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Current and emerging issues impacting workers' comp FALL 2013

Regulation Alone WON'T CONTROL PHYSICIAN DISPENSING

Deadly Drug Combinations
Escaping Notice

BEYOND OPIOIDS ALTERNATIVE
Pain Management Therapies

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FALL 2013

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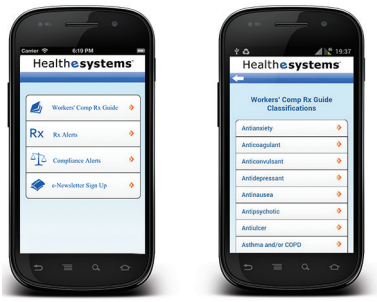

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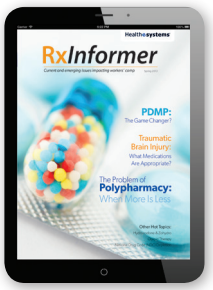

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THE OPIOID EPIDEMIC

HOW DID WE GET HERE AND HOW CAN WE MOVE FORWARD?

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.

The opioid epidemic is so well documented by the CDC, various research groups and a number of states that its dimensions are common knowledge. The costs to society in general, employers, insurers, individuals and their families are staggering. For most of us the epidemic is old news but we have yet to fully address its causes and stem the tide. In order to do so, it is important to understand how we reached this point. There were and continue to be a confluence of factors that have caused the almost perfect storm.

The key to the problem is physician prescribing and the desires of most well-intentioned physicians to cure and relieve injury and reduce, if not eliminate, pain. As I frequently state to my team at Healthesystems, "If the physician does not write the opioid prescription, then there will not be a problem." Of course, that oversimplifies the issue, but not by much.

Physicians have come under tremendous pressure in the last two decades to adequately treat pain. Most of the push has been outside the workers' compensation arena in the treatment of cancer-related and post-operative pain. However, the vast majority of occupational injuries are soft tissue injuries that do not require surgery and are non-cancerous. Nonetheless, treating physicians feel the same pressures to address pain from all causes.

The public and state medical boards have set clear expectations that patients in pain shall have adequate pain relief. Since pain is subjective, the question will always be, "What is adequate pain relief?" Is it no pain or is it a sufficient reduction in pain to allow improvement in function or resumption of activities of daily living?

There has also been the prevailing thought that patients truly in pain would rarely become dependent or addicted to opioids and that long-term use was safe and effective. Unfortunately, the science behind such conclusions was relatively weak and has since been refuted. We had a supposed breakthrough in pain management with the FDA approval of OxyContin and the vigorous marketing and physician adoption that followed. It is not a coincidence that the inflection point in the slow upward curve in opioid use in the U.S. occurred in 1998 when it was released.

That was just the beginning of the flood of opioids that were developed, approved and marketed for moderate to severe pain. Each new opioid was designed to be

either longer acting, faster acting or easier to administer. Many physicians saw these changes as opportunities to do a better job treating pain. Unfortunately, patients were becoming dependent, addicted or abusive in their use. That did not stop increased prescribing for acute and chronic soft tissue pain, for which these medications ostensibly were not intended.

The pain management movement also gained strength in the 1990s and early 2000s with more physicians migrating into pain medicine as self-designated specialists or completing one of the growing number of pain management training programs. Primary physicians started to learn from the specialists how to prescribe opioids with a greater sense of confidence and safety. The standard of care evolved to one that included the use of opioids earlier and more aggressively. Now we have multiple generations of physicians who have become accustomed to the current paradigm of opioid prescribing. The pendulum has swung far to one direction. How do we swing it back?

The key to the solution starts back at the beginning— with the prescribing physician. We need to educate physicians on the proper limited role of opioids in the treatment of most work-related injuries. The focus needs to return to restoration of function in injured workers with pain relief as a tool as opposed to a goal. We must provide evidence-based guidelines such as those developed by ACOEM and other specialty societies and a small number of states. Physicians respond to comparative data about their prescribing patterns and will modify behavior when they understand that they are not within the mainstream. It is incumbent on us to notify physicians about their performance and assist in education on evidence-based practice.

In the articles that follow, we take a close look at some of the leading opioid therapy guidelines and provide insights and recommendations regarding the complex issue of pain management. Included is an article about complementary and alternative therapies that are gaining traction.

While we are treating the root cause of the epidemic, we need tools to control the spread and reduce the "symptoms" of the epidemic— overdose deaths, suicides, addiction, lack of functional recovery, polypharmacy, abuse, diversion and fraud.

I encourage payers to make aggressive use of strict formularies, pre-authorization requirements, pharmacist interventions, peer-to-peer interventions, informed consent for injured workers, letters of medical necessity, step therapy, opioid treatment agreements, and urine drug testing. We should continue advocating for these tools within the medical community and in state capitals.

These tools can be even more effective if we integrate them into a comprehensive program that works on the front end to identify emerging drug therapy risks before they escalate. Physicians know the high risk behaviors and circumstances seen in practice. We also have the data analytics to identify these risks earlier. The challenge is to blend the two so we can proactively manage drug therapy risks and assure more appropriate patient care.

The pharmacy benefit community, payers, physicians and injured workers must become re-aligned to appropriately treat injuries and restore function. Our combined efforts can reduce the needless use of opioids and the tremendous costs that they have on our workers' compensation system and society.

MED WATCH

WORKERS' COMP PROFESSIONALS SHOULD KEEP AN EYE ON THESE MEDICATIONS

FORECAST OF ANTICIPATED GENERICS

The cost savings associated with generic drug use over brand name products is significant. The Congressional Budget Office analyzed Medicare Part D prescription costs and noted that generic drug use saved $33 billion over brand name drugs.[1] In 2007, 30 percent of prescriptions were for single-source brand name products. These prescriptions, however, accounted for 68 percent of the total cost of prescriptions under Part D.

The forecasted generic products are noted below for the remainder of 2013 and 2014. Based on historical trends, price reductions tend to be seen six to eight months after the first generic version is available, when several competing generics become available.

Cymbalta®
(duloxetine)
originally 2Q 2013; no new date available

Antidepressant. FDA-approved to treat major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathic pain, fibromyalgia, chronic musculoskeletal pain.

Lidoderm®
(lidocaine patch)
3Q2013

Pain Medication. FDA-approved for relief of pain associated with postherapeutic neuralgia.

Exalgo®
(hydromorphone ER)
4Q2013

Pain Management Opioid. FDA-approved to treat moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time.

1Q 2014

2Q 2014

Celebrex®

(celecoxib)

2Q2014

Pain Management NSAID (Oral). FDA-approved to treat ankylosing spondylitis, primary dysmenorrhea, acute pain, osteoarthritis, rheumatoid arthritis.

Nexium®

(esomeprazole)

2Q2014

Gastrointestinal Antiulcer. FDA-approved for treatment of GERD, risk reduction of NSAID induced gastric ulcer, H. Pylori eradication to reduce risk of duodenal ulcer reoccurrence.

Pennsaid®

(diclofenac)

2Q2014

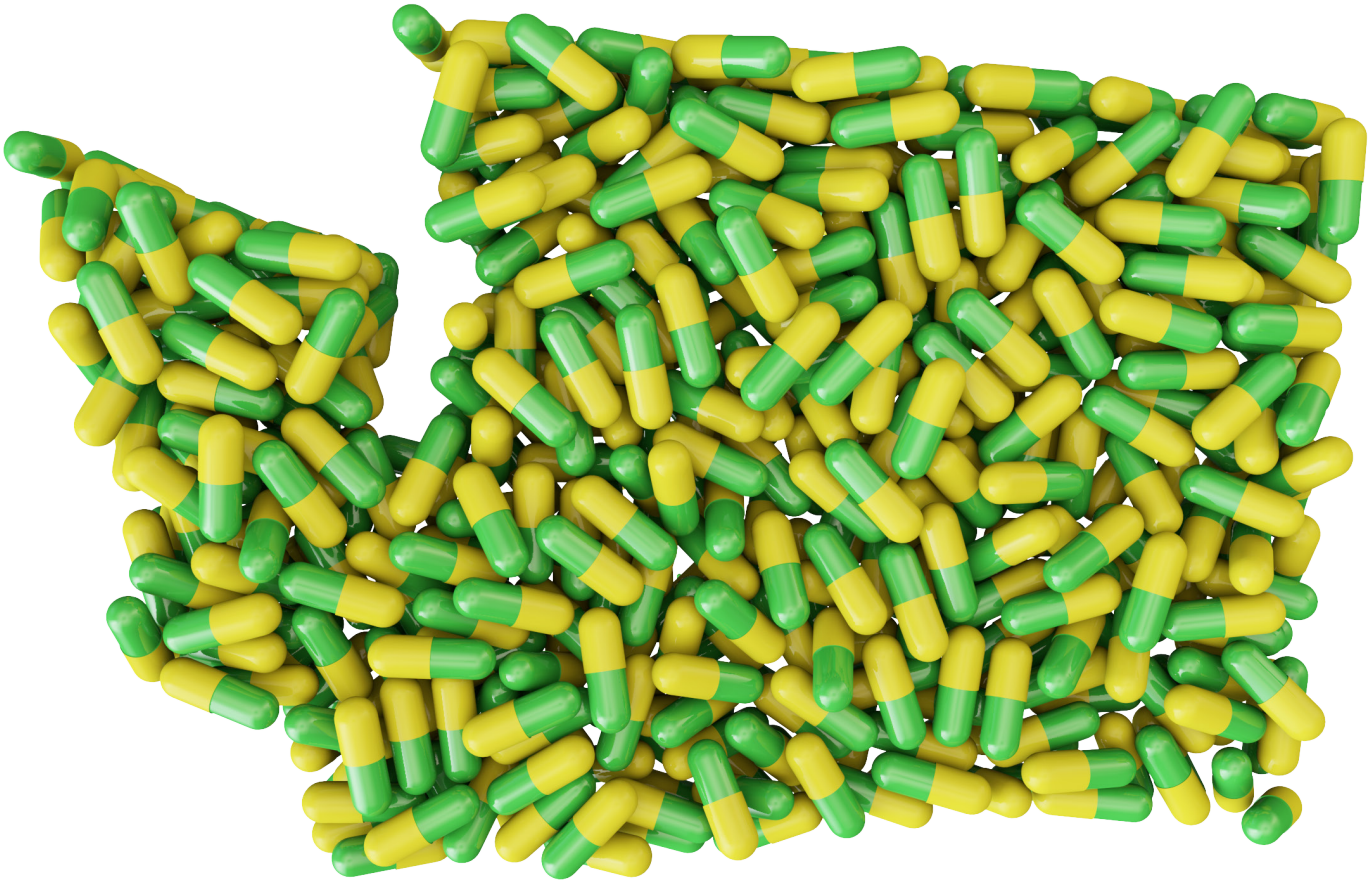
Pain Management NSAID (Topical). FDA-approved for the treatment of signs and symptoms of osteoarthritis of the knee(s).

