

**Claimant:** 61 year old male
**Injury:** Lower back strain
**Therapy:** Failed back surgery (Lumbar Postlaminectomy Syndrome)

### RUNAWAY POLYPHARMACY




But when more drugs are prescribed and taken than are clinically warranted, the patient is at risk of serious harm including death[10] from adverse effects, drug/drug interactions, drug/disease interactions, and incorrect dosing. To illustrate these potential harms, an example of runaway polypharmacy in workers' compensation appears in the above graphic. Such inappropriate polypharmacy is associated with significant morbidity and mortality, costing United States health plans more than $50 billion per year.[11]

To reduce the risks of polypharmacy, a comprehensive review of each drug in the patient's drug regimen should be performed by prescribers at least annually.[12] PBMs should proactively uncover instances of polypharmacy and report this data to payers so they can request patient drug regimen reviews as needed. Eliminating unnecessary or potentially problematic medications can simplify medication use for the patient, and reduce the risk of adverse drug reactions and excessive healthcare expenditures. It is also an opportunity to ensure that the patient understands why the medications have been prescribed, how to take them, and what to do in the event of side effects. Clinical tools are available to assist in the review of complex drug regimens,

### The Cost of Polypharmacy

If early detection and clinical intervention do not occur, instances of polypharmacy can quickly **grow out of control**

POLYPHARMACY COSTS CAN CERTAINLY ADD UP:
**Delayed return to work + dangerous drug/drug interactions + incorrect dosing**

DRUG COSTS CAN EXCEED
**$7,000 + per month (or more)**

Clinical Intervention is Imperative. Intervention can lead to:
**Decreased drugs, improved patient outcomes, increased safety, reduced costs**

such as the Hyperpharmacotherapy Assessment Tool (HAT) which can help identify polypharmacy and all sources of medications, direct a decrease in inappropriate drug use, and optimize the dosing regimen.[13] Prescribers can access the HAT and request permission to use the tool by visiting: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546482/figure/fig1/

When reviewing polypharmacy, some questions to ask include:

- ✓ Does the patient use multiple prescribers and multiple pharmacies?
- ✓ Is the patient taking the medications as prescribed?
- ✓ Can the patient describe the purpose, dosing, and side effects of the drugs?
- ✓ Are there any adverse effects that may be caused by the medications?
- ✓ Are there any drug-drug or drug-disease interactions suspected?
- ✓ Does the dosage or frequency need to be adjusted based on patient-specific characteristics such as age, liver or kidney function?
- ✓ Is the medication even appropriate for the age of the patient? (Older patients require special consideration.)
- ✓ Is there another, equally effective, lower cost drug available?
- ✓ Is there a non-drug therapy option?
- ✓ Is there a risk of addiction from long-term use?
- ✓ Have treatment goals been achieved?

After review, a treatment plan should be developed by the prescriber to slowly eliminate inappropriate medications, unless serious drug-related problems have been identified, in which case immediate action may be necessary. It is recommended to avoid making multiple drug changes at one time. Instead, one drug should be discontinued at a time by tapering dosage and closely monitoring the patient for possible withdrawal symptoms and worsening disease. A PBM should help identify instances of potential polypharmacy and work with payers to optimize the drug therapy regimen. Ultimately, eliminating inappropriate polypharmacy may enhance drug therapy outcomes and improve the patient's quality of life while reducing healthcare expenditures.

"Most individuals who are prescribed five or more drugs are taking unique drug combinations … [representing] an 'uncontrolled experiment' with effects that cannot be predicted from the literature."[14]

— Werder. *J Family Practice.* 2003.

"Healthcare practitioners have a societal obligation to simplify approaches and curb excessive prescribing of drugs while honoring their commitment to improving health and curing, mitigating, and preventing disease."[15]

— Zarowitz. *Pharmacotherapy.* 2005.

Healthesystems has reported on Polypharmacy in past issues of *RxInformer*

Visit the *RxInformer* archive

www.healthesystems.com/rx-archive

## Examples of Inappropriate Polypharmacy[16]

*(as seen in a typical workers' compensation claims population)*

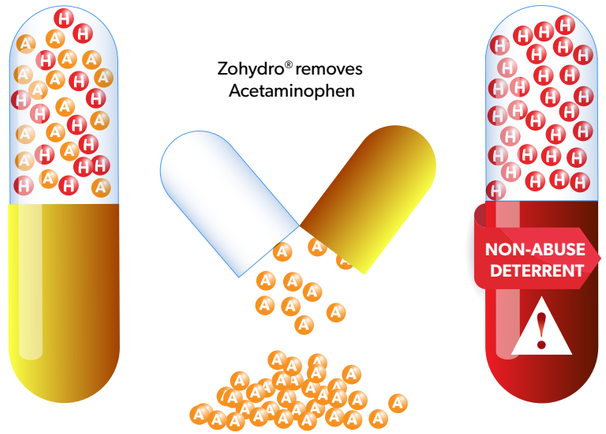
| Harm | Select Drugs in Regimen | Result |
|---|---|---|
| Adverse Effect | Multiple high dose short-acting opioids: **fentanyl lozenges, oxycodone** | Opioid-induced hormone deficiency, constipation, and narcotic bowel syndrome causing additional prescriptions for testosterone, Viagra®, laxatives, and an ulcer medicine (e.g., omeprazole) |
| Drug/Drug Interaction | Multiple drugs causing similar and additive effects: **Cymbalta®, cyclobenzaprine, Nucynta®, tramadol** | Serotonin syndrome resulting in anxiety, insomnia, and additional prescriptions to counteract these effects (alprazolam (Xanax®) and other sedating drug) |
| Drug/Disease Interaction | **Tramadol, tizanidine, Lyrica®, and ibuprofen** in a patient with chronic kidney disease | Increased kidney toxicity and possible adverse effects due to enhanced drug toxicity |
| Incorrect Dosing | **Diclofenac DR** 200 mg/day long term regular use | Higher doses and longer duration of use are associated with greater risk of gastrointestinal bleeding/ulcers and high risk for serious cardiac events |

! A recent study, *Comorbidities in Workers' Compensation*, by the National Council on Compensation Insurance (NCCI) observed that workers' compensation claims for patients with multiple chronic conditions were associated with double the medical costs than a claim without additional medical conditions. They were also more likely to accrue more time away from work.[17] NCCI found that drug abuse, diabetes, hypertension, and chronic pulmonary disease were common, costly, and seem to be increasing. Another common condition, obesity, was observed in 29% of musculoskeletal injuries and in 27% of sprains/strains. There is currently not enough published research available to determine if there is a correlation between obesity and cause of injury, and what treatments are directly associated with injuries versus other conditions present outside of the work-related injury.

# Hydrocodone:

## Use, Abuse and Controls on Prescribing

Hydrocodone is one of the most abused drugs in the U.S. and long-term use warrants close scrutiny and frequent re-evaluation




**Hydrocodone/ Acetaminophen Product**

**Zohydro®**

One of the missions of the U.S. Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States.[18] The Controlled Substances Act[19] specifies what constitutes a "controlled" substance and these qualifiers include:

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effect, if known.
3. The state of current scientific knowledge regarding the drug or other substance.
4. Its history and current pattern of abuse.
5. The scope, duration, and significance of abuse.
6. What, if any, risk there is to the public health.
7. Its psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Controlled substances are defined by levels of control on prescribing, referred to as schedules. There are five levels of control on these medications ranging from Schedule I (the highest abuse potential and the most controlled) to Schedule V (the least abuse potential and the least controlled). The five schedule levels are described in the sidebar and notes are included to demonstrate the decreasing level of control.

In most cases, the drug schedules assigned to each controlled substance help provide the necessary level of control. However, the drug hydrocodone may require tighter control than is currently in place.

### Controlled Substance Act

I. Schedule I — *Note: There is no recognized medical use of a Schedule I drug*
   a. The drug or other substance has a high potential for abuse.
   b. The drug or other substance has no currently accepted medical use in treatment in the United States.
   c. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

II. Schedule II — *Note: Each time a Schedule II drug is needed by a patient, a new, hardcopy prescription from the prescriber is required.*
   a. The drug or other substance has a high potential for abuse.
   b. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
   c. Abuse of the drug or other substances may lead to severe psychological or physical dependence.

III. Schedule III — *Note: This schedule allows for a prescription to be filled a total of six times within sixmonths from the date written.*
   a. The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.
   b. The drug or other substance has a currently accepted medical use in treatment in the United States.
   c. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

IV. Schedule IV — *Note: This schedule allows for a prescription to be filled a total of six times within six months from the date written.*
   a. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
   b. The drug or other substance has a currently accepted medical use in treatment in the United States.
   c. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

V. Schedule V — *Note: This schedule allows for a prescription to be filled a total of six times within six months from the date written. Also, some of these medications can be obtained without a prescription by the patient completing a form at a pharmacy.*
   a. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
   b. The drug or other substance has a currently accepted medical use in treatment in the United States.
   c. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

### Current Prescribing of Hydrocodone-Containing Products

Hydrocodone-containing products are the most frequently prescribed opioid in the United States.[20] Several of the brand names for the combination of hydrocodone/ acetaminophen include Vicodin®, Norco®, and Lorcet®. These combination products are classified as Schedule III which means that the opioid hydrocodone is perceived to have moderate-to-low physical dependence or high psychological dependence. At the time of this article, combinations of hydrocodone with acetaminophen or ibuprofen are the only products available. However, there is a hydrocodone-only product under review for approval by the FDA. It is a long-acting product named Zohydro®. Based on public information, it appears that Zohydro is not formulated to be abuse resistant or abuse deterrent.

Hydrocodone combination products currently available are recognized as highly abused. News reports abound regarding celebrity accidental overdoses and rehabilitation facility admissions as a result of hydrocodone/ acetaminophen use. Further, the 2011 report from the National Forensic Laboratory Information System (NFLIS) notes that:[21] of the top 25 drugs identified from law enforcement actions, hydrocodone is 6th overall.

Even more telling, the number of hydrocodone reports tripled in the 2001 to 2010 reporting period, making hydrocodone second only to oxycodone for analgesics products of concern. The following is quoted directly from the report: "In 2010, more than 70% of narcotic analgesic reports were oxycodone or hydrocodone." If Zohydro was introduced without an abuse deterrent formulation, it is likely that there would be substantial abuse of this product and this statistic could rise – given the fact that hydrocodone-containing products are currently highly abused.

Based on this information, it would be reasonable to think that perhaps more control is needed on hydrocodone-containing products. Yet, there is disagreement between the DEA and the FDA on this issue. The DEA has been trying to reschedule the hydrocodone/ acetaminophen products to Schedule II. However, the FDA has been resistant to this action.[22]

Despite the hesitancy on the part of federal regulators, other parties at the state level are taking action to more strongly control use of hydrocodone products. The Governor of Kentucky

**Hydrocodone vs. Zohydro:**

The immediate release hydrocodone combination products contain hydrocodone 5 mg, 7.5 mg or 10 mg per tablet. Zohydro, because it is a long-acting agent, will contain a 12-hour dose of hydrocodone. The maximum dose per tablet of Zohydro will be 50 mg.

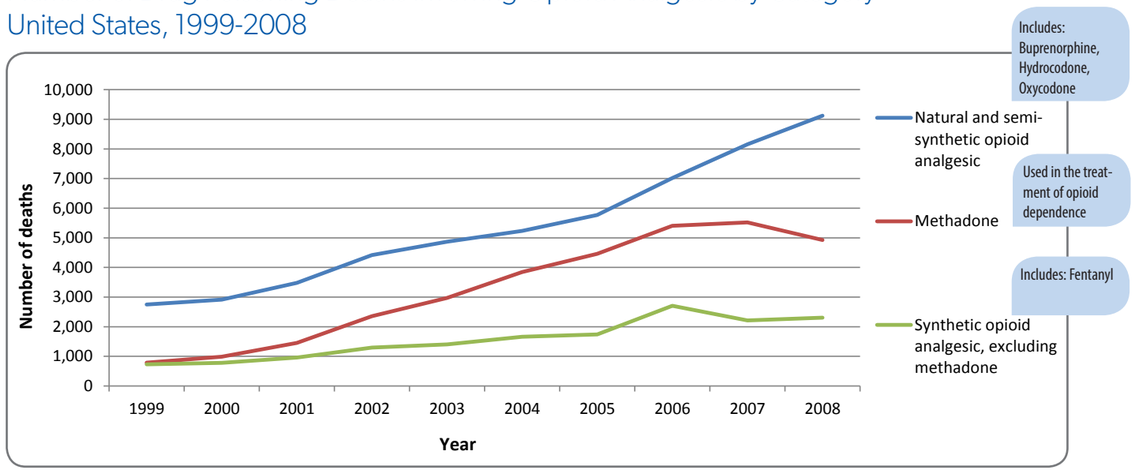
## National and Regional Estimates for the 10 Most Frequently Identified Drugs

*Estimated number and percentage of total drug reports submitted to laboratories from January 2011 through December 2011 and analyzed by March 31, 2012.*

| | National | | West | | Midwest | | Northwest | | South | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Drug** | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| Cannibis/THC | 536,630 | 32.32% | 68,819 | 23.26% | 163,982 | 43.39% | 99,188 | 33.98% | 204,641 | 29.47% |
| Cocaine | 333,645 | 20.10% | 35,064 | 11.85% | 57,292 | 15.16% | 74,633 | 25.56% | 166,656 | 24.00% |
| Methamphetamine | 160,960 | 9.70% | 84,911 | 28.69% | 22,506 | 5.96% | 1,484 | 0.51% | 52,059 | 7.50% |
| Heroin | 119,765 | 7.21% | 20,887 | 7.06% | 36,463 | 9.65% | 36,996 | 12.67% | 25,419 | 3.66% |
| Oxycodone | 59,953 | 3.61% | 6,266 | 2.12% | 9,052 | 2.40% | 15,193 | 5.20% | 29,441 | 4.24% |
| Hydrocodone | 46,872 | 2.82% | 7,197 | 243.00% | 9,093 | 2.41% | 3,488 | 1.19% | 27,093 | 3.90% |
| Alprazolam | 43,231 | 2.60% | 3,785 | 1.28% | 6,846 | 1.81% | 6,576 | 2.25% | 26,025 | 3.75% |
| MDMA | 13,031 | 0.78% | 4,766 | 1.61% | 1,905 | 0.50% | 1,912 | 0.65% | 4,447 | 0.64% |
| Clonazepam | 11,474 | 0.69% | 1,243 | 42.00% | 2,295 | 0.61% | 28,860 | 0.98% | 5,076 | 0.73% |
| Buprenorphine | 10,922 | 0.66% | 909 | 31.00% | 1,660 | 0.44% | 4,445 | 1.52% | 3,907 | 0.56% |

U.S. Drug Enforcement Administration, Office of Diversion Control. (2011).National Forensic Laboratory Information System: 2011 Annual Report. Springfield, VA: U.S. Drug Enforcement Administration. Available at: http://www.deadiversion.usdoj.gov/nflis/2011annual_rpt.pdf. Accessed March 10, 2013.

## Number of Drug Poisoning Deaths Involving Opioid Analgesic by Category United States, 1999-2008




NOTES: Opioid analgesic categories are not mutually exclusive. Deaths involving more than one opioid analgesic category shown in this figure are counted multiple times. Natural and semi-synthetic opioid analgesics include morphine, hydrocodone, and oxycodone; and synthetic opioid analgesics include fentanyl. Access data table at http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#4.
Source: CDC/NCHS, National Vital Statistics System.

Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. Drug poisoning deaths in the United States, 1980–2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011. Available at: http://www.cdc.gov/nchs/data/databriefs/db81.htm. Accessed March 10, 2013.

**Zohydro Concerns:**

Zohydro is a long-acting opioid analgesic containing hydrocodone alone. It is intended to treat moderate to severe chronic pain when around-the-clock pain control is needed. The formulation uses the same drug release technology as Avinza®. Neither of these potent opioids is abuse resistant or abuse deterrent. The FDA Advisory Panel voted 11 – 2 against recommending approval for Zohydro, citing safety concerns.[26] Specific concerns cited were: potential for increased drug abuse, addiction, diversion and overdose deaths with this product compared to other similar products. The committee also stated "… *that the FDA should not approve ER/LA opioids without tamper-resistant or abuse-deterrent formulations.*"

signed a law requiring prescribers to check the state's prescription monitoring program before prescribing any drugs on Schedule II and drugs containing hydrocodone. The new KASPER law further requires prescribers to obtain 12 months of history from the state monitoring program before prescribing Schedule II and Schedule III drugs containing hydrocodone to a patient on the first visit and every three months thereafter.[23] In addition to the Kentucky action, an FDA advisory panel voted 19 to 10 for stricter controls in hydrocodone-containing products.[24] Further, the State of New York has made hydrocodone-containing products Schedule II which is stricter than the current DEA classification.[25] The industry is taking note and acting on the growing abuse of hydrocodone.

Arguments against increasing the control of hydrocodone products cite concerns for limiting patient access to medications. This concern is part of a larger issue — appropriate use of opioids for chronic, non-cancer pain management.

All stakeholders in the issue of opioid use, whether hydrocodone or another agent, need to keep the patient in mind. Chronic pain is a lifelong challenge that many injured workers are faced with. Opioids may be appropriate for end-of-life issues, but they may not be the answer for a lifetime of pain control. Claims professionals, payers and prescribers should be aware of the abuse potential for hydrocodone products and closely monitor any new opioid that does not offer an abuse deterrent formulation.

Healthesystems recommends close monitoring and drug plan prior authorization for Zohydro use when it becomes available. As with any long-term opioid use, regular patient monitoring and documentation from the prescriber regarding functional improvement, random urine drug testing results and periodic dose reductions or attempts to discontinue opioids are also strongly encouraged.

# Central Nervous System

## Stimulant Use on the Rise

Medications such as Adderall® and Ritalin® pose risks to work comp patients if not prescribed properly.

Often, opioids are at the center of focus in attempts to manage medication utilization and spend in workers' compensation. However, they are not the only class of medication that can be both costly and dangerous. Central Nervous System stimulants, or CNS stimulants, pose significant health risks and are increasingly abused.

CNS stimulants include medications used to treat attention-deficit hyperactivity disorder (ADHD), narcolepsy and weight loss. Based on their intended use, it may seem surprising that this class of medications is often used to treat workers' compensation patients — but they are prescribed, and frequently the subject of abuse and misuse.

### A Real-World Problem

A recent New York Times article titled "Drowned in a Stream of Prescriptions," tells the tragic tale of a a 24-year-old college graduate who developed an addiction to CNS stimulants, suffered a mental breakdown, and subsequently committed suicide.[27] The tragedy was compounded because the individual was not stealing or buying these medications off the street. Instead, they were being prescribed to him — despite the facts that he was taking more than prescribed, was becoming psychotic, and his family had voiced their concerns to the prescriber. This example illustrates the extreme consequences of disease state mismanagement and potential drug abuse that can occur with CNS stimulants.

An increase in the abuse of CNS stimulants is apparent when examining findings on drug-related emergency department visits. The rate of emergency department visits in the U.S. involving drug misuse (accidental) or abuse increased significantly from 2004 to 2011, with cases involving CNS stimulants increasing by 292% – a larger increase than any other drug class.[28] Between 2005 and 2010, the number of visits involving CNS stimulants increased from 13,379 to 31,244, about half of these cases are the result of "nonmedical use," which in many cases can be attributed to abuse.[29]

CNS stimulants are having a huge impact on increased emergency department visits.



### Commonly Prescribed CNS Stimulants[30]

| Medication | Indication | Risks* |
|---|---|---|
| Adderall® (amphetamine/ dextroampehtamine) | ADHD, narcolepsy | Contraindicated in patients with history of substance abuse, cardiac disease, hyperthyroidism |
| Vyvanse® (lisdexamfetamine) | ADHD | |
| Focalin® (dexmethylphenidate) | ADHD | Contraindicated in patients with anxiety, glaucoma, Tourette's |
| Ritalin® (methylphenidate) | ADHD, narcolepsy | |
| Provigil® (modafinil) | Narcolepsy, circadian rhythm disruption, sleep apnea | Caution when prescribing to patients with history of substance abuse and cardiac disease |

**Additional risks may occur. This is not a comprehensive list of risks.*

Why are we seeing the rapid increase in the use of CNS stimulants? One reason may include the fact that people are being diagnosed more often with the conditions that these drugs are intended to treat, particularly ADHD. For many people, certain effects of these drugs are desirable, including loss of appetite (to assist in weight loss), a feeling of euphoria and increased alertness. Because of these factors, CNS stimulants are a desirable drug to abuse.