Lunesta®

(eszopiclone)

2Q2014

Sleep Aid. FDA-approved to treat insomnia.



STATE OF WASHINGTON

SHIFTS PARADIGM ON OPIOID PRESCRIBING

FAST FOCUS

Several states have been putting controls in place to better manage the use of Schedule II opioids in workers' compensation. Payers may be able to look towards states like Washington and others that have implemented evidence based guidelines to incorporate similar methodology when operating in states without controls.

Within the last decade, opioid treatments for chronic, non-cancer pain have grown significantly. An estimated 32 percent of all workers' compensation patients nationally received opioids and in increasingly higher doses.[2] In the state of Washington, from 2002-2005, 42 percent of workers with compensable back injuries received an opioid prescription in the first year after injury, most often at the first medical visit for that injury. A study published in the *Clinical Journal of Pain*, found that 16 percent of those same workers were still receiving opioids one year after injury.[3]

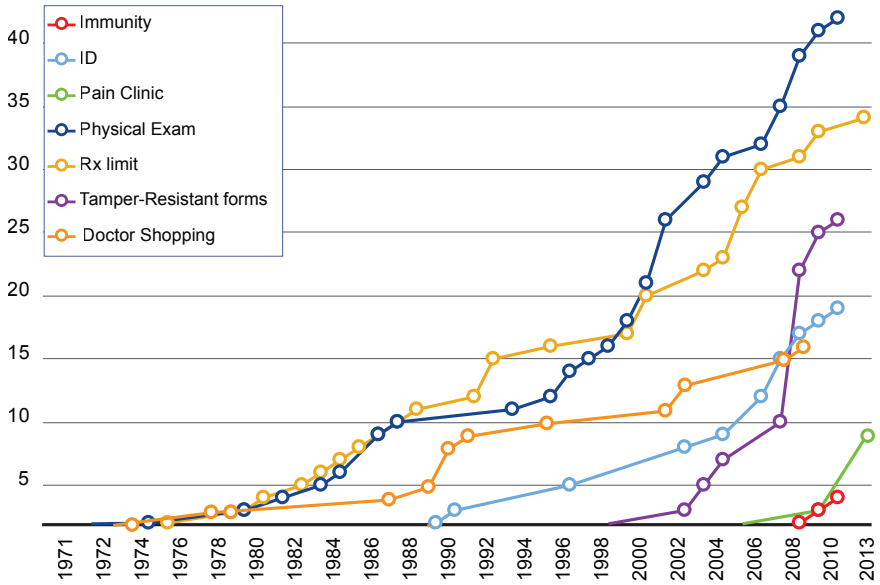
Injured workers in Washington were prescribed opioids at a rate that exceeded the national rate and state regulators enacted opioid control measures several years ago. They implemented a guidelines supplement that addresses each phase of an injured worker's treatment plan and created some of the most stringent, evidence-based controls in the country around the use of opioids for pain management. The guidelines supplement became effective in July 2013.

The actions taken by the state of Washington are certainly not the only measures being used to reduce opioid prescribing and gain control of abuse and overprescribing. Across the country, there is much activity at the state level regarding use of opioids in workers' compensation. States are taking a variety of measures that include:

- Prohibiting patients from obtaining controlled substances from multiple health care practitioners without the prescribers' knowledge of the other prescriptions (Doctor Shopping)
- Providing immunity from prosecution for possession of narcotics for a person seeking medical attention or help for someone else needing medical attention (Immunity)
- Requiring patients to provide identification prior to receiving a controlled substance (ID Required)
- Regulating pain clinics to prevent these facilities from prescribing controlled substances indiscriminately or inappropriately (Pain Clinic)
- Requiring a physical exam of a patient by a health care provider prior to prescribing an opioid (Physical Exam)
- Setting prescribing or dispensing limits for controlled substances (Rx Limit)
- Mandating the use of tamper-resistant forms intended to prevent the use of fraudulent prescriptions to obtain controlled substances (Tamper-Resistant Forms)

CUMULATIVE INCREASES IN STATES AUTHORIZING PRESCRIPTION DRUG-ABUSE RELATED LAWS BY TYPE

Lines represent the cumulative increase over time and eliminate years in which there was no activity



CDC. Home & Recreational Safety: Cumulative number of states authorizing prescription drug abuse-related laws by type of law, United States, 1970-2010. http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws
NAMSDL. State Regulation of Pain Clinics & Legislative Trends Relative to Regulating Pain Clinics. Aug. 20, 2013.

These efforts are critical. The Centers for Disease Control recently reported that the U.S. is facing an epidemic of opioid overdoses.[4] The chart above ▲ demonstrates the increased interest in this area by the type of legislation being enacted or considered by several states.

Only nine states have implemented regulations to address *pill mills* – a term that describes a doctor's office, clinic, or health care facility that routinely conspires in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws regarding the prescribing or dispensing of controlled prescription drugs.[5] While not all pain clinics are dispensing inappropriately, the lack of regulation in pain management clinics allows such clinics to prescribe controlled substances with no state oversight — often without conducting a physical exam or collecting a medical history. Nine states have taken steps in the right direction but there is great opportunity for other states to address the loopholes in state opioid control statutes.

In other areas, however, states have made progress. As opioid use has risen, so too have the safeguards enacted by various states to ensure patients' health and safety. Healthesystems encourages workers' compensation payers in states where no restrictions exist to consider adopting their own opioid therapy guidelines within their pharmacy benefits plan designs – whether they draw from the Washington guidelines, other states or a combination — while taking into consideration the impacts of those guidelines on their total claims population.

THE WASHINGTON MODEL

While the state of Washington's guidelines supplement is considered to be among the most stringent in the country, it should be noted that the guidelines apply only to injuries covered by the state's fund and not to the state's self-funded employers. The limitations on opioid use are a growing trend that may become the standard of care and, therefore, will be of interest to all workers' compensation payers. These guidelines emphasize proper and necessary care at all phases of opioid therapy, which includes:

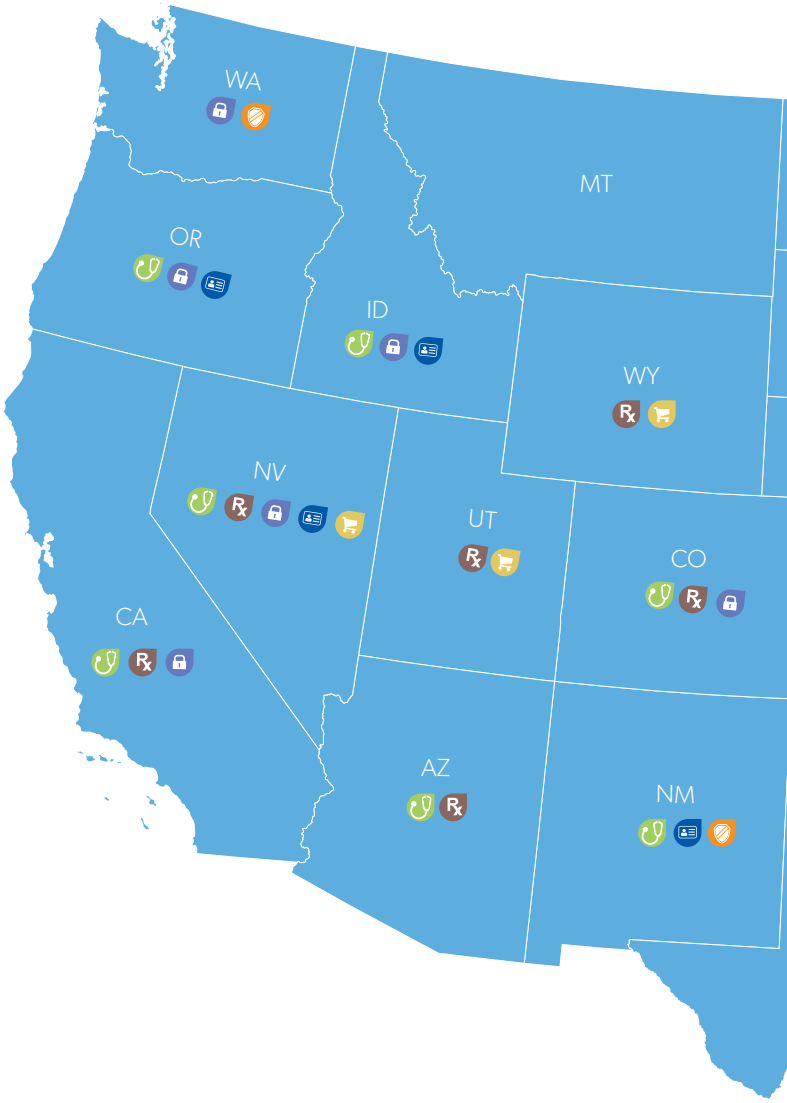
- Frequent assessment for clinically meaningful improvement in function
- Baseline and periodic urine drug testing
- Screening for patient characteristics that suggest risk for abuse or diversion
- Documentation, re-assessment and discontinuation if improvement in function is not demonstrated
- Signed pain management agreements
- Realistic pain management goal-setting
- Use of the state prescription drug monitoring program (PDMP) prior to prescribing opioids and periodically during opioid therapy

SUMMARY

When it comes to regulating opioid therapy, there are myriad competing interests and significant opportunity for all stakeholders – payers, PBMs, prescribers and others – to help shape the legislative process and bring more visibility to opioid use in the workers' compensation arena.

Payers doing business in states without stringent opioid management legislation should consider their own evidence-based controls depending on state regulations.

By advocating for decreased opioid use, increased documentation of patients using opioids in therapy, and thoughtful use of any available alternative therapies, payers may be able to effect more positive changes in their states and within their own book of business.