### Gauging Appropriate Use

CNS stimulants may be prescribed to injured workers to manage shift-work sleep disorder or other work-related injuries that have resulted in excessive fatigue. Unfortunately, they are also often prescribed off-label (to be used for a reason other than what the drug was approved for) to counteract the sedation caused by large amounts of CNS depressants. When a patient is prescribed a depressant such as opioids, benzodiazepines and hypnotics a side effect is often daytime fatigue – and prescribing a CNS stimulant will counteract the depressant. This is not an appropriate practice, and is strongly discouraged. The medications causing sedation should be adjusted, rather than adding a CNS stimulant with its own risks and adverse effects.

Injured workers need to be assessed prior to prescribing a CNS stimulant. Screening the patient for a history of substance abuse is important, since certain types of CNS stimulants should be withheld in these cases (see table). Even if they are not abused, these medications carry a high risk of dependence, and cannot be abruptly stopped, as this could result in withdrawal, agitation, anxiety and depression. Even when taken as prescribed, this class of medications can cause increased heart rate, insomnia and agitation. It was reported that about one third of emergency department visits related to CNS stimulants between 2005 and 2010 were the result of adverse reactions alone, drawing attention to the risks associated with even appropriate use. The example given in the New York Times article illustrates the fact that there can never be enough checks and balances in place to assure appropriate therapy. A pharmacy benefits manager is part of this checks and balance process, and should play a significant role in identifying potential risks, drug-drug and drug-disease interactions and inappropriate use of these medications. It is important to ensure that injured workers are prescribed these medications for appropriate reasons, and that all other medication options have been tried before a CNS stimulant is used. The safety of the injured worker and appropriate management is critical to recovery.

# Traumatic Brain Injury:

## What Medications Are Appropriate?

Traumatic brain injury is a complex workers' comp condition which may require a complex treatment regimen

Head injuries and concussions have recently gained increased exposure in the media, with particular focus on football and other sports related injuries. Concussions and head injuries are not new problems; however, the spotlight is now shifting to the long term effects of these injuries. The workers' compensation industry is also affected by long term medical coverage for head injuries occuring in the workplace. The reported incidence of workers' comp traumatic brain injuries range from 6 per 1000 claims to 17 per 1000 claims.[31,32] Although not the largest category of workers' compensation injuries, drug therapy for this condition warrants evaluation.

The most common cause of mild traumatic brain injury (mTBI) is falls, followed by motor vehicle accidents and injury due to strike by or against an object.[33] The extent of damage can range from mild to severe. While the consequences of a severe traumatic brain injury can be extensive, the majority of patients do not require long term medical therapy.[34] Incidences of lasting effects from mTBI occur in less than 5% of cases. If persistent symptoms do occur, first line therapy includes education and non-drug treatment such as cognitive behavior therapy, physical therapy, relaxation techniques and modification of the home environment.

The 2009 Department of Defense/ Veterans Administration Clinical Practice Guidelines state that in nearly all cases, non-drug treatment should be a main focus and medications should be secondary considerations and targeted to the specific symptoms. Since there



### mTBI Symptoms and Recommended Treatment

**SLEEP DISTURBANCES**

Recommended Treatment

- Cognitive behavior therapy (CBT)
- Sleep hygiene
- Careful assessment of patient history to avoid issues that may be causing sleep disturbance such as: daytime naps, use of CNS stimulants, caffeine intake late in the day, alcohol use, illicit drug and nicotine use and stimulating activities

Concerns

The use of drugs such as benzodiazepines and sedatives are not recommended.

If therapy is needed on a short term basis, zolpidem IR (a non-benzodiazepine sedative) is recommended until CBT can be completed

**HEADACHES**

Recommended Treatment

- Non-opioid analgesics (i.e., acetaminophen, ibuprofen/ naproxen)
- Imitrex® (i.e., sumatriptan)
- Anticonvulsants (e.g., topiramate or divalproex)
- Beta blockers (e.g., metoprolol)
- Antidepressants (e.g., amitriptyline)

Concerns

Opioids, benzodiazepines, barbiturates and combination products such as butalbital/aspirin/caffeine are generally not recommended because of poor efficacy, risk of rebound headaches and/ or risk for physical dependence or abuse. High risk of medication overuse -- closely monitor

**FATIGUE**

Recommended Treatment

- Implementing good sleep habits
- If symptoms persist, treatment with a CNS stimulant may be required
- Methylphenidate is considered first-line therapy (except for patients with a substance abuse history)

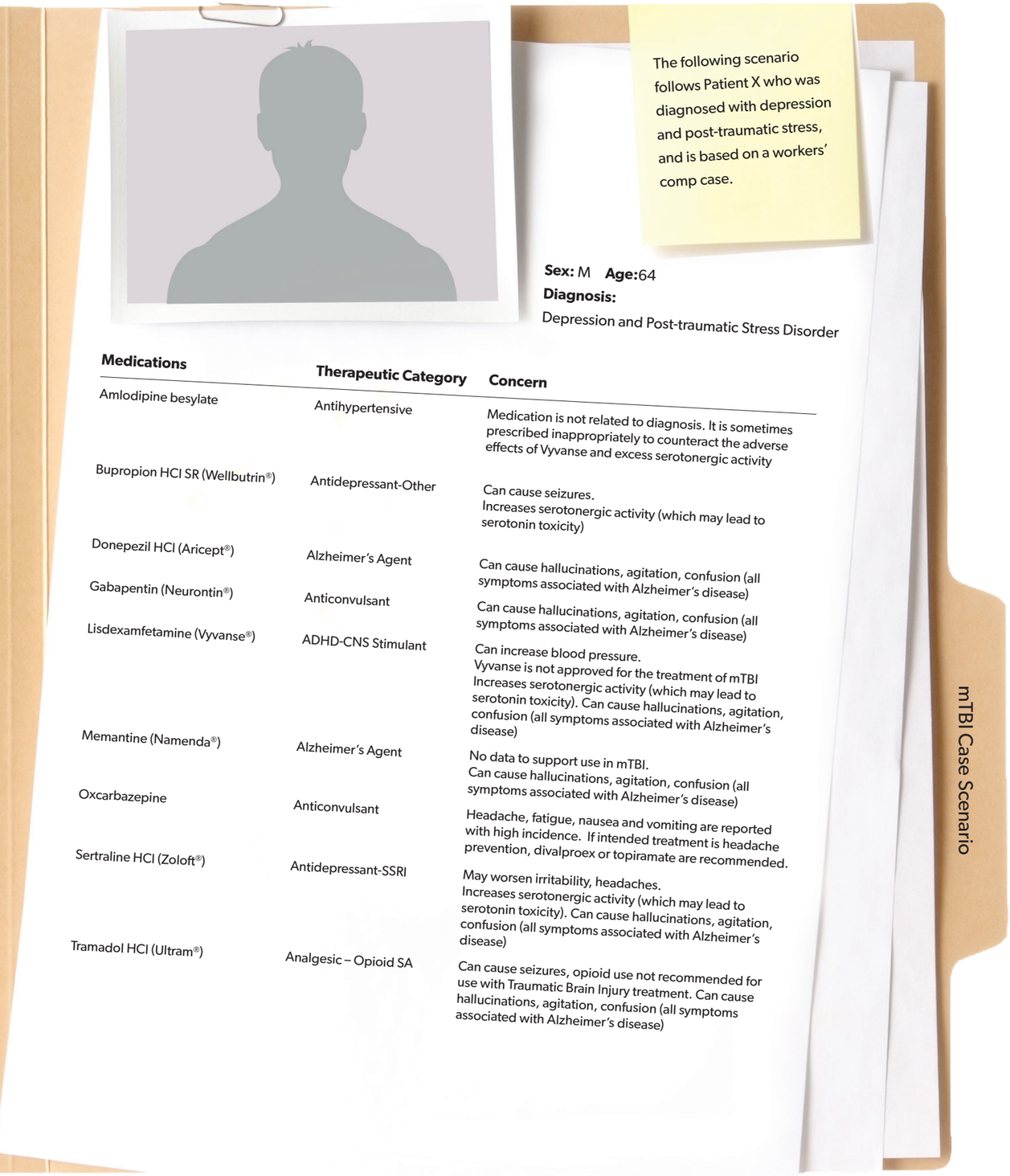
Concerns

Caution is advised with the use of stimulants as they can result in dangerous spikes in body temperature, escalation of blood pressure, and irregular heart rates including potential for heart failure or seizures.

may be multiple conditions resulting from mTBI, treatment may involve several drugs. Given the increased risk for adverse effects and drug-drug interactions in this population, it is recommended that response to therapy is documented and that long-term use of medications is critically evaluated and monitored. Evaluations should include stopping treatment if symptoms have resolved.[35]

The residual conditions associated with mTBI are varied and the list of potential effects is extensive. The graphic above illustrates some of the more common symptoms, recommended treatments and concerns that should be taken into consideration.

Studies of TBI show that these patients tend to be more sensitive to medication effects.[36] Therefore, all medication use should be carefully evaluated. The general rule of 'start low and increase doses slowly' is advised.[37,38] Caution is also advised when combinations of medications are prescribed since side effects can be cumulative. Additionally, combining medications with similar side effects can increase the likelihood of these side effects occurring. See the table on page 20 for possible side effects. Additionally, circumstances such as age, co-morbid conditions such as diabetes, hypertension and cardiac disease all must be considered when selecting the most appropriate drug therapy. A comprehensive medication review by the patient's physician may help eliminate unnecessary medications, identify potential medication reactions, and ultimately provide a safer regimen for the injured worker.



The following scenario follows Patient X who was diagnosed with depression and post-traumatic stress, and is based on a workers' comp case.