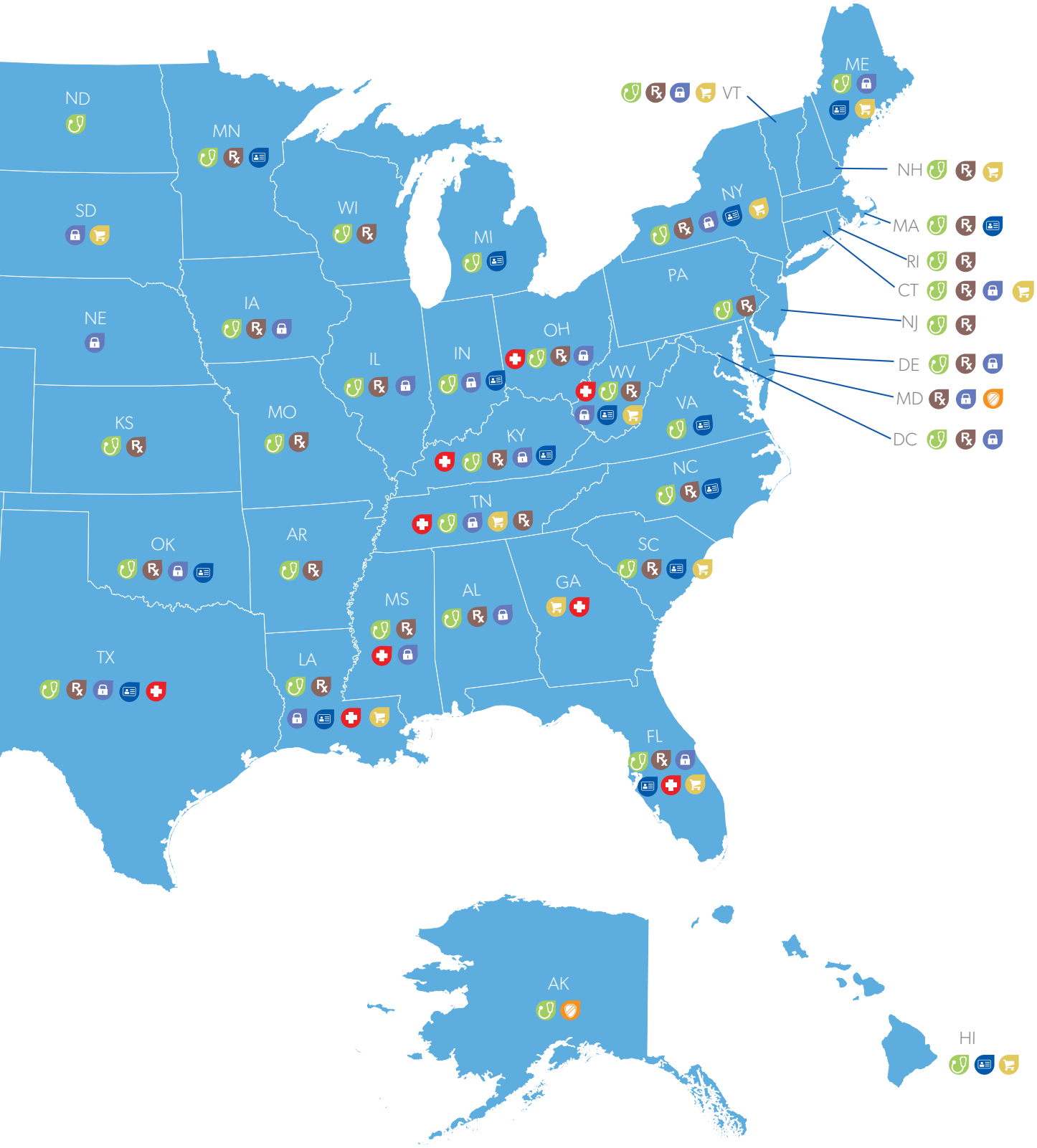


KEY

- Pain Clinic
- ID
- Rx Limit
- Physical Exam
- Immunity
- Doctor Shopping
- Tamper-Resistant Forms

For more detailed information on the Washington supplemental guidelines, visit the Washington State Department of Labor & Industries website: www.ini.wa.gov

LAWS ENACTED OR IN PROGRESS



Source:
Center for Disease Control and Prevention (CDC) www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/state/index.html
NAMSDL. State Regulation of Pain Clinics & Legislative Trends Relative to Regulating Pain Clinics. Aug. 20, 2013.
www.namsdl.org/NAMSDL%20Part%202%20Revised%20August%202013.pdf

OPIOID THERAPY:
EFFECTIVE CASE PLANNING

FAST FOCUS

Healthesystems included some of the leading opioid therapy guidelines issued by various state and industry groups in this planning guide.

Opioid use is rarely indicated beyond the acute phase of injury in workers' compensation. Long-term opioid prescribing and the use of opioids overall are major challenges for workers' compensation payers. Chronic use is associated with extended disability durations, less successful outcomes and higher medical costs.[6,7,8,9] Long-term use can also lead to drug abuse and is often an indicator of misuse and diversion. Many states have implemented guidelines or rules to limit opioid use and require documentation by prescribers to justify continued opioid therapy.

Medical guidelines published by the American College of Occupational and Environmental Medicine (ACOEM), and the Official Disability Guidelines (ODG) cite the ineffectiveness of opioid analgesics for many work-related types of injuries. Continuing these medications beyond when they are necessary or when objective signs of improvement in functional ability are absent increases risks to injured workers.

GUIDELINES FOR OPIOID THERAPY

The ODG[10] as well as several leading state and industry guidelines for opioid prescribing divide pain into three phases following injury and make recommendations for each phase.[11,12]

WITHOUT EARLY CLINICAL INTERVENTION

15% OF PATIENTS USING **OPIOIDS**

↑INCREASE DOSE STRENGTH (MED) by

414% WITHIN 1 YEAR

—BASED ON HEALTHESYSTEMS CLINICAL FINDINGS

THREE PHASES FOLLOWING INJURY

2-6 weeks
following injury

Opioid analgesics are recommended for short-term use in the case of pain that follows severe injury or surgery. Therapy should not continue beyond the acute phase. Long-acting or extended release opioids are rarely appropriate in the acute phase of an injury.

ACUTE PAIN

1-3 months
following injury

Continuing opioid use in the subacute phase of injury increases the risk that the patient may experience dependency on medication, and can prolong a return to work.

It is extremely important to screen for associated depression, anxiety, and substance abuse disorders

SUBACUTE PAIN

3 months
following injury

Use of opioid analgesics is not recommended as first-line therapy in chronic pain, and all other options should be maximized.

If used, doses should remain under 120mg daily oral morphine equivalents (MED). Patients should be routinely screened for psychiatric comorbidities, risk of abuse and misuse, and adherence to therapy using such tools as urine drug screening.

CHRONIC PAIN

INDUSTRY SCREENING TOOLS

Substance Abuse

CAGE-AID: CAGE Adapted to Include Drugs
AUDIT: Alcohol Use Disorders Identification Test
DAST: Drug Abuse Screening Test

Risk Assessment

OAPP-R: Screener and Opioid Assessment for Patients with Pain-Revised
ORT: Opioid Risk Tool
DIRE: Diagnosis, Intractability, Risk, Efficacy

For Use During Treatment

COMM: Current Opioid Misuse Measure
PADT: Pain Assessment & Documentation Tool
ABC: Addiction Behaviors Checklist
Chabal: 5-Point Prescription Opiate Abuse Checklist

Mental Health

HAM-A: Hamilton Depression Scale (HAM-D)
HAM-D: Hamilton Depression Scale (HAM-D)
BDI: Beck Depression Inventory

BEFORE STARTING THERAPY

Healthesystems drew these guidelines from the leading guidelines issued by ACOEM, ODG, Agency Medical Directors Group, American Pain Society, American Academy of Pain Medicine[13], and the states of Washington and Colorado.[14]

Opioids should only be one part of a treatment plan. There are other considerations prior to starting opioids.

- Optimize alternative therapies such as NSAIDs, acetaminophen or neuropathic agents if nerve pain is present.
- Determine if there are underlying psychological issues such as anxiety, depression and post-traumatic stress disorder.
- Screen the patient for risk of drug abuse, misuse or diversion.
- Decide what conditions will warrant discontinuing opioids.

STARTING OPIOID THERAPY

If the patient is a candidate for opioid therapy:

- Start therapy with the end in mind.
- Check the State's Prescription Drug Monitoring Program (PDMP).
- Assess the patient's complaints in light of objective evidence from imaging or physical exam findings.
- Discuss with the patient the risks versus benefits of opioid therapy, goals of therapy and weaning steps that will be followed.
- Set realistic expectations about controlling pain.
- Establish a return to work date.
- Conduct a baseline urine drug screen to evaluate use of non-prescription medications or illegal substances.
- Perform baseline assessments that measure physical, social, and psychological factors such as pain and functional ability, activities of daily living, daily social and work activities, mental state and well-being.
- Document the patient's understanding of risks by having a signed informed consent on file, a written treatment plan, expected duration of therapy and the expectation that a single provider and single pharmacy will be used for prescriptions.

CONTINUING OPIOID THERAPY

- Continue therapy only if improvement in pain relief and function is documented.

WHEN PAIN PERSISTS

If pain persists after opioid therapy has been discontinued, recommend other therapies such as:

Neuropathic agents

— Anticonvulsants - gabapentin, pregabalin

— Antidepressants- venlafaxine, duloxetine, nortriptyline, desipramine

Non-opioid analgesics

— NSAIDs, acetaminophen

Physical and occupational therapy

Alternative therapies (see page 18)

— Massage, Acupuncture, Chiropractic therapy

DIS-CONTINUING OPIOID THERAPY

A number of circumstances may warrant discontinuation of opioid therapy. The following or similar scenarios may require referral for detoxification or to a pain management or addiction specialist.

- Lower back pain and/or a strain/sprain injury continues in to the chronic phase.
- Pain persists despite frequent or high-doses of opioids, especially if doses exceed 120mg MED.
- The patient is experiencing side effects, especially if they are severe enough to require addition of medications to treat opioid-induced adverse effects.
- Ongoing screenings reveal a risk for drug misuse, abuse or addiction.
- Concerns arise such as psychological issues, substance abuse, arrests, overdoses, violent behavior or hospitalizations related to opioid use.
- The treatment agreement is violated.
  - Inconsistent office dose counts, frequent early refills, aberrant urine drug screening results
  - State PDMP reveals multiple prescribers or multiple non-affiliated prescribers

DOSE TAPERING

Discontinuation of therapy has many approaches and can range from a slow dose reduction to a more rapid reduction every few days. There is a lack of evidence to make specific recommendations on the rate of dose reduction. This must be assessed on a case-by-case basis, though a slower rate may help reduce symptoms of opioid withdrawal.

Factors that may influence the rate of dose tapering include the patient's fear of pain, the current morphine equivalent dose, and severity of withdrawal symptoms that might occur as tapering starts.

INPATIENT DETOXIFICATION

Patients who are not able to wean or taper successfully within a primary care setting may need more aggressive intervention. Patients who may be at high risk of failure may also be candidates for more aggressive intervention such as medication-assisted detoxification or in-patient treatment.