**Sex:** M **Age:**64
**Diagnosis:**
Depression and Post-traumatic Stress Disorder

| Medications | Therapeutic Category | Concern |
|---|---|---|
| Amlodipine besylate | Antihypertensive | Medication is not related to diagnosis. It is sometimes prescribed inappropriately to counteract the adverse effects of Vyvanse and excess serotonergic activity |
| Bupropion HCl SR (Wellbutrin®) | Antidepressant-Other | Can cause seizures.<br>Increases serotonergic activity (which may lead to serotonin toxicity) |
| Donepezil HCl (Aricept®) | Alzheimer's Agent | Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |
| Gabapentin (Neurontin®) | Anticonvulsant | Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |
| Lisdexamfetamine (Vyvanse®) | ADHD-CNS Stimulant | Can increase blood pressure.<br>Vyvanse is not approved for the treatment of mTBI<br>Increases serotonergic activity (which may lead to serotonin toxicity). Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |
| Memantine (Namenda®) | Alzheimer's Agent | No data to support use in mTBI.<br>Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |
| Oxcarbazepine | Anticonvulsant | Headache, fatigue, nausea and vomiting are reported with high incidence. If intended treatment is headache prevention, divalproex or topiramate are recommended. |
| Sertraline HCl (Zoloft®) | Antidepressant-SSRI | May worsen irritability, headaches.<br>Increases serotonergic activity (which may lead to serotonin toxicity). Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |
| Tramadol HCl (Ultram®) | Analgesic – Opioid SA | Can cause seizures, opioid use not recommended for use with Traumatic Brain Injury treatment. Can cause hallucinations, agitation, confusion (all symptoms associated with Alzheimer's disease) |

mTBI Case Scenario

## Review and Analysis

A thorough review of the Patient X mild Traumatic Brain Injury scenario on the left was conducted by a Healthesystems clinical pharmacist. An analysis of the medication profile identified several concerns. The use of multiple medications in this regimen may actually worsen the patient's condition. Since a consideration for all mTBI patients is an increased risk for seizures, the use of medications associated with potentially lowering the seizure threshold should be avoided. Therefore, the concurrent use of oxcarbazepine and gabapentin (anticonvulsants) with bupropion, tramadol, and lisdexamfetamine is concerning, since all of these medications can cause seizures.

Further examination raised the question of certain drugs' relationship to the patient's injury including memantine, amlodipine, and lisdexamfetamine. Memantine is approved for the treatment of Alzheimer's disease, and is not recommended to treat mTBI. Amlodipine is used for the treatment of chronic stable angina, vasospastic angina, coronary artery disease, and hypertension. There is no known diagnosis related to mTBI to support the use of this drug. Lisdexamfetamine is likely being prescribed to treat fatigue associated with mTBI; however, the preferred agent is methylphenidate. Based upon the injury and diagnosis, there is no known therapeutic reason for lisdexamfetamine to be prescribed for this patient.

The case study above demonstrates a good example of possible inappropriate polypharmacy, with several medications being prescribed to treat the adverse effects of other medications.

An even deeper review of the above drug regimen reveals:

- Oxcarbazepine may be prescribed for the treatment of seizures; however, this agent may worsen incidence and severity of headaches.
- Many drugs used in this regimen can produce adverse effects that may mimic signs of Alzheimer's disease – and additional drugs are being prescribed to then treat Alzheimer's disease.
- The CNS stimulant lisdexamfetamine may be prescribed to counteract fatigue related to the use of two anticonvulsants.
- Amlodipine may be prescribed to treat drug induced high blood pressure.
- The combination of tramadol, sertraline, and lisdexamfetamine may lead to increased serotonin activity. Symptoms of excess serotonin activity or serotonin toxicity may include symptoms such as agitation, anxiety and high blood pressure.

Although this case is complex, and may require the use of multiple medications, an analysis performed by Healthesystems clinicians revealed that the selection of drugs does not follow recommendations of the current guidelines. Communication with the prescriber regarding the intended use of each prescribed medication is imperative and is the next step in eliminating unnecessary or potentially harmful drug therapy. It is not uncommon for claims such as this case study to spin out of control when multiple medications are involved and when the treatment is complex. The costs associated with these types of claims are detrimental – both to the payer in terms of drug cost and the employer in terms of lost work, but more importantly to the patient, in terms of the cost to their health and well-being. Close involvement by clinicians can help to curb excessive and inappropriate drug use, and ultimately, deliver a better outcome for the payer and the patient.

The table below provides a look into medications which may be used to treat injured workers with mTBI. Claims professionals should pay close attention to the potential side effects of the drugs listed as well as possible drug interations that could occur.

## Medications Used to Treat mTBI, Side Effects and Drug Interactions*

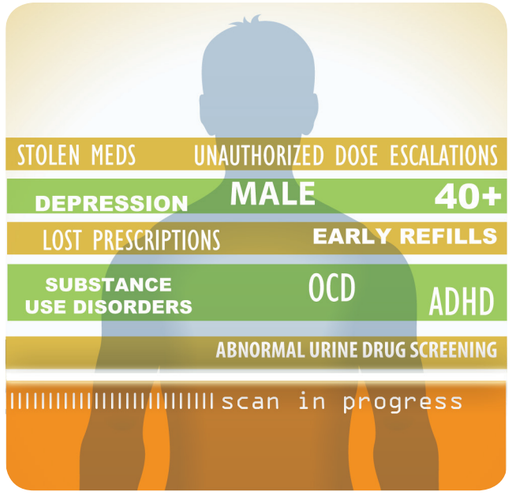
| | Acetaminophen | Amantadine | Amitriptyline | Benzodiazepines (alprazolam, diazepam, clonazepam, lorazepam) | Citalopram | Divalproex | Meclizine | Methylphenidate | Metoprolol |
|---|---|---|---|---|---|---|---|---|---|
| Potential Side Effects | Liver and kidney toxicity with excess doses<br>Maximum acute dose in 24 hour period 4 grams<br>Chronic use 2600 mg in 24 hour period | Nausea, dizziness, dry mouth | Sedation, cardiac arrhythmias, anticholinergic effects (dry eyes, dry mouth, urinary retention) | Sedation, abuse/dependence | Nausea, insomnia, agitation, sexual dysfunction | Dizziness, sedation, nausea, visual disturbances | Sedation, hallucinations, blurred vision | Insomnia, appetite suppression, headaches, dizziness, psychosis, aggression, cardiac events, and dangerous spikes in body temperature and blood pressure, and seizures | Bradycardia, hypotension, sedation |
| Potential Drug Interactions | OTC acetaminophen with combination opioid analgesics such as hydrocodone/acetaminophen, oxycodone/acetaminophen, butalbital/acetaminophen/caffeine (Fioricet®) | Monoamine oxidase inhibitors such as phenelzine | Other medications with sedation as an adverse effect: opioids, benzodiazepines, sedatives, hypnotics, other antidepressants such as SSRI and SNRIs | Increased sedation when combined with sleeping pills or opioids | Other antidepressants, tramadol, and CNS stimulants | Caution with other medications that can cause dizziness, effects may be increased with combination; Monitor for liver toxicity | Other medications with sedation as an adverse effect: opioids, benzodiazepines, sedatives, hypnotics | Serotonergic agents such as antidepressants | Antihypertensives; Caution in patients with asthma or diabetes |

| | Modafinil | NSAIDs (celecoxib, diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) | Opioids | Prazosin | Sertraline | Topiramate | Triptans (sumatriptan, zolmitriptan) | Zolpidem |
|---|---|---|---|---|---|---|---|---|
| Potential Side Effects | Headache, insomnia, appetite suppression, dizziness, psychosis, aggression, cardiac events, and dangerous spikes in body temperature and blood pressure, and seizures | GI upset, GI bleeding, ulcer formation, kidney toxicity (particularly in elderly or patients with hypertension or kidney disease) | Sedation, dependence, dizziness, hyperalgesia | Orthostatic hypotension (drop in blood pressure and dizziness upon rising from laying or seated position) | Nausea, insomnia, dry mouth, sexual dysfunction | Dizziness, anorexia, sedation, unsteady walk | Unusual taste with nasal formulation, dizziness, hypertension, injection site reactions, chest tightness | Morning "hangover" effect, excess daytime sedation, sleep driving, eating, or walking.[39] |
| Potential Drug Interactions | Serotonergic agents such as antidepressants | Aspirin, butalbital/aspirin/caffeine (Fiorinal®), warfarin | Caution with other medications that can cause sedation | Other blood pressure lowering medications | Other antidepressants, tramadol, and CNS stimulants | Caution with other medications that can cause dizziness, effects may be increased with combination; May worsen cognitive functions | Ergot alkaloids, CNS stimulants, serotonergic agents such as antidepressants, tramadol, tapentadol; caution in patients with cardiac disease, coronary artery disease | Increased sedation when combined with benzodiazepines or opioids |

**Information provided in this table is not all-inclusive. Refer to drug package insert for full prescribing information.*

# Performing Risk Assessment in **Opioid Therapy**

Screening patients for a predisposition to opioid abuse prior to treatment can help prevent abuse and develop better treatment plans.




SCAN RESULTS

Risks scan  Behavioral risks scan

The number of opioid prescriptions has risen dramatically in the United States in the past 20 years, in spite of weak evidence to support their long-term safety and efficacy.[40] The Centers for Disease Control and Prevention have termed the overuse of opioids an 'epidemic' in the United States. While much focus is being given in workers' compensation to controlling the utilization of opioids to treat chronic pain resulting from workplace injuries, more attention must be given to ensure that only the right patients are chosen to receive opioid therapy in the first place.

Risks of opioid therapy such as psychological dependence, misuse and abuse, are well known, and persist among all users. But, for patients with current or previous substance use disorders (SUD), these risks can not only be much higher, but also limit the benefit of opioids in treating pain related to the injury.[41]

Other risks for opioid abuse include:

Age (older than 40 years)

Sex (male)

Family history of substance abuse

Smoking

Presence of a psychological disorder (e.g., ADHD, obsessive-compulsive disorder, depression)

These issues may limit the effectiveness of opioid therapy and/or be predictive of future complications with use.[42]

## Risk Assessment Can Help Predict Abuse

A recent study found that chronic pain patients who also had a psychiatric disorder were more likely to receive opioids than other pain patients. It further showed a correlation with higher doses of opioids and higher rates of psychiatric illness.[43] It is therefore imperative that underlying issues which may be predictive of greater opioid utilization and abuse potential be uncovered before the first prescription is written. There are several clinical tools – among them the DIRE, ORT, and SOAPP-R – that can be used by prescribers to help uncover pre-existing issues and predict future abuse potential. The accompanying table on page 23 illustrates comparisons between these valuable assessment tools.