FOR MORE INFO

American College of Occupational and Environmental Medicine
www.acoem.org/Guidelines.Opioids

Washington State Guidelines
www.lni.wa.gov

Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain
www.agencymeddirectors.wa.gov

OpioidRisk: Extended Release/Long Acting Opioid REMS Training
www.opioidrisk.com

Department of Health and Human Services, Substance Abuse and Mental Health Services Administration
www.dpt.samhsa.gov

RED FLAGS IN OPIOID THERAPY

EARLY IDENTIFICATION OF FRAUD, DRUG ABUSE OR MEDICATION MISUSE

FAST FOCUS

Analyzing each claim from multiple perspectives can reveal risky situations if data are readily available and you know what to look for.

The large number of workers' compensation claimants receiving prescriptions for opioid therapy requires payers to dig deeper into the data to uncover inappropriate behaviors – whether it is risky prescribing practices, questionable claimant behavior or activities that are indicative of fraud, drug abuse or medication misuse. Often the signs that a claim is veering off course escape notice because the details may seem insignificant and unrelated.

However, looking at a claim from multiple perspectives often reveals associations among activities that can add up to questionable, if not suspicious behaviors. Even claims with a relatively low drug spend may deserve a closer look.

FDA Changes Labeling Requirements for Long Acting Opioids

In October the FDA announced class-wide safety labeling changes and new post market study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain. This is the latest effort by the FDA to combat misuse, abuse, addiction, overdose and death from these potent drugs.

There are a number of red flags that can alert claims professionals to take early action so they can prevent problems. **A close review of claims involving opioids may be in order if any of these circumstances are present.**

MEDICATION COMBINATIONS

- Prescriptions for short-acting opioids, carisoprodol and benzodiazepine — a combination dubbed the *holy trinity* by abusers because of the feeling of euphoria often associated with taking them together. (See page 23)
- Prescriptions for short-acting opioids and carisoprodol - a combination dubbed the *Las Vegas cocktail* by abusers for their combined effects which can mimic heroin.
- New prescriptions written for opioids or high-cost compounded products after an extended period involving no prescription therapy, despite no indication that the injury was re-activated.
- Concurrent use of more than one type of long-acting opioid.

HOLY TRINITY

Opioid (Vicodin®) + **Carisoprodol** (Soma®) + **Benzodiazepine** (Xanax®)

VEGAS COCKTAIL

Opioid (Vicodin®) + **Carisoprodol** (Soma®)

PATTERNS OF PRESCRIBING

- Only opioid therapy is prescribed.
- Prescriptions for brand names that indicate *dispense as written* per the prescriber (DAW1) or dispense as written per the injured worker (DAW2), particularly when opioids, sedatives and muscle relaxants are specified.
- Opioids continue to be prescribed even when objective improvements are not documented over an extended period of time.
- Prescriptions for 4 or more medications concurrently.
- High dollar spends for individual prescriptions or overall prescription therapy.

PHARMACY TRANSACTIONS & DISPENSING TRENDS

- A consistent pattern of early refills for opioids within the allowable five to seven day window. This could indicate stockpiling and lead to risks for abuse, diversion and misuse. After six months, this pattern can yield an additional month supply.
- A pattern of refilling prescriptions on time for opioids, carisoprodol and benzodiazepine, and refilling prescriptions late or not at all for non-opioid, adjuvant, neuropathic medications such as Cymbalta® or gabapentin. This could signal use of the medication for something other than pain relief.
- Prescriptions for opioids from multiple physicians from separate practices, which can indicate an unauthorized dose escalation or doctor shopping.
- A frequent change in pharmacies for opioid fills when the pharmacies are not part of a chain or network.
- Doses that indicate moderate to high opioid risk.

MONITORING TOOLS

Many PBMs make a variety of tools available to assist payers in identifying and managing claims with potential for high opioid risk. They may take the form of subject-specific reports, papers, calculators and the like. However, implementing more proactive and intuitive tools such as the Healthesystems risk management dashboard, can provide a more innovative approach to view and manage high-risk claims in real time.

RECOMMENDED ACTIONS

To the extent that claims professionals have the proper reports and tools available to identify red flags in claims involving opioid therapy, they can appropriately enlist help from other stakeholders and take early action to avert problems.

Depending on the payer, this can include:

- Escalating a claim to a claims manager, nurse case manager or medical director within their organization
- Reaching out to a clinical pharmacist at their PBM.
- Performing comprehensive drug regimen reviews such as the Healthesystems Independent Pharmacotherapy Evaluation (IPE) — a drug history therapy review by a clinical pharmacist that provides the prescribing physician with evidence-based drug therapy analysis and valuable guidance regarding alternative drug regimen approaches.
- Coordinating clinical teleconsults with the prescribing physicians, where state rules allow, and coincide them with completed drug regimen reviews.

BEYOND OPIOIDS:

ALTERNATIVE PAIN MANAGEMENT THERAPIES

FAST FOCUS

The medical community is making strides toward gaining a better understanding of complementary and alternative medicine therapies and integrating them into treatment protocols. In certain scenarios these therapies could end up being cost savers and deliver a better result for injured workers.

As state legislators enact stricter regulations around opioid use and workers' compensation payers recognize the complications long-term opioid use creates, better ways to manage chronic pain are being considered. No longer can opioids be used as the sole or predominant therapy to treat chronic pain. The number of patients turning to complementary and alternative medicine (CAM) therapies for pain relief is rising, but this popularity has yet to result in a parallel increase in acceptance and use within traditional medicine.[15] A closer look at these modalities may be warranted.

Complementary medicine therapies are used in concert with conventional medicine. As the name implies, alternative medicine therapies are used in place of conventional medicine.

CAM therapies employed for chronic pain relief include: YOGA | ACUPUNCTURE | ACUPRESSURE CHIROPRACTIC | MASSAGE | HERBS AND SUPPLEMENTS | MEDITATION | WARM WATER THERAPY BIOFEEDBACK | CRANIOSACRAL THERAPY

The medical community is making strides towards gaining a better understanding of CAM modalities and integrating them into traditional medicine protocols. Funded research on complementary and alternative medicine therapies is now recognized by the National Institutes for Health. The Pain Management Task Force commissioned by The Office of The Army Surgeon General studied a number of CAM therapies and made recommendations for incorporating them into pain management protocols in its Final Report published May 2010[16].

PATIENT-CENTERED CARE

In a traditional medical model, a patient presents a complaint of pain to a provider and may be given a prescription for a medication. The patient's responsibility is to take the medication. He or she is a passive participant in their own care. This can lead to recurrent cases of poor outcomes, problems with multiple prescriptions, and some patients' disillusion with the medical system[17].

The alternative to the traditional model is the integrative model which takes a whole person approach and focuses on self-care, self-responsibility and self-awareness. In February 2009, the Institute of Medicine acknowledged patient-centered care as one of the five critical dimensions of high-quality care. Research shows that focusing the health care system around the patient can improve patients' satisfaction with care and clinical outcomes. Patient-centered care empowers the patient to be responsible and participatory in his or her health and healing process, which can improve patient functionality.[18,19]

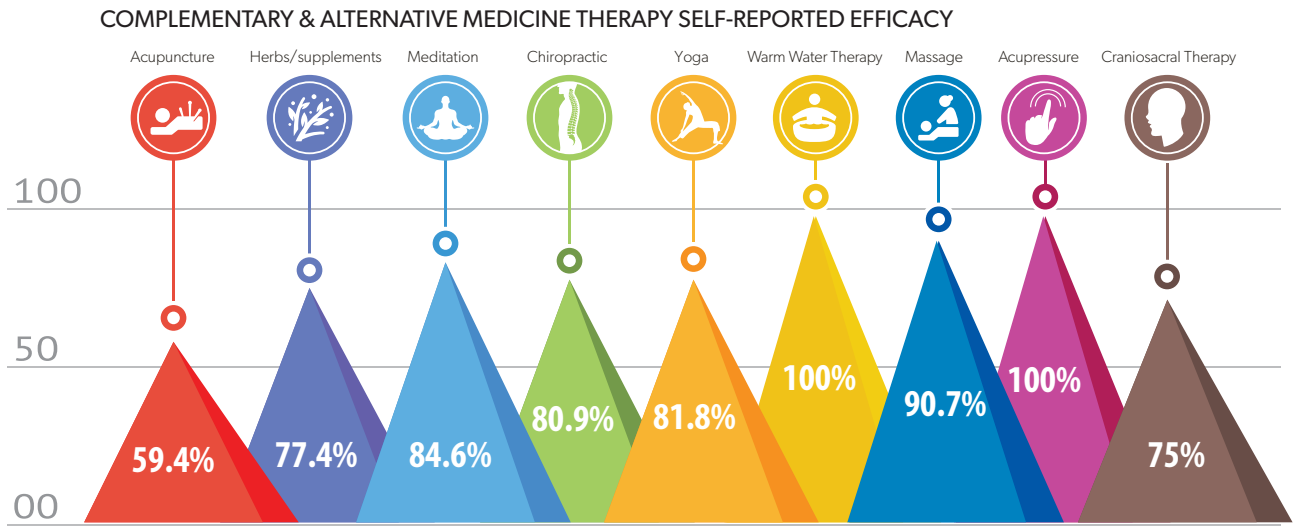
The integrative model approaches pain control from multiple areas of a patient's life. It includes a multidisciplinary team approach that encompasses:

- Biological/physical management
- Emotional/psychological factors
- Social/family/cultural factors[20]

The Army's Pain Management Task Force recommended 13 modalities of complementary and alternative medicine therapies and stressed self-help by incorporating active phases for each. Yoga is brought into the therapy regimen through facility-based classes — a passive method of providing therapy. The patient is later transitioned to self-directed yoga through videos — an active method.