None of these tools, however, are lie detectors; they cannot prevent a patient's deception if that is their intent. These tools should be used to complement the prescriber's clinical assessment along with the use of other data, and should be part of obtaining a comprehensive patient history prior to opioid prescribing.

Assessing risk in opioid use is not limited to pre-screening, of course. All opioid patients, even those compliant with prescribed therapy, should undergo additional routine screening for behavioral issues that may complicate treatment.

Behavioral risks include screening for:

- ✓ Early refill requests
- ✓ Claims of lost/stolen prescriptions
- ✓ Unauthorized dose escalations
- ✓ Abnormal urine drug screening

These behaviors may raise a 'yellow flag' of caution, and patients who demonstrate these risks should warrant closer monitoring.

## Patient Pre-Screening Tools

| Screening / Monitoring Tools[44] | | |
|---|---|---|
| **DIRE** (Diagnosis, Intractability, Risk, Efficacy score) | **ORT** (Opioid Risk Tool) | **SOAPP-R** (Screener and Opioid Assessment for Patients with Pain – Revised) |
| Physician-administered | Patient-administered | Patient-administered |
| 7 items | 5 items | 24 items |
| Less than 2 minutes to administer and score | Less than 1 minute to administer and score | 5 minutes to administer and score |
| Developed for primary care physicians | Developed for pain patients | Developed for pain patients |
| Patient score closely linked to patient compliance and effectiveness of opioid therapy | Score ≥8 indicates high risk | Less susceptible to overt deception than other versions |

## Additional Considerations

Obtaining a comprehensive patient history is also a critical initial step when prescribers consider long-term opioid use. Pre-existing substance use disorders, as well as other psychiatric conditions can, if improperly accounted for and addressed, significantly impair attaining functional goals and lead to aberrant opioid use behavior. It is important that prescribers identify patient-specific risks and accommodate this risk into a patient-specific opioid treatment and monitoring plan.

Payers and claims professionals managing injured workers' care should request documentation from prescribers that these forms of screening are performed as part of the overall treatment plan in every case. Prescribers should also be able to describe how opioid prescribing and/or monitoring would be altered if the injured worker's risk level changes. The information gained through screenings helps to develop better treatment plans and allows for informed decisions, which assist in producing better patient outcomes. Educating all prescribers on the importance of pre-screening and monitoring patients for these risks before an opioid is prescribed is a critical challenge in addressing our nation's opioid epidemic.

**VIDEO SERIES**

Learn more about screening tools and early warning signs in our video series

# PDMP:
## The Game Changer?

Prescription drug abuse could be monitored and prevented if PDMPs are given the funding and attention they deserve.

*Prescription Drug Monitoring Programs (PDMPs) have the potential to offer a real-time glimpse into controlled substance prescribing patterns and patient drug-seeking behavior. That is, if these state-sponsored programs are appropriately utilized, mandated and funded. As it stands, plans are being developed to improve PDMPs, but as is the case with many interstate projects, time and cost are hindering factors. Regardless, the potential remains for PDMPs to be a serious contender in the fight against prescription drug abuse.*

### A Clinical Perspective:

#### PDMPs Offer Promise

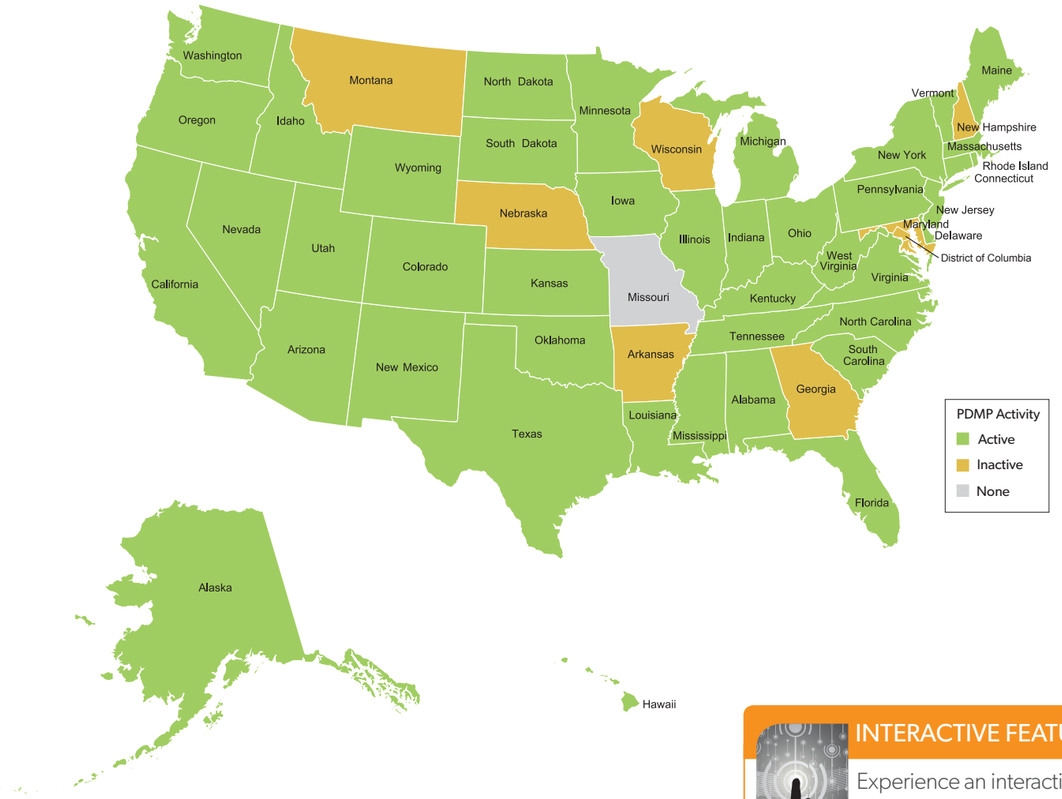
The opportunity to impact the trajectory of the opioid epidemic is within our reach, but as a nation, we can't seem to keep a hold of it. Prescription Drug Monitoring Programs could be an effective tool to help overcome prescription drug abuse.

A PDMP is a statewide, electronic database created to monitor the prescribing and dispensing of controlled substances. These databases are secured and access is authorized only to relevant parties, such as health care practitioners, pharmacists, law enforcement officers and other regulatory agencies.

The ultimate purpose of a PDMP is to encourage and facilitate *legitimate* medical use of controlled substances, and to discourage drug abuse, misuse, diversion and doctor-shopping. There are many advantages to a PDMP – but the limited funding, interstate variability, lack of third-party access, and lack of communication between states restricts the potential.



States with PDMPs




**INTERACTIVE FEATURE**

Experience an interactive map in the *RxInformer* iPad App to see more PDMP info

#### Most States Have an Active PDMP

Currently, 49 states, the District of Columbia, and one U.S. territory have passed legislation enacting a PDMP and 43 states have a PDMP that is actively collecting and reporting data. The Drug Enforcement Agency (DEA) plays no role in overseeing states PDMPs, but a variety of other regulatory bodies do oversee and administer state PDMPs, including law enforcement agencies, Boards of Pharmacy, Departments of Health, professional licensing agencies and substance abuse agencies. [See map above]

All states with PDMPs monitor Schedule II controlled substances, which include certain opioids, stimulants, and depressant drugs with very high abuse potential. Some examples of Schedule II drugs include morphine, oxycodone, codeine, methylphenidate, dextroamphetamine and some barbituates. In New York, due to the recent iSTOP legislation, hydrocodone is now considered a Schedule II controlled substance with stricter prescribing limits. (See page 10 for more information on the use and abuse of hydrocodone-containing drugs)

Many states also monitor Schedules II-V drugs, and some states expand their focus to include other drugs of possible abuse, such as tramadol and carisoprodol. On January 12, 2012, carisoprodol became a schedule IV substance in all states.

Each state determines who is authorized to access the PDMP for that state, however, most states grant authority to prescribers and pharmacists, as this information relates to the treatment of a specific patient.

States may also provide PDMP data to other entities, such as state medical examiners, law enforcement, other state PDMPs, licensing/regulatory boards, or research organizations for data analysis. Typically, law enforcement does not gain access to patient-specific PDMP data unless requested as part of an ongoing investigation. A few states even allow patient access to the PDMP and may grant patients a report of their own record if requested, but patients are not allowed direct access to the database.

## PDMPs Are Underutilized

Although more research on the effectiveness of PDMPs is warranted, current data suggests that the benefits of a using a PDMP may reduce doctor-shopping, alter prescribing behavior, and curb rates of opioid abuse.[45,46]

A recent study, published in September 2012 by researchers at the Heller School for Social Policy and Management, assessed the role of PDMPs and offered recommendations for improving PDMP effectiveness, such as offering proactive reports, mandating prescriber use, and improving data quality through timeliness, completeness and consistency.[47]

However, several issues currently stand out as being barriers to immediately realizing the full impact of PDMPs. Wide variability exists among states in how data is contained and reported, and since PDMPs are not active in all states, no uniformity presently exists on data-sharing and interstate operability. This concept is not yet widely embraced, although a handful of states has begun to take the step towards data sharing. The fact is that injured workers do travel between states, cross state lines to visit doctors, and use pharmacies in neighboring states. Historically, there has not been a widely adopted vehicle in place to share prescription drug monitoring information across states, except between Kentucky and Ohio. These two states currently have interchange of data in place. Interstate operability is one of the keys to early intervention and abuse avoidance.

There is movement to change this. The Prescription Monitoring Information Xchange (PMIX) architecture, sponsored by the Alliance of States with Prescription Monitoring Programs, is one ongoing attempt to facilitate the sharing of encrypted PDMP data across state lines. Its goal is to implement a standardized, secure, scalable approach for the exchange of electronic PDMP data among states. Each state can participate in the PMIX program by passing its own legislation to share real-time information with other defined partnering states.[48]

The National Association of Boards of Pharmacy (NABP) has expanded on the concept with additional technology to facilitate ease of data sharing. This technology platform, *InterConnect*, will be compatible with the PMIX architecture. It is estimated that 25 states will be using the NABP software for data sharing by early to mid-2013.[49] Currently, 15 states participate in the *InterConnect* program. See the interactive map in the *RxInformer* App version of this publication to view the participating states.

The National Council for Prescription Drug Programs (NCPDP), the organization that provides national coding standards for the insurance industry, recently published recommendations for improving PDMPs. NCPDP proposes improving standardization of data by requiring a minimum data set and standard transaction format across all states, enacting real-time reporting leveraging current electronic prescribing capability, and the inclusion of a central data repository to provide multistate access to comprehensive data.[50]

Currently, states may not report data in a real-time fashion, and pharmacy submission requirements vary from daily, weekly, bi-weekly, to monthly. States may retrospectively analyze and report information contained in the database. Available research suggests that issuing reports proactively – to prescribers or pharmacies when suspicious trends are identified – may have a more significant impact on curbing abuse.[51]

Furthermore, not all states mandate that prescribers consult the PDMP database before issuing a script for a controlled substance. However, in 2012, four states (Kentucky, Massachusetts, New York, and Tennessee) passed legislation mandating that prescribers consult the state PDMP before issuing a script, and Florida currently has proposed similar legislation as well.[52]

New York's recently enacted iSTOP legislation requires enhancement and modernization of the existing Department of Health's secure prescription monitoring program registry, to include information about dispensed controlled substances reported by pharmacies on a "real time" basis, to curb abuse and diversion. The legislation, in most cases, requires health care practitioners to consult the PMP Registry before prescribing or dispensing certain controlled substances prone to abuse and diversion. In addition, the law mandates electronic prescribing for all controlled substances, with limited exceptions.

The Kentucky All Schedule Prescription Electronic Reporting (KASPER) System tracks controlled substance prescriptions dispensed within the state. This PDMP, which has documented success, reports all scheduled prescriptions for an individual over a specified time period, the prescriber and the dispenser. Practitioners, pharmacist and law enforcement have access to the KASPER system.

## Future Considerations

It is known that chronic opioid use may predict lengthened disability, and long-term use of opioids is associated with extended disability and less successful outcomes[53,54,55] as well as higher medical costs and more costly claims.[56] Third-party payer access by entities with a significant stake in curtailing opioid misuse and abuse is the next logical step in the evolution of state PDMPs.

A report released by the California Workers' Compensation Institute (CWCI) claimed that payer access to the California state PDMP, Controlled Substance Utilization Review and Evaluation System (CURES), could have cut California workers' compensation claim costs by an estimated $57.2 million – by identifying inappropriate opioid prescribing not recommended by evidence-based medical literature or the Medical Treatment Utilization Schedule.[57]

However, none of these benefits may be realized if the databases are not operational, which remains a serious problem looming over many states plagued by lack of funds. Currently, a mix of grants, licensing fees, general revenue, and board funds constitute funding for state PDMPs, none of which is a reliable source of sustainable income. While state PDMPs offer the potential to champion the fight against prescription drug abuse, they will not gain the advantage unless funding and access is provided.

# PDMPs: Treatment Guidelines & Closed Formularies

## Can Control Overutilization if …

**A. National standards were utilized**
**B. Compliance was mandatory**
**C. Payers/providers "buy in" to evidence-based medicine**
**D. All of the above**

As you may have guessed, the answer is D - all of the above. As of April 2013, all but one state (Missouri) have legislation which establishes, and in some cases mandates, use of a statewide PDMP program (see PDMP map on page 25). At least half of the states' workers' compensation systems have adopted treatment guidelines of some kind, and four jurisdictions (Ohio, North Dakota, Texas and Washington) have preferred or closed formulary plans in place. So why is it, with all these available tools, that our workers' compensation system struggles to hold down costs and improve medical outcomes? The answer is complex and indicative of a system that is in a state of constant change.

### PDMPs Offer Promise, But There Are Obstacles

The previous article in this journal, *The Game Changer*, addresses the potential of PDMPs to control prescription drug abuse. It references two state PDMP programs in New York and Kentucky that hold promise and are a step in the right direction for establishing the guidelines of a national solution.

In 2011, Arizona's legislature passed a law that required physicians treating injured workers to check PDMPs and report data when certain criteria were met. According to the Arizona Criminal Justice Commission[58] as of July 2012, only 22% of Arizona physicians are using the PDMPs on a regular basis, since this program is not mandated. As a result, opioid prescribing is still a challenge in this state. As previously discussed, PDMPs hold promise for curbing abuse and diversion, but mandated use is a critical step.

### Treatment Guidelines

For as long as physicians have been practicing medicine, evidence based treatment guidelines have been published. Treatment guidelines are byproducts of a medical field that thrives on research methodologies and clinical investigation. It would be easy to assume there is a single source of research that compiles all the data into an easy to understand "cookbook" for treating most types of injuries. However, the ingredients for successful medical outcomes can be as complex and unique as the injured worker themselves, and no such cookbook exists. Numerous compilations of research and data are assembled by organizations such as the Work Loss Data Institute, publisher of the Official Disability Guides, and the American College of Occupational and Environmental Medicine (ACOEM). While these guidelines are popular in the workers' compensation industry, there are a dozen or more state specific, "consensus based" versions of medical treatment guidelines in existence. In addition to these workers' compensation specific treatment guidelines, the National Institute of Health has published their own studies and guidelines for over one hundred years. [59]

Despite this wealth of guidance and research, it is not an easy task for physicians and payers to agree on what constitutes appropriate medical care. With each patient, there is a unique medical history, and though the experts may agree on the symptoms, there is less agreement among doctors on how to treat those symptoms. Often, claims professionals find themselves asking "What, if any, guideline was this treatment plan based upon?" Once the guideline is determined, the claims professional then has to reference the appropriate set of guidelines for that state and discern if the care is in accordance with the guideline and if not, what options they can pursue to resolve the conflict. For national insurers and employers with workers in many states, this is one of the many challenges in managing medical treatments and costs. Visit the IAIABC website to view the states and the various medical treatment guidelines.

### Drug Formularies

In recent years, state workers' compensation systems have begun to embrace the idea of implementing closed formularies similar to the way group health plans offer "tiered" coverage plans. Monopolistic states (states with special legislation requiring workers' compensation coverage be provided exclusively by the state's designated program) were early adopters of formularies. Washington State and Ohio periodically update their drug formularies with prior authorization requirements for some classes of drugs and for off label use. Texas took a different approach and adopted the ODG guidelines as the basis of their closed formulary, where designated "N" drugs require the prescribing physician to complete a letter of medical necessity. Formularies are another mechanism to ensure better oversight and monitoring by both the payer and the provider. Early results from the Texas system indicate the closed formulary system has made a positive, measurable impact on the overall quality and cost of health care delivery to Texas injured workers.[60]

As long as PBMs have been serving workers' compensation payers, they have offered similar types of tools to help manage pharmacy costs. Texas is the first free market system to adopt a closed formulary, but other states are examining these results and considering a similar approach. New Hampshire's legislature considered a bill earlier this year which would have implemented a closed formulary similar to Texas and made generic drugs mandatory. Though the state ultimately removed that measure from the bill, other states may decide to follow the closed formulary tactic given the positive results to date in Texas.

### Putting it All Together

For seasoned claim and medical professionals, closed formularies and medical treatment guidelines are just two of the many ingredients needed to manage claim outcomes and reduce costs. The potential to add PDMP access in the future is still unknown, since privacy issues, data sharing concerns and funding challenges exist. In the meantime, employing the tools that do exist is important. Pharmacy benefit managers can successfully manage medication plans, and facilitate access to valuable data, so that informed and timely claims decisions are made. Coupled with consistent communication among all parties – payers, providers, injured workers and PBMs – creates the most reliable recipe for successful outcomes.

**VIDEO SERIES**

Watch an interview with President Daryl Corr about state efforts to control costs

# National Drug Codes (NDC)

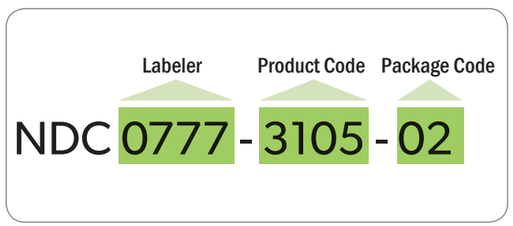
## Depletion Dilemma on the Horizon

**All stakeholders need to prepare for a wide-reaching and imminent change.**

The pharmaceutical industry is headed towards a shortage of National Drug Codes (NDCs) – and everyone from payers to prescribers and patients will be impacted. It is important to recognize and understand this depletion issue now, so steps can be put in place today to alleviate the challenge this will cause in the future.

### A Look Behind the Code

The National Drug Code is a unique ten-digit, three-segment numeric identifier assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act. The segments within each number identify the labeler or vendor, the product (within the scope of the labeler), and the trade package (of the product).




- The first segment, the **labeler code**, is four or five digits long and assigned by the Food and Drug Administration (FDA) upon submission of a Labeler Code Request. A labeler is any firm that manufactures, repacks or distributes a drug product.
- The second segment, the **product code**, is three or four digits long and identifies a specific strength, dosage form, and formulation for a particular firm.
- The third segment, the **package code**, is one or two digits long and identifies package forms and sizes. In very exceptional cases, product and package segments may contain characters other than digits.[61]

While the labeler code is assigned by the FDA, both the product and package segments are assigned by the labeler.[61] In the past labelers were able to re-assign old product codes that were no longer being used to new products; but according to new FDA validation procedures, once an NDC code has been assigned to one product (defined by key properties including active ingredients, strength, and dosage form) it can no longer be reassigned to a different product.

It was recently reported that the FDA is quickly running out of NDCs for assignment to new medications/products. This issue was reported to be related to the FDA's requirement to have new NDCs assigned when manufacturers or companies are repackaging medications. This may be directly related to the increase in repackaging seen in the workers' compensation market.

Healthesystems has published several reports regarding the cost and utilization impact of repackaged drugs on the workers' compensation industry.

Read our white paper

http://www.healthesystems.com/clinical-resources/opioid-repack.aspx

The three segments that make up each NDC code are arranged into one of the following sets of digit strings: 4-4-2, 5-3-2, or 5-4-1, with all of these strings totaling ten digits.[61]

The Centers for Medicare and Medicaid Services (CMS) had created an 11-digit NDC derivative based on the FDA 10-digit string, which pads the labeler, product, or package code segments of the NDC with leading zeroes wherever they are needed to result in a fixed length 5-4-2 configuration (but always written without dashes).[61] This format was adopted by data standards selected pursuant to HIPAA regulation, thus other government agencies' lists and databases (such as the UMLS) may contain the 11-digit derivative of the original NDC.