COGNITIVE BEHAVIOR THERAPY

Treatment guidelines for the management of chronic low back pain published by the American College of Physicians and the American Pain Society include first-line recommendation for cognitive behavior therapy (CBT).[21] CBT provides coping skills for managing the psychological aspect of pain. It incorporates such tools as biofeedback and may be particularly useful in patients with high levels of anxiety associated with pain, who may be prone to pain catastrophizing.[22,23]



Patients who are educated and understand that they may continue to have some pain often experience improved functionality, especially if they are involved in treatment planning.[24]

EFFECTIVENESS

A study funded by the National Institutes for Health through the National Institute on Drug Abuse surveyed 908 patients using opioids to control chronic pain and found that nearly half were also using some form of complementary and alternative medicine therapy.[25]

Are these therapies effective? According to patients in the study, the answer is yes, though medical science does not fully understand how some of these therapies work.[26]

LESS COSTLY OVER TIME

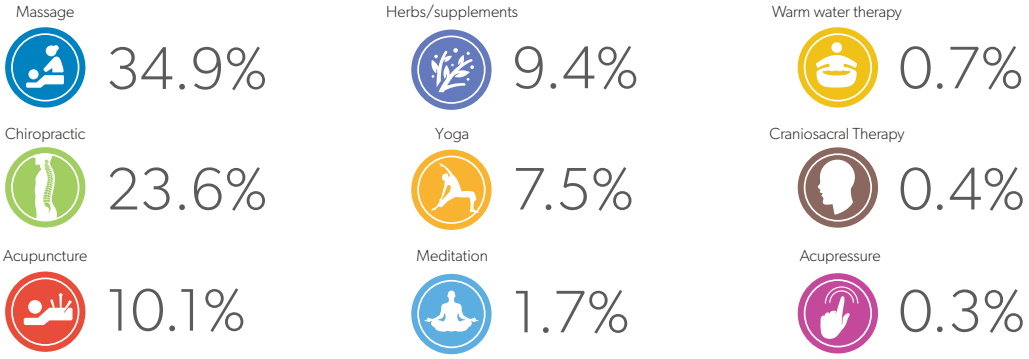
Despite growing evidence, complementary and alternative medicine protocols are not widely used.[27,28] Perceived costs may be one factor. The lack of in-depth study on efficacy may be another. When the true costs of long-term opioid therapy are weighed against the cost of complementary and alternative therapies such as massage, acupuncture and chiropractic therapy, payers might consider incorporating CAM modalities to improve pain treatment and prevent the more costly consequences related to opioid use.

Spending in the U.S. in 2005 across federal, state, and local governments for the treatment of substance abuse and addiction was estimated at $467.7 billion and was over 10 percent of the combined governmental budget of $4.4 trillion. A 2010 Medicaid study compared costs of opioid therapy abuse. This analysis found that total costs for patients with opioid use or dependence were 68 percent higher than costs for the matched control group.[29]

A study published in 2010 in the *Journal of Alternative and Complementary Medicine* found that the average cost per patient was less for complementary and alternative medicine users versus nonusers with an average savings of $1420 per patient.[30]

According to the 2012 findings by The Accident Fund and Johns Hopkins University, a study of 1,200 workers' compensation claims in Michigan over a four-year period revealed that the cost of claims where long-acting opioids were prescribed were nearly 3.9 times more likely to exceed $100,000 than claims without such prescriptions.[31]

FREQUENCY OF COMPLEMENTARY ALTERNATIVE MEDICINE THERAPY USE IN LIFETIME



Source: Fleming et al; CAM therapies among primary care patients using opioid therapy for chronic pain, BMC Complement Altern Med. 2007; 7: 15. Copyright ©2007 Fleming et al; licensee BioMed Central Ltd.

SUMMARY

At first glance, complementary and alternative medicine therapies may be perceived to be a more costly means of controlling chronic pain. These therapies are often needed for a shorter duration than opioid therapy so their overall costs could be lower than opioid therapy. As a result, these therapies could end up being the true cost savers and deliver a better result for the injured worker and employer.

100% of patients in this study found acupressure effective, yet only **.3%** of all patients had used it.

FOR MORE INFO

National Health Statistics Report: Complementary and Alternative Medicine Use Among Adults and Children

State of Michigan: Non-Opioid Pain Treatments

National Center for Biotechnology Information (National Institutes of Health): CAM therapies among primary care patients using opioid therapy for chronic pain

Evidence-Based Complementary and Alternative Medicine www.hindawi.com/journals/ecam/

DEADLY DRUG COMBINATIONS ESCAPING NOTICE

THERE IS A WELL-ESTABLISHED STREET MARKET FOR SHORT-ACTING OPIOIDS, CARISOPRODOL & BENZODIAZEPINE.

FAST FOCUS

This potentially deadly drug mixture may not be on every payer's radar screen because of the relatively low AWP for each drug. But when abuse is involved, payers need to seriously consider the ultimate cost that could result from the abuse of this drug combination — including detoxification and rehabilitation — as well as the real potential for loss of life.

The challenge for workers' compensation payers is to identify and monitor risky drug combinations before they endanger the injured worker or are diverted to the street. The risks inherent in opioid therapy have been well documented and significant efforts are being made by legislators, federal agencies, PBMs, payers and others to reduce opioid use in the workers' compensation population. But opioid use alone is not the only concern.

What is escaping the notice of many payers is a popular but dangerous drug combination of short-acting opioids, muscle relaxants and anti-anxiety drugs. The combination is called the *holy trinity* by drug abusers because of the feeling of euphoria that it can produce — similar to that of heroin. There is a ready street market for these drugs, making them ripe for diversion. This led Healthesystems to dub the combination the *unholy holy trinity*.

C.S. Schade, MD, PhD, a past president of the Texas Pain Society, said he could "conceive of no legitimate medical reason" that the three medications would be prescribed together.[32] And while only a small number of claimants are prescribed this potentially deadly combination, payers should be aggressive in managing these outliers.

IDENTIFYING PROBLEM CLAIMS IS THE FIRST STEP

The challenge for PBMs and payers is to identify abusive drug behaviors before the therapy spirals out of control. Opioid drug therapy is a major cost driver in workers' compensation and is well known to pose high risks for abuse, drug diversion and accidental or unintentional drug overdoses. Each component of the combination carries its own risk for abuse and addiction.

- The addictive properties of carisoprodol — perennially in the top 20 of prescribed medications in worker's compensation population[33]— led the DEA to classify it as a controlled substance in 2011.[34]
- Benzodiazepines and opioids comprise eight of the top ten most abused medications in the US.[35]

COMMON COMPONENTS OF THE HOLY TRINITY

Short-Acting Opioids
Vicodin®, Lortab® and Opana®

Muscle Relaxants
Carisoprodol marketed as Soma®

Anti-Anxiety Drugs
Benzodiazepines marketed as Xanax®, Valium® and Klonopin®

It is becoming more well-known that drug overdoses seldom involve one agent. Opioid abusers learn to predict the effect of an opioid dose and can easily overdose when they seek to augment the euphoria with alcohol and/or other medications. When they augment it with carisoprodol and benzodiazepine, the risk for overdose is raised exponentially.

- Of the 1.25 million medication-related emergency department visits in 2009, carisoprodol, alone or in combination, accounted for more than 30,000.
- The far more commonly prescribed opioids accounted for more than 397,000 emergency visits.
- Benzodiazepines, which have little to no clinical justification for long-term use, accounted for a remarkable 373,000 emergency trips.[36]
- Combining multiple central nervous system depressants such as Ambien®, Lunesta®, Valium, Xanax® and Halcion®, contributes to approximately 50 percent of opioid overdose deaths.[37]

ESCAPING NOTICE

Individually, opioids, carisoprodol and benzodiazepine have low average wholesale prices (AWP), costing pennies to about $1 per tablet. However, when abuse is involved, payers need to seriously consider the ultimate costs that could result from the abuse of this drug combination — including detoxification and rehabilitation — as well as the real potential for loss of life.

TAKING THE NEXT STEPS

The Healthesystems clinical and technology teams work together to create complex system logic and edits that identify claimants who are being prescribed all three types of drugs during their treatment. The information is shared with claims professionals along with clinical guidance on best practices for achieving an optimal outcome for the injured worker.

Healthesystems recommends that payers and PBMs clearly identify claimants who are being prescribed the opioid/ carisoprodol/ benzodiazepine combination and implement aggressive strategies to manage them. This could include clinical outreach to the prescriber(s), requests for justification of medical necessity, escalation for review to a clinical professional or a combination of efforts.

CELEBRITY DEATHS INVOLVING PRESCRIPTION **OPIOIDS IN COMBINATION**

The use of opioids in combination with alcohol and other prescription drugs was a factor or direct cause of death for several high profile actors and athletes.

HEATH LEDGER
Actor, 28
Oxycodone, hydrocodone, diazepam, temazepam, alprazolam and doxylamine[38]

DANA PLATO
Actress, 34
Carisoprodol and hydrocodone[39]

DEREK BOOGAARD
Professional hockey player, 28
Alcohol and oxycodone[42]

EDWARD FATU "UMAGA"
Professional wrestler, 36
Hydrocodone, carisoprodol and diazepam[41]

ERICA BLASBERG
Professional Golfer, 25
Butalbital, temazepam, alprazolam, codeine, hydrocodone and tramadol[40]

TOPICAL ANALGESICS:
EXPENSIVE AND AVOIDABLE

FAST FOCUS

Close management of custom compounds has decreased their prevalence in workers' compensation. But private-label topicals and homeopathic products have filled the void. Neither is FDA-approved. Both warrant close monitoring because of their high costs and lack of proven efficacy.

Some very expensive topical creams and gels are creeping into the workers' compensation prescription files. Previously, the issue of custom compounds was highlighted and the attention to these prescriptions has resulted in a decrease in the number of prescriptions seen. However, the price of these compounds has increased significantly.

In addition to the compounds that are still being prescribed, other topical products are increasingly seen in the workers' compensation setting. In this article, a spotlight is turned on to expose more expensive topicals — private-label analgesics and homeopathic products.

SUMMARY OF PRIMARY ISSUES

Issue	Custom Compounds	Private-Label Analgesics	Homeopathic Products
NDCs Available	✕	✓	✓
FDA-approved	✕	✕	✕
Proven clinical benefit	✕	✕	✕
Prepared by compounding pharmacy for a specific patient	✓	—	—
Contain high levels of NSAIDs	✓	—	—
Contain 2-3x the FDA-approved concentration of methyl salicylate and/or menthol	✓	✓	—
Can cause skin burns	✓	✓	—
Prescribers unaware of compound ingredients	✓	✓	✓
Prescribers unaware of high costs	✓	✓	✓
Expiration dating required	—	—	✕

TOPICAL PRIVATE-LABEL PRODUCTS

There are private-label companies marketing products similar to inexpensive, over-the-counter products, but with catchy names, inflated claims and prices. Private-label topical compounds are products containing OTC ingredients such as high-potency methyl salicylate, menthol, camphor or are homeopathic agents. These mixtures largely approximate OTC formulations but come with substantially higher prices justified by the manufacturer because they contain higher concentrations of some ingredients than their OTC counterparts.

- They are given brand names such as Medrox Rx® and Terocin® in an attempt to confer legitimacy, and can mislead prescribers into thinking they contain prescription drugs.
- Many believe that a product with an NDC code means it is FDA-approved. This is not true.
- The manufacturer's label may state that these products require a prescription, but they are not FDA-approved and do not require a prescription according to FDA guidance.
- Methyl salicylate and menthol products are a safety concern because of rare, but severe skin burn cases which resulted in an FDA warning for over-the-counter products containing much lower concentrations of the ingredients.[43]
- No clinical trials to prove efficacy are required for these products so a patient may remain in pain needlessly.

FINANCIAL CONCERNS

When compared with comparable over-the-counter (OTC) preparations, the private-label products' prices are stunning. Why would anyone pay $110 per ounce for a private-label product when the over-the-counter product costs just $5 per ounce?

PATIENT SAFETY

Another concern is patient safety. The private-label products contain much higher concentrations of ingredients than the over-the-counter products. These higher concentrations don't necessarily translate into better products. However, they do increase the risk for skin burns as announced by the FDA for the lower concentration over-the-counter products.[44]

Example: Private-label topical vs. OTC
Private-label topical is **$500 more expensive**

CUSTOM COMPOUNDS

A mixture of prescription and non-prescription ingredients, these topicals are prepared in a compounding pharmacy for specific patients. Challenges and concerns with these compound mixtures include:

- Some compounds contain very high concentrations of non-steroidal anti-inflammatories (NSAIDs) — 10 to 30 times what is approved by the FDA for topical use.
- Others contain double or triple the concentration of methyl salicylate and/or menthol that has been reported by the FDA to cause rare but serious skin burns[45] or high concentrations of lidocaine, which has resulted in deaths.[46,47]
- No clinical trials to prove efficacy are required for these products so a patient may remain in pain needlessly.

INGREDIENT COMPARISON

Private-Label Topicals		Comparable OTC Products	
Product Name & Ingredients	**Price per 1 ounce**	**Product Name & Ingredients**	**Price per 1 ounce**
Dendracin® Lotion Neurodendraxcin Methyl Salicylate 30% Menthol USP 10% Capsaicin 0.0375%	**$110.00**	Ziks cream Methyl Salicylate 12% Menthol USP 1% Capsaicin 0.025%	**$5.00**
Exoten C or Xoten-C lotion Methyl Salicylate 20% Menthol USP 10% Capsaicin 0.002%	**$89.00**	Flex-All Ultra Plus® Methyl Salicylate 10% Menthol USP 16% Camphor 3.1%	**$1.60**
Medi-Derm cream Methyl Salicylate 20% Menthol USP 5% Capsaicin 0.035%	**$100.00**	Rapid Alivio Roll On Methyl Salicylate 10% Menthol USP 3.5% Capsaicin (not specified)	**$3.20**
Medrox® ointment Methyl Salicylate 20% Menthol USP 5% Capsaicin 0.0375%	**$75.00**	Castiva Arthritis Pain Relief cooling lotion Methyl Salicylate 14% Menthol USP 5%	**$2.80**
Medrox® Rx ointment Methyl Salicylate 20% Menthol USP 7% Capsaicin 0.05%	**$103.00**	Walgreens Ultra Strength Muscle Rub Methyl Salicylate 30% Menthol USP 10% Camphor 4%	**$1.75**
Medrox® patch/pad Methyl Salicylate 20% Menthol USP 5% Capsaicin 0.0375%	**$29.00 per patch/ pad**	Salonpas pain relieving patch Methyl Salicylate 6.3% Menthol 5.7% Camphor 1.2%	**$.10 to $.50 per patch**
Terocin® lotion Methyl Salicylate 25% Menthol USP 10% Capsaicin 0.025% Lidocaine 2.5%	**$99.00**	No comparable products	

HOMEOPATHIC TOPICALS

Homeopathic topicals usually contain extremely dilute substances. In most cases, they are so diluted that the ingredients cannot be detected by laboratory assays. Challenges and concerns with these topicals include:

- No clinical trials to prove efficacy are required for these products so a patient may needlessly remain in pain without any improvement in condition.
- There is no expiration dating required on these products.
- These products are expensive. When comparing ingredients, they all seem to be strikingly similar.

▲ **Ingredients** (green are in common)

Aconitum Napellus	Chamomilla	Hypericum Perforatum
Arnica Montana	Colchicinum	Millefolium
Belladonna	Echinacea Angustifolia	Symphytum Officinale
Bellis Perennis	Echinacea Purpurea	Zingiber Officinale
Calendula Officinalis	Hamamelis Virginiana	

RECOMMENDED ACTIONS

Due to serious patient safety concerns, lack of proven efficacy and the inflated costs associated with these products, Healthesystems recommends claims professionals deny requests for these topicals or request a Letter of Medical Necessity.

POLYPHARMACY:
MORE DRUGS, MORE PRESCRIBERS, MORE RISK

FAST FOCUS

While the exact definition of the number of concurrent medications may vary – typically greater than three to five – polypharmacy applies to situations where more medications than are clinically indicated are being prescribed, usually resulting in unnecessary drug use. Healthesystems has reported on the risks of polypharmacy for several years, and more information about this topic can be found in the *RxInformer* archives.

Workers' compensation claimants are often prescribed complicated medication regimens that can lead to situations of polypharmacy. When three or more medications are prescribed to an injured worker at the same time, often an attempt is being made to treat the side effects of other drugs. And when a complex drug therapy regimen involving opioids is involved, patients and payers are at even more risk for unintended consequences.

In workers' comp, the drug mix for treating pain can change over time, often because prescribers add new drugs to combat the side effects of opioid therapy. It also frequently includes the overlapping of various drug types for treating pain, including the use of multiple opioids.

TOP 5 DRUG CLASSES

Typically seen in a polypharmacy scenario for treating pain

1. **ANALGESICS – OPIOIDS**
2. MUSCULOSKELETAL AGENTS
3. ANTICONVULSANTS
4. ANTIDEPRESSANTS
5. ANALGESICS – ANTI-INFLAMMATORIES

Between years one and three of drug therapy, patients are more likely to have an average of three or more physicians prescribing opioids compared to later years.

LIKELIHOOD THERE WILL BE **Multiple Opioids Prescribed**

Information based on a review of the top 10 workers' comp drug classifications when at least one opioid was prescribed.

Polypharmacy has largely negative connotations of inappropriate or irrational therapy on the part of prescribers. There are some situations in which polypharmacy is appropriate or necessary but the increased risk is not always accompanied by increased effectiveness.

COSTS

The unique nature of workers' compensation removes cost as a consideration for patients to submit to diagnostic studies, accept treatments and fill prescriptions for medication, since most injured workers incur no out of pocket cost for treatment. When cost is not a concern for patients and prescribers, it becomes an even greater concern for payers, not only for the costs of the initial polypharmacy, but also for the additional treatments to address resulting adverse effects.

If early detection and clinical intervention do not occur, polypharmacy and its associated financial and human costs can quickly spin out of control.

CLINICAL INTERVENTION

Clinical intervention is imperative and can include drug regimen reviews and various forms of outreach to physicians. Intervention can lead to:

- Decreased number of drugs used
- Improved patient outcomes
- Increased safety
- Reduced costs

FOR MORE INFO

For more resources about Polypharmacy, including a Polypharmacy Intervention Checklist, visit the Healthesystems Polypharmacy Resource Center: www.healthesystems.com/polypharmacy

RxInformer Archive
To read past articles by Healthesystems on the topic of polypharmacy: www.healthesystems.com/rxinformer

Policy Impact: Prescription Painkiller Overdoses: www.cdc.gov

BRINGING VISIBILITY TO HIDDEN HOME HEALTH COST$

FAST FOCUS

High dollar home health cases can become difficult to close or settle because of the expectations in place with the claimant and the claimant's family or caregivers. Program management can provide the oversight and information needed to keep home health claim costs from spiraling out of control.

Although less than half of one percent of medically active workers' compensation claims include home healthcare services, these costs can approach two percent of total medical costs. That is partly because cases involving extensive use of home health are often severe in nature or involve major surgery. Healthesystems sees the majority of home health services ordered for registered nurses, licensed practical nurses, certified nursing assistants and companion care. They are ordered for a variety of tasks ranging from wound care and dressing changes to catheter care, helping patients ambulate and assisting with activities of daily living.

Payers generally manage home health services informally rather than programmatically — relying on individual claims adjusters or nurse case managers to monitor services and determine if they are being provided properly. Often, the logic is that these claims make up such a small portion of the overall mix that it would be too difficult to automate associated processes for managing and monitoring them.

HOME HEALTH CLAIMS ON AUTOPILOT

In many cases, home health services are provided without objective case review to ensure that the services provided are relevant and appropriate to the injured worker's needs. For example, a physician may order a set number of hours for a home health registered nurse to visit an injured worker who was discharged from the hospital post operatively — without specifying details of the services needed. A registered nurse might be sent daily at great expense to perform wound care when a licensed practical nurse could perform the service with weekly supervision at a significantly lower cost. Essentially, home health services are put on autopilot and patients may not receive the proper type or level of services.

Closer case management with a third party's involvement to ensure objective case review can put payers back in control of their home health spending. In the case of the injured worker discharged post operatively, a well-managed home health care program might include an initial home assessment and the development of a care plan that adjusts everything from the services provided, frequency of visits and the skill level of the provider, to the patient's changing needs to keep costs from spiraling.

Cases involving high dollar home health spends can become difficult to close, settle or manage retrospectively because of the expectations already in place with the claimant and the claimant's family or caregivers. They may be reluctant to change caregivers, even if such a change may result in significant savings and provide more appropriate care.

DETAILS PROVIDE THE BIG PICTURE

Payers should be able to answer these questions at both a program and claim level, especially when it is clear that home health services are going to be needed long-term and will likely represent significant dollars.

- Are there detailed plans for managing the claims that are driving my costs?
- What services are being provided?
- Are the services provided at the correct level and quantity?
- What are the identifiable impacts of home health services?

Many payers have difficulty answering these questions at both the claim and program levels because information about the services is generally provided by bill review data which lacks the transparency and consistency that payers need. The payer has a limited ability to aggregate data about the quality, complexity or other details of the services provided.

Healthesystems has long recognized the value of quality data and its role in managing home health services through our ancillary benefits management program (ABM). Another key to effectively managing home health services is to implement unique identifying codes for every type and level of home health service to allow payers to identify the quantities, increments and intensity level of each service, as well as the expertise level of its provider.

Having this granular level of detail in a consolidated or master product and service catalog provides payers with transparency into the services an injured worker is receiving — information that is not available through HCPCS and CPT-4 coding alone. Payers get a full understanding of exactly what services the patient is receiving, who is providing them and at what cost. It also levels the playing field across billing entities, state jurisdictions and regional preferences and allows for a true apples-to-apples comparison of results and outcomes.

UNMASKING THE MYSTERY

The most commonly-provided resource in home health is the aide or certified nurse assistant. In the latest version of the HCPCS coding manual, there are at least three different codes that can be used to identify these types of services.

In addition, depending on the billing entity's definition of the service, other codes are also available. By creating a proprietary coding and mapping process used by all contracted providers, there is transparency into exactly what service is being provided.