### Far-reaching Impact

An NDC number assigned to a medication is an integral component to many pharmacy processes, including dispensing, claims adjudication, formulary management, billing, and many others. These unique codes are also used in patient profiles and even make their way to hospital bedsides as verification of patient identity with prescribed medications. A change to the structure of this important coding system will have a far reaching impact as all parties will need to make programmatic changes to allow for a new coding system.

### Contributing Factors

A practice which may be contributing to the forthcoming depletion of NDCs is that of repackaging drugs. This is the practice in which repackaging companies purchase large quantities of prescription drugs from manufacturers and then repackage them into smaller quantities and resell them. As part of the repackaging process, drugs are assigned a new NDC. Assigning a distinct, new NDC allows the repackaging company to increase the average wholesale price (AWP) of the repack drug compared to the original drug price.

Drug repackaging activity has been rising over the last several years and as such has become one of the contributors to the depletion of available NDC's.

### Next Steps and Solutions

The FDA has recommended a potential solution of increasing the first segment to a six digit labeler code. The National Council of Prescription Drug Programs (NCPDP), the organization that provides national coding standards for the insurance industry, is concerned about the potential impacts to the industry. NCPDP has established an NDC Depletion Task Group to evaluate the impacts and to assist in educating the FDA Office of Compliance about issues surrounding potential solutions and advise the FDA about other options that may be available to minimize the impact of a new coding system.

It is important for all stakeholders to be actively engaged in the solution to this far-reaching dilemma. Preparing for a change to the coding structure now will alleviate problems with exchanging the prescription data in the future. Payers, PBMs and other stakeholders should begin to evaluate their systems' capabilities for receiving, and the resulting impact of, a longer NDC value.

# The State of the States

## Texas

*New Data Call*

The Texas Department of Insurance (TDI), Division of Workers' Compensation has issued an April 1, 2013, deadline for designated carriers to demonstrate compliance with provisions related to the final stages of the ODG closed formulary implementation. TDI has asked carriers to submit data to the department via a form designed by the Workers' Compensation Research and Evaluation Group. The data call is intended to ensure carrier compliance for legacy claims; that is - claims with injury dates prior to September 1, 2011. Claims included in the data call were identified by having at least one "N" drug from the ODG closed formulary dispensed between September 1, 2012, and March 1, 2013.

Early analysis of the closed formulary impact indicates opioid prescriptions and costs have decreased since the formulary was implemented in 2011. TDI will continue to assess the formulary's efficacy going forward. Part of the analysis will involve data from legacy claims, once those claims become subject to the closed formulary on or before September 1, 2013. For further information, please refer to TDI's data call instructions.

## Kentucky

*Governor Signs Changes to Pill Mill Law*

Kentucky's Governor signed House Bill 217 into law on March 4, 2013, amending last year's pill mill law and fortifying reporting rules for pharmacies and prescribers of certain drugs. The new law requires physicians to assess a patient's mental condition, and check the state's prescription drug monitoring database (KASPER) for the previous 12 months before prescribing any Schedule II or III drugs. Previously, physicians were only required to assess the patient's physical condition, and the law did not specify the length of the patient's drug history that physicians were required to review. Additionally, physicians must now conduct patient drug history reviews and modify or terminate prescriptions as needed based on the review. This new process is specific to certain patients receiving Schedule II or III drugs with hydrocodone as a single ingredient or component of another drug, such as hydrocodone with acetaminophen. The law will also require the state licensing boards to conduct criminal background checks for license applicants who want to prescribe or dispense controlled substances.

Since taking effect on July 20, 2012, Kentucky's landmark pill mill law (2012 HB1) has demonstrated success in combating prescription drug abuse in the state. According to the Governor's Office, the pill mill law reduced total doses of all controlled substances by 10.4% after six months, however stakeholders agree the law needs some changes. In regards to the new legislation (HB 217) Governor Beshear's office released the following statement: "Unlicensed pain management clinics have closed up shop and prescriptions for the most addictive drugs have dropped every month since implementation." Some patient advocate groups and the Kentucky Medical Association voiced concerns during the legislative session regarding patient difficulty in accessing medical care following the law change in 2012, and the imposition of physician liability for physicians who are treating patients with long term chronic pain symptoms. It is still too soon to fully understand how or if these concerns will be resolved by the 2013 revisions to law.

## Idaho

*Legislature Approves Pharmacy Fee Schedule*

In late 2012, the Idaho Industrial Commission proposed a workers' compensation pharmacy fee schedule, which has recently been approved by the state's legislature. The fee schedule will become effective on July 1, 2013, and addresses reimbursement for brand, generic, repackaged and compound drugs. Particularly, repackaged drugs will be reimbursed based on average wholesale price of the original NDC and compound drugs will be reimbursed at the ingredient level. Legislative approval was contingent upon an agreement that the Commission consider testimony from the Idaho Pharmacy Association (IPA) regarding the adequacy of a $5.00 dispense fee for brand and generic drugs. The Commission has indicated its intent to adopt a temporary rule which will address the IPA concerns, and is expected to occur prior to the effective date of the new fee schedule. The determination of the dispense fees has not been decided.

## Oregon

*Medical State Reporting and Electronic Billing Rules*

The Oregon Workers' Compensation Division (WCD) is preparing to adopt a new set of rules in response to the recently updated Medical EDI standards, now available through the IAIABC. The new standards were approved in late 2012 and include a new EDI Implementation Guide for Medical Bill Payment Records (Release version 2.0, 2012 edition) and a new Medical Payment Reporting Supplement (Release 2.0 - 2012 edition). Since the IAIABC's adoption of the Implementation Guide and the Reporting Supplement, Oregon's WCD has begun to plan for the adoption of these new standards, as well as their e-billing rules. EDI Medical Release 2.0 will now allow for more robust information, such as compound ingredients, to be sent via electronic data interchange (EDI) transactions. Several attendees requested that the Rules Advisory Committee push the proposed EDI 2.0 implementation deadline back to early 2014 to give participants more time to prepare their systems for implementation. The Rules Advisory Committee also discussed consolidating different sections of rules to harmonize the EDI rule and the draft e-bill rules. The Oregon E-billing Advisory Committee will continue to meet until a proposed draft is ready for stakeholder comment. For more information on e-billing or medical state reporting in Oregon, or to sign up for the rules advisory committee meetings or minutes, please contact fred.h.bruyns@state.or.us at the WCD.

## Florida

*Debate on Drug Reimbursement Continues*

Florida lawmakers are contemplating legislation to close an existing loophole which requires payers to reimburse repackaged, physician dispensed medications at rates that are sometimes up to 1000% greater than identical drugs dispensed in a pharmacy setting. This is the fourth consecutive year the legislature has debated this issue, but this year presents a unique issue. Opponents to closing this costly loophole have introduced legislation of their own, which could have a devastating impact on overall pharmacy spend in the state. The opponent's strategy is to pass legislation which would prohibit payers from de-authorizing care with a physician on the basis that the physician is dispensing medications to injured workers in office, and would also repeal language in existing law which permits a payer to reduce out-of-network pharmacy transactions to in-network rates, when the injured worker fails to obtain their medications within the pharmacy network.

## California

*Healthesystems Supports Legislation to Eliminate Requirement to Attach Prescriptions to Pharmacy Bills*

Healthesystems has demonstrated support of California Senate Bill 146, which would eliminate the requirement that providers attach prescriptions to each pharmacy bill in order to establish eligibility for reimbursement. The need for SB 146 grew out of the broad workers' compensation reform legislation passed in 2012, and the Division of Workers' Compensation Medical Billing and Payment Guide, which require prescriptions or referrals to be attached to a bill if the services are provided by someone other than the primary treating physician.

However, the Division's adopted electronic billing standard for pharmacy bills (NCPDP Telecommunications Standard Version D.0) does not currently support the inclusion of attachments, making pharmacy billers incapable of compliance and subject to denials. If this billing issue is not addressed, a pharmacy's ability to fill workers' compensation prescriptions will be affected, which may limit access to necessary medication. As SB 146 continues to move through the legislative process, Healthesystems will continue to communicate its support of the bill to state legislators.

# By the **Numbers**


Inappropriate **polypharmacy** is associated with significant morbidity and mortality costing United States' health plans more than **$50 BILLION** per year. Berenbeim DM. Manag Care Q. 2002

## A Typical Polypharmacy Scenario:

**12 DIFFERENT MEDICATIONS** prescribed potentially causing

**06 SIDE EFFECTS**

**07 DRUG INTERACTIONS**

**September**

**1**

2013

Texas legacy claims will be subject to the closed formulary

Incidents of traumatic brain injury in workers' comp can occur in as many as

17 per 1000 claims


In 2010, more than 70% of narcotic analgesic [law enforcement] reports involved **oxycodone** or **hydrocodone**

**2x** Workers' comp claims for patients with **MULTIPLE CHRONIC CONDITIONS** were associated with **DOUBLE THE MEDICAL COSTS** than a claim without additional medical conditions - Laws C, Colon D. Comorbidities in Workers Compensation. NCCI Research Brief 2012



# References


Stemming The Tide on the Opioid Epidemic

1. CDC. Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic. MMWR 2012; 61 (01); 10-13, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm. Accessed April 1, 2013.
2. CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999-2008. MMWR 2011; 60: 1-6, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm. Accessed April 1, 2013.

Med Watch

3. FDA Drug Safety Communication: Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist). Food and Drug Administration. http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm. Accessed January 10, 2013.
4. National Institute for Clinical Excellence (NICE). Guidance on the use of zaleplon zolpidem and zopiclone for short-term management of insomnia. *NICE Technology Appraisal Guidance*. April 2004; No. 77.