This holds true for miscellaneous HCPCS or CPT-4 codes such as 99600, which are sometimes used in home health, though more appropriate codes are available. While miscellaneous codes appear less frequently in home health than they do in durable medical equipment, they still represent over five percent of paid amounts. Some agencies and providers are accustomed to billing the majority of their services under the miscellaneous code making it impossible for the payer to know what they are paying for. In addition to variability in coding, there is also wide variation in the paid amounts for some of the most commonly-supplied services.

An effective ancillary benefits management program that incorporates insights garnered from detailed coding and service authorizations can provide payers with the information they need to achieve better outcomes for injured workers and sharply focus on how home health dollars are spent.

CODING CAN VARY FOR SIMILAR SERVICES

HCPCS Code	Description
S5125	Attendant Care Services; Per 15 Minutes
S5126	Attendant Care Services; Per Diem
S5130	Homemaker Service, NOS; Per 15 Minutes
S5131	Homemaker Service, NOS; Per Diem
S5136	Companion Care, Adult (LADL/ADL);Per Diem
*G0156	Services Of Home Health/Hospice Aide In Home Health Or Hospice Settings, Each 15 Minutes
S5120	Chore Services; Per 15 Minutes
S5121	Chore Services; Per Diem
*S9122	Home Health Aide or Certified Nurse Assistant, Providing Care In The Home; Per Hour
T1004	Services of a Qualified Nursing Aide, Up To 15 Minutes
*T1021	Home Health Aide or Certified Nurse Assistant, Per Visit
T1022	Contracted Home Health Agency Services, All Services Provided Under Contract, Per Day

** Codes most commonly used for home health aides.*

COST FOR SIMILAR SERVICES CAN VARY WIDELY

HCPCS or CPT-4 Code	Description	Rank of Code Based on % of Paid Value	Difference △ between high and low cost	
			Per Unit	Per Hour
S9122	Home Health Aide Or Certified, Per Hour	1	$299	
S9124	Nursing Care In Home By LPN, Per Hour	2	$1,050	
S9123	Nursing Care In Home By RN, Per Hour	3	$1,126	
99600	Unlisted Home Visit Service or Procedure	4	$574	
T1030	RN Home Care, Per Diem	5	$542	
G0154	Home Health Services of RN/LPN, Each 15 Min	6	$534	$2137
G0156	Home Health Services of Aide, Each 15 Min	7	$146	$584
S5136	Adult Companion Care, Per Diem	8	$457	
S5125	Attendant Care Service, Each 15 Min	9	$414	$1656
S9097	Home Visit Wound Care	10	$200	

PROGRAMMATIC OVERSIGHT BENEFITS ALL STAKEHOLDERS

A review of historical bill data from claims involving expenditures for home health services prior to being managed by the Healthesystems ancillary benefits management program found both cases that were properly managed along with others that realized significant annual savings when Healthesystems applied closer case management and review. We are certain that our ancillary benefits management program can keep home health claims off of autopilot and offer payers additional opportunities for savings through multi-faceted review and coordination with key stakeholders.

A SINGLE PORTAL

The programmatic management of home health services creates efficiencies for claims professionals at a time when adjusters and nurses are hard pressed to be more efficient and productive. The Healthesystems program arranges order fulfillment, service delivery and program management electronically through a nationwide network of connected partners. Healthesystems supplies the system platform and overall program management processes but these partners are key stakeholders in managing the care.

All transactions are managed using a single online portal, which eliminates these common time-intensive activities for claims professionals:

- Hunting down documentation
- Responding to authorization requests
- Finding and negotiating with agencies to fulfill requests
- Reconciling provider bills to authorizations
- Responding to appeals in billing

Claims are adjudicated prospectively, virtually eliminating appeals. Less than one percent of home health bills processed through Healthesystems have an appeal while the industry sees 15 percent or more of the bills appealed or in many cases, just re-billed. When needed, payers can find home health notes quickly and easily in electronic format.

As a part of Healthesystems' best practices, claims are reviewed regularly and at the time of reauthorization to determine if services remain appropriate to the patient's needs. Real-time edits based on client protocols are applied at initial authorization, reauthorization and as services are delivered, relieving claims professionals and nurse case managers of many administrative burdens. When milestones or other events occur in the service or life of a claim, stakeholders are automatically alerted to take appropriate action or initiate processes

REGULATION ALONE WON'T CONTROL PHYSICIAN DISPENSING

FAST FOCUS

Repackaged drugs and physician dispensing are among the many factors that can significantly drive up pharmacy costs in workers' compensation. They are frequently not managed effectively.

As more states enact rules to control or limit the practice of physician dispensing or put fee schedule structures in place to regulate pricing, it is understandable that workers' compensation payers in affected states might feel secure that the regulations have addressed the matter. Unfortunately, physician dispensing is a moving target and payers and PBMs need to stay abreast as the market responds to changing rules. Healthesystems has been aggressively managing physician dispensing and repackaged drugs since 2009, and continues to develop solutions to address ongoing changes.

THE MARKET RESPONDS

Recent market trend analysis performed by Healthesystems indicates that even in certain markets where strict physician dispensing rules exist and guidelines are followed, there is a growing trend of repackaged drugs being dispensed at inflated prices in close proximity to physicians' offices. For example, in the state of Texas, dispensing drugs in a physician's office is prohibited in all but a few well-defined circumstances. Trends are showing growth in the number of repackaged drugs dispensed by registered pharmacies located in the same building as physicians' offices. The billing activity mimics the excessive markup practices frequently associated with physician-dispensed repackaged drugs. In those cases, drug repackagers assign new national drug codes (NDC) to the repackaged drugs, and then assign a significantly higher average wholesale price (AWP) than that of the original NDC for the medication.

In many areas of the country, turnkey office dispensing services are provided to physicians by outside firms that market benefits of patient convenience and safety. However, this questions whether the large cost difference between these drugs, and the same drugs dispensed at a retail pharmacy outweigh the proposed benefits, especially when studies prove differently.

VIGILANCE NEEDED

When prescription drugs — repackaged or otherwise — are adjudicated outside of the PBM environment, studies show the drug cost for claims increase. Furthermore, patients are subject to increased health risks because the drugs miss many of the drug review edits, such as duplicate therapy and drug to drug interactions, provided by the retail pharmacy point-of-sale (POS) process. Managing the entire process in the traditional POS pharmacy environment can achieve better results for injured workers and lower pharmacy spending.

Controlling the costs and risks associated with physician dispensing requires a dynamic solution that can capture and adjudicate prescriptions in the PBM environment. Vigilant monitoring of new state rules and the market's response to them is vital so programs can be adjusted.

Some payers and PBMs may not always have what is needed to properly address the situation. When physician dispensing is not well managed, costs continue to rise and patient safety is compromised. Innovative technology is needed to blend clinical expertise and complex logic to track physician dispensing trends. For Healthesystems, this is an ongoing effort that increases pharmacy savings and achieves better treatment outcomes by maximizing opportunities in the clinical environment.

POSSIBLE OPTIONS

When presented with claims involving problematic physician dispensing, claims professionals can exercise various options such as:

- Reaching out to the injured worker with education about the risks of physician-dispensed medication and suggest network pharmacy use and if available, mail order service.
- Alerting other stakeholders by escalating the claim to a case manager, if available.
- Contacting a clinical pharmacist at the PBM for guidance.

THE COST OF PHYSICIAN DISPENSING

Depending on the area of the country, physician-dispensed drugs may represent only a small portion of the total pharmacy spend in workers' compensation. Regardless, the excessive markups are significant and so are the potential savings if managed properly. In the states where the practice is prevalent, physician dispensing costs may make up a larger percentage of the total spend. From 2010-2011, physician dispensing accounted for an estimated one in six prescriptions written for workers' compensation patients.

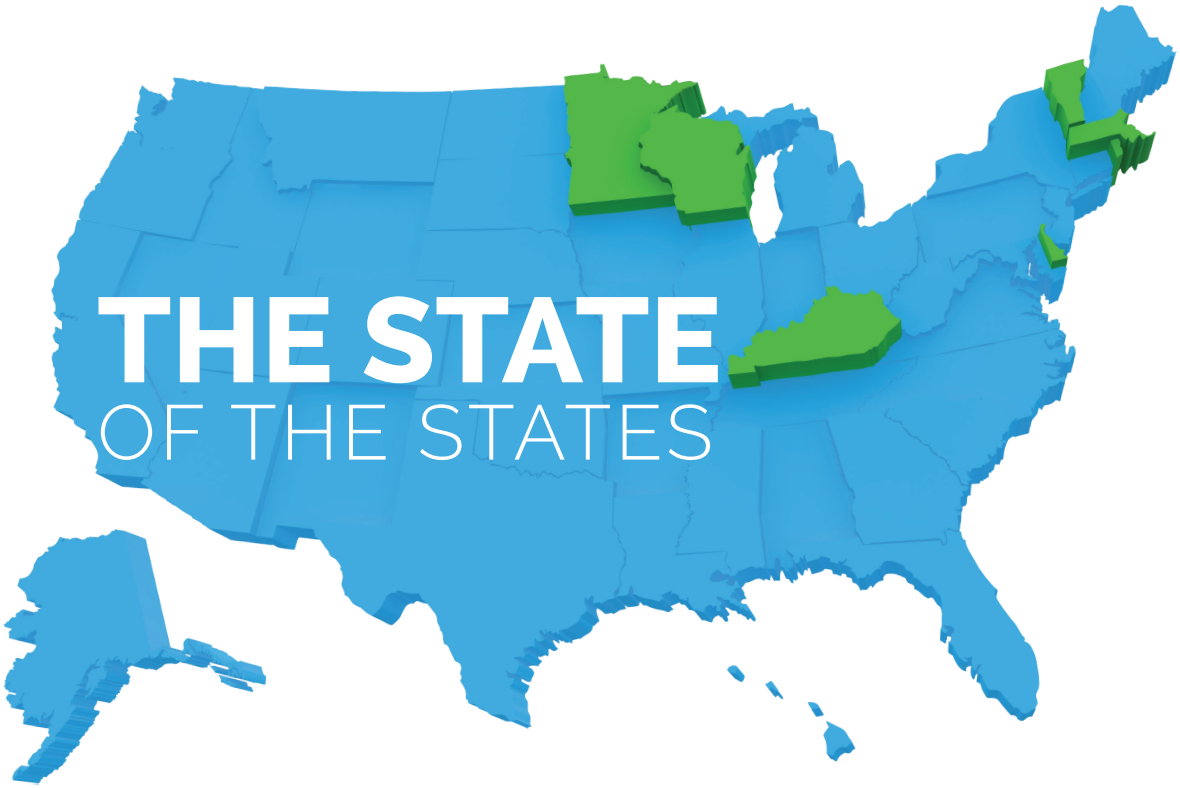
- Five states — California, Florida, Connecticut, Illinois and Maryland — accounted for the highest prevalence of physician dispensing and spending on physician-dispensed drugs.[50] In those states, physician-dispensed drug costs are estimated at 45 to 59 percent of the total cost of prescriptions.[51]
- A WCRI 2013 study considering transactions in 22 states reported that drug costs for the top five physician-dispensed drugs ranged from 32 to 151 percent higher when compared with comparable pharmacy-dispensed drugs.[52]
- NCCI studies documented increases of up to 17 percent in physician dispensing between 2007-2008 and 2010-2011. Spending for physician-dispensed drugs grew at a much higher rate — up to 41 percent during the same period — despite pricing at pharmacies for comparable medications remaining the same or decreasing.[53]

Repackaging and physician dispensing are frequently among the many factors that significantly drive up pharmacy costs in workers' compensation when they are not identified and managed effectively.