Polypharmacy: When More Is Less

5. Werder SF, Preskorn SH. Managing polypharmacy: walking the fine line between help and harm. *J Family Practice.* 2003;2(2): Available at: http://www.jfponline.com/Pages.asp?AID=601. Accessed March 18, 2013.
6. Laws C, Colon D. Comorbidities in workers compensation. NCCI Research Brief. 2012. Available at: https://www.ncci.com/nccimain/IndustryInformation/ResearchOutlook/Pages/Comorbidities-in-Workers-Comp.aspx. Accessed February 5, 2013.
7. Bushardt RL, et al. *Clin Interventions Aging.* 2008;3(2):383-389.
8. Zarowitz BJ, et al. *Pharmacotherapy.* 2005;25(11):1636-1645.
9. Werder SF, Preskorn SH. Managing polypharmacy: walking the fine line between help and harm. *J Family Practice.* 2003;2(2): Available at: http://www.jfponline.com/Pages.asp?AID=601. Accessed March 18, 2013.
10. Werder SF, Preskorn SH. Managing polypharmacy: walking the fine line between help and harm. *J Family Practice.* 2003;2(2): Available at: http://www.jfponline.com/Pages.asp?AID=601. Accessed March 18, 2013.
11. Berenbeim DM. *Manag Care Q.* 2002;10(3):1-5.
12. Bushardt RL, et al. *Clin Interventions Aging.* 2008;3(2):383-389.
13. Bergman-Evans B. *J Gerontol Nurs.* 2006;32:6-14.
14. Werder SF, Preskorn SH. Managing polypharmacy: walking the fine line between help and harm. *J Family Practice.* 2003;2(2): Available at: http://www.jfponline.com/Pages.asp?AID=601. Accessed March 18, 2013.
15. Zarowitz BJ, et al. *Pharmacotherapy.* 2005;25(11):1636-1645.
16. Tharp D. 2013. Healthesystems data on file.
17. Laws C, Colon D. Comorbidities in workers compensation. NCCI Research Brief. 2012. Available at: https://www.ncci.com/nccimain/IndustryInformation/ResearchOutlook/Pages/Comorbidities-in-Workers-Comp.aspx. Accessed February 5, 2013.

Hydrocodone: Use, Abuse and Controls on Prescribing

18. D*EA Fact Sheet.* Washington, DC: Drug Enforcement Administration, Office; of Public Affairs; December 2012. Available at: http://www.justice.gov/dea/docs/1207_fact-sheet.pdf. Accessed February 20, 2013.
19. Title 21United States Code Controlled Substances Act, Part B-- Authority to Control; Standards and Schedules, Section 811. Authority and Criteria for Classification of Substances . Available at: http://www.deadiversion.usdoj.gov/21cfr/21usc/811.htm. Accessed February 20, 2013.
20. Hydrocodone. Rockville, MD: Office of Diversion Control, Drug Enforcement Administration; June 2011. Available at: http://www.deadiversion.usdoj.gov/drugs_concern/hydrocodone.pdf. Accessed March 19, 2013.
21. U.S. Drug Enforcement Administration, Office of Diversion Control. (2011). *National Forensic Laboratory Information System: 2011 Annual Report.* Springfield, VA: U.S. Drug Enforcement Administration. Available at: http://www.deadiversion.usdoj.gov/nflis/2011annual_rpt.pdf. Accessed February 11, 2013.
22. Fiore C. Vicodin triggers interagency war. *MedPage.* December 22, 2012: Available at: http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/36593. Accessed March 19, 2013.
23. Gov. Beshear Signs HB 217, makes common sense improvements to landmark prescription drug abuse bill. Communications Office. March 05, 2013. Available at: http://migration.kentucky.gov/newsroom/governor/20130305hb217.htm. Accessed March 10. 2013.
24. Kuehn, BM. FDA committee: more restrictions needed on hydrocodone combination products. *JAMA.* 2013; 309(9): 862.
25. A.G. Schneiderman alerts medical professionals to new hydrocodone rule change under Rx drug law. Press release 2/27/2013. Available at: http://www.ag.ny.gov/press-release/ag-schneiderman-alerts-medical-professionals-new-hydrocodone-rule-change-under-rx-drug . Accessed March 10, 2013.
26. Kuehn BM. FDA Committee: More Restrictions Needed on Hydrocodone Combination Products *JAMA*, March 6, 2013; 309(9): 362.

Central Nervous System: Stimulant Use on the Rise

27. Schwarz, A. Drowned in a Stream of Prescriptions. The New York Times. February 2, 2013.
28. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The DAWN Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits. Rockville, MD. February 22, 2013
29. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 24, 2013). *The DAWN Report: Emergency Department Visits Involving Attention Deficit/Hyperactivity Disorder Stimulant Medications.* Rockville, MD.
30. Clinical Pharmacology.

Traumatic Brain Injury: What Meds Are Appropriate?

31. Kristman VL, Cote P, Van Eerd D, et al. Prevalence of lost-time claims for mild traumatic brain injury in the working population: Improving estimates using workers compensation databases. Brain Injury. 2008;22:51-59.
32. Kraus JF, Fife D. Incidence, external causes, and outcomes of work-related brain injuries in males. J Occup Med. 1985;27:757-760.
33. Cifu D, Bowles A, Hurley R et al. VA/DoD Clinical practice guideline for management of concussion/mild traumatic brain injury. *J Rehabil Res Dev.* 2009; 46(6):CP1-68.
34. Cifu D, Bowles A, Hurley R et al. VA/DoD Clinical practice guideline for management of concussion/mild traumatic brain injury. *J Rehabil Res Dev.* 2009; 46(6):CP1-68.
35. Cifu D, Bowles A, Hurley R et al. VA/DoD Clinical practice guideline for management of concussion/mild traumatic brain injury. *J Rehabil Res Dev.* 2009; 46(6):CP1-68.
36. Wheaton P, Mathias JL, Vink R. Impact of pharmacological treatments on cognitive and behavioral outcome in the postacute stages of adult traumatic brain injury-a meta-analysis. *J Clin Psychopharmacol.* 2011;31(6):745-757
37. Young JA. Pharmacotherapy for traumatic brain injury: Focus on sympathomimetics. *J Pharmacothera.* 2012;134:1-7.
38. Arciniegas DB, Anderson CA, Topkoff J et al. Mild traumatic brain injury: a neuropsychiatric approach to diagnosis, evaluation, and treatment. *Neuropsychiatr Dis Treat.* 2005 1(4):311-327.
39. US Food and Drug Administration. Risk of next morning impairment after use of insomnia drugs: FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist).

Performing Risk Assessment in Opioid Therapy

40. Manchikanti L, Vallejo R, Manchikanti KN, et al. Effectiveness of long-term opioid therapy for chronic non-cancer pain. *Pain Physician.* 2011;14:E133-156.
41. Workman, E., et al. Comorbid Psychiatric Disorders and Predictors of Pain Management Program Success in Patients with Chronic Pain. Prim Care Companion J Clin Psychiatry. 2002; 4(4): 137–140.
42. Sullivan MD, Edlund MJ, Fan MY, et al. Risks for possible and probable opioid misuse among recipients of chronic opioid therapy in commercial and medicaid insurance plans: the TROUP Study. *Pain.* 2010;150:332-339.
43. Kobus, A., Smith, D., Morasco, B., Johnson, E., Yang, X., Petrik, A., Dey, R. Correlates of Higher-Dose Opioid Medication Use for Low Back Pain in Primary Care. The Journal of Pain, Vol 13, No 11 (November), 2012: 1131-1138.
44. Moore TM, Jones T, Browder JH, Daffron S, Passik SD. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. *Pain Med.* 2009;10(8):1426-1433.

PDMP: The Game Changer?

45. Julie Worley, "Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research," *Issues in Mental Health Nursing,* vol. 33, no. 5 (2012), pp. 319-328.
46. Liza M. Reifler et al., "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse," *Pain Medicine,* no. 13 (2012), pp. 434-442.
47. Thomas Clark et al, Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices, 6 (2012).
48. Alliance of States with Prescription Drug Monitoring Programs. Available at: http://www.pmpalliance.org/. Accessed January March 14, 2013.
49. National Association of State Boards of Pharmacy (NABP), *NABP PMP InterConnect,* 2012, http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect.
50. National Council for Prescription Drug Programs (NCPDP), *NCPDP Recommendations for Improving Prescription Drug Monitoring Programs (PDMP),* 2013, Available at: www.ncpdp.org. Accessed March 14, 2013.
51. Ronald Simeone and Lynn Holland, *An Evaluation of Prescription Drug Monitoring Programs,* Simeone Associates, Inc., No. 2005PMBXK189, September 1, 2006. Sponsored by the U.S. Department of Justice (DOJ), Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA).
52. Thomas Clark et al, Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices,6 (2012).
53. Franklin GM, Stover BD, Turner JA, et al; Disability Risk Identification Study Cohort. Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort. Spine *(Phila Pa 1976)* 2008;33(2):199-204.
54. Webster BS, Verma SK, Gatchel RJ. Relationship between early opioid prescribing for acute occupational low back pain and disability duration, medical costs, subsequent surgery, and late opioid use. *Spine (Phila Pa 1976)* 2007; 32:2127-2132.
55. Kidner CL, Mayer TG, Gatchel RJ. Higher opioid doses predict poorer functional outcome in patients with chronic disabling occupational musculoskeletal disorders. *J Bone Joint Surg Am.* 2009;91(4):919-27.
56. Leider HL, Dhaliwal J, Davis EJ, et al. Healthcare costs and nonadherence among chronic opioid users. *Am J Manag Care.* 2011;17(1):32-40.
57. Alex Swedlow and John Ireland. *Estimated Savings from Enhanced Opioid Management Controls Through Third Party Payer Access to CURES.* January 2013. California Workers' Compensation Institute (CWCI).

PDMPs: Treatment Guidelines & Closed Formularies

58. Arizona Substance Abuse Partnership. Prescription Drug Abuse in Arizona; Using Data to Understand the Problem and Guide the Development of Solutions. July 20, 2012. Assessed 4/8/13. http://cabhp.asu.edu/events/si-session-54
59. National Institutes of Health. Assessed 4/8/13. http://www.nlm.nih.gov/
60. Texas Department of Insurance. Fewer Texas Workers' Compensation Claims Include Opioids and Not-Recommended Prescriptions. June 19, 2012. Assessed 4/8/13. http://www.tdi.texas.gov/news/2012/news201225.html

NDC Depletion Dilemma

61. FDA. National Drug Code Directory. 4/8/2013 Update. http://www.fda.gov/Drugs/InformationOnDrugs/UCM142438. htmen.wikipedia.org/wiki/National_Drug_Code#cite_note-SPL_Validation_Procedures-3

Healthesystems™

www.healthesystems.com | 800.921.1880 | info@healthesystems.com