A 2013 WCRI report listed the five drugs most commonly dispensed by physicians[48]. Healthesystems' experience is similar but included gabapentin and oxycodone/acetaminophen in place of Ibuprofen and cyclobenzaprine, when system logic and edits that incorporate state-specific regulations and fee schedules were applied to this group. **Overall, Healthesystems has successfully reduced the cost of repackaged drugs on average up to 70 percent.**

TOP PHYSICIAN-DISPENSED DRUGS[49]

Drug	Avg. % of Savings from Billed Amount Through Proper Adjudication
1 Hydrocodone/Acetaminophen	9.6%
2 Ibuprofen	13.3%
3 Meloxicam	6%
4 Tramadol	7%
5 Cyclobenzaprine	12%
6 Gabapentin	5.1%
7 Oxycodone/Acetaminophen	8.6%



THE STATE OF THE STATES

RHODE ISLAND

Pain Management & Pharmaceutical Protocols Adopted

The Rhode Island Medical Advisory Board has adopted "Chronic Noninterventional, Non-Cancer Pain Protocols." The pain protocols, which are new, outline recommendations for evaluation and treatment procedures for the management of chronic, non-cancer pain in injured workers where the pain is not acute or acutely postoperative in nature. The protocols recommend the use of assessment tools for evaluation of functionality and pain, patient education, pain contracts and drug screening. The protocols also include discussion of classes of medications used to treat chronic pain, with a particular focus on opioids.

In addition, the Medical Advisory Board revised the Pharmacy Protocol for the first time since 2001. The Board amended the recommendations to limit the prescribing of opiates to 30 days and require physician-to-physician review when prescribing a brand name medication after therapeutic failure of the generic equivalent, when prescribing off-label use of a medication.

DELAWARE

Pharmacy Fee Schedule Regulations

The Delaware Health Care Advisory Panel (Panel) voted unanimously to adopt revisions to pharmacy fee schedule regulations. The revised regulation will decrease the pharmacy fee schedule and re-establish dispensing fees that have been absent from the Delaware fee schedule since 2008. It will also limit reimbursement for repackaged drugs to the AWP of the underlying drug product while requiring reimbursement for compound drugs to be separately calculated using the NDC for each drug included in the compound. A new drug formulary, based on the Delaware Medical Assistance Program and classified by Preferred Agents and Non-Preferred Agents, was adopted and became effective September 11, 2013. On October 10, 2013, the Office of Workers' Compensation subsequently issued a communication clarifying use of the formulary, with a revised formulary and justification form dated October 2, 2013.

The formulary contains five categories of drugs, primarily focusing on narcotics. If a drug in one of the categories contained in the formulary is not listed in the formulary, then it is not allowed. As of September 11, 2013, Oxycontin, oxycodone extended release, Actiq and transmucosal fentanyl may only be used with prior written approval by the employer or carrier with one exception—an injured

worker on a stable dose of Oxycontin prior to September 11, 2013, may continue to use this medication without prior authorization. In the October 10, 2013, communication, the OWC clarified that prior authorization is not required for any other drug and removed corresponding notations referencing prior authorization from the formulary.

When a drug listed as a Non-Preferred Agent in the formulary is prescribed, the physician (or authorized person) must complete the justification form designated by the OWC and the physician must document two Preferred Agent trials in the medical record. When a physician prescribes any brand name drug outside the five categories of drugs covered in the formulary, the justification form must be completed; however, no Preferred Agent trial is required. Instructions on the justification form direct the prescriber to give the completed form to the injured worker, along with the prescription; and the injured worker must give the justification form and prescription to the pharmacist. Upon receipt of a completed justification form, the pharmacist must dispense the non-preferred or brand name drug. If the pharmacy does not receive a justification form for brand name drugs not contained in the formulary, the pharmacist is required to substitute the generic equivalent.

MINNESOTA

Treatment Standards Address Long-Term Opioid Use

The Minnesota legislature approved Senate SB 1234 containing the latest workers' compensation reform efforts that were negotiated and agreed upon by the labor and business members of the Minnesota Workers' Compensation Advisory Council. Effective October 1, 2013, one of SB 1234's provisions will amend Minnesota law by adding long-term use of opioids or other scheduled medications to alleviate intractable pain to the existing treatment standards list, as well as require the use of written contracts between the injured worker and health care provider who prescribes the medication.

Additionally, SB 1234 will provide the Commissioner of Labor and Industry the authority to develop rules establishing standards and criteria for long-term opioid and scheduled pain medication use. The Department of Labor is already considering the adoption of rule amendments to the treatment parameters. As a result, a draft rule proposal governing long term use of opioid analgesics is available on the Department of Labor's website, www.dli.mn.gov. The proposal would dictate which patients are eligible for long-term use of opioids and require the health care provider to identify any possible contraindications, establish a long-term treatment program, prepare and sign a written agreement between the patient and doctor and require consistent monitoring of the prescriptions. Further development of the proposed draft rule will be forthcoming.

NEW HAMPSHIRE

Pharmacy-Related Study Bill Enacted

New Hampshire Governor Maggie Hassan signed New Hampshire Senate Bill 71 on June 28, 2013, requiring the establishment of a committee to study the use and misuse of prescription drugs in workers' compensation cases. The committee is charged with studying the extent of misuse and abuse of opiates and other prescription medications commonly abused by injured workers. The committee will consider the direct and indirect social and economic costs of opioid misuse, as well as the effectiveness of other state laws. The committee will also study whether the state should establish a closed formulary, interagency opioid dosing guidelines and pain treatment guidelines governing utilization. In addition, the committee will contemplate enhancing the controlled drug prescription health and safety program.

Legislators from both chambers will make up the committee membership. Legislative recommendations made by the committee were due by November 1, 2013. Healthesystems will monitor the development of these recommendations.

WISCONSIN

Considering Repackaged Drug Price Cap

One of many proposals being considered by Wisconsin Workers' Compensation Advisory Committee (WCAC) during the "agreed bill" process is a price cap on repackaged drugs. The proposal provides language that will establish the reimbursement rate for repackaged drugs at the average wholesale price (AWP) set by the original manufacturer of the underlying drug, if it can be determined, or the AWP of the lowest cost, therapeutically-equivalent drug. Alternatively, labor groups are proposing a more conservative price control, which is to apply the state's current pharmacy fee schedule to repackaged drugs.

Wisconsin handles workers' compensation legislative changes differently than almost any other state in that the Advisory Council has an "agreed-bill process" in which labor and management representatives propose, consider and provide feedback regarding changes to the workers' compensation law before those changes are submitted to the Legislature. In order for any amendment to be accepted in the "agreed-bill process", it must be approved unanimously by all voting members of the Council. The process is designed to reach consensus before going to the Legislature, which traditionally approves the WCAC recommendations. Therefore, the real efforts to enact repackaged drug reimbursement changes are with the WCAC. With the help and collaboration of our clients and insurer advocacy groups, Healthesystems was a key contributor to the recommended proposed repack language addressed in the management proposal.

KENTUCKY

Pill Mill Law Reducing Rx Drug Abuse

According to statements by Kentucky Gov. Steve Beshear, the state's landmark pill mill legislation (House Bill 1) has been a huge success in combating prescription drug abuse in the state since becoming law one year ago. Gov. Beshear credits HB 1 with saving lives based on a decrease in the number of deaths blamed on prescription overdoses for the first time in ten years. The legislation included multiple provisions to help prevent the abuse and diversion of prescription drugs:

- It requires all prescribers to register with the Kentucky All Schedule Prescription Electronic Reporting System (KASPER), the state's prescription monitoring system
- It requires prescribers to access KASPER before issuing prescriptions.
- It requires medical licensure boards to investigate prescribing complaints immediately.
- It allows better coordination between health regulators and law enforcement to address abuse.

The number of reports requested through KASPER more than tripled from almost 811,000 in 2011 to nearly 2.7 million in 2012 because of the requirement of HB 1 that all prescribers register with (KASPER), which tracks controlled substances dispensed in Kentucky. With the increase in users and reports requested, prescribing trends have significantly changed. Specifically, there has been a reduction for the first time in ten years in the number of prescriptions issued for the most heavily abused substances such as hydrocodone, oxycodone and alprazolam.

Another major impact of HB 1 is that 20 non-physician owned pain management facilities have been shut down. Since the bill's passage, many facilities have voluntarily closed their doors, and the Cabinet for Health and Family Services has issued "cease and desist" letters to another four non-compliant pain management facilities.

Even with the recent success, Kentucky is still actively working to reduce and prevent prescription drug abuse. Over the next 12 months, the CHFS and University of Kentucky, under contract, will continue to evaluate HB 1's effectiveness. The goal will be to measure the impact of the legislation on prescription drug abuse, develop additional recommendations and mitigate unintentional consequences.

FEDERAL LAW

Compounding Bill Introduced

Last year's nationwide meningitis outbreak that was traced to contaminated compounded drugs from Massachusetts caused more than 700 illnesses and 55 deaths and triggered demands for stricter federal regulation. In response, a bipartisan group of United States Senators introduced legislation to Congress (S. 959 - The Pharmaceutical Compounding Quality and Accountability Act) that would subject compounding manufacturers to extensive federal regulations.

The proposal establishes a clear distinction between traditional compounding, which would continue to be regulated by state pharmacy boards, and a new category of "compounding manufacturers" that make sterile products without, or in advance of, a prescription. Additionally, S. 959 would only apply to compound manufacturers who sell compounds across state lines. This new legislation is believed to be needed because compounding manufacturers are not currently regulated by the FDA, but instead are regulated to varying degrees at the state level. As a result, interstate compounding commerce often falls in the proverbial regulatory crack, as states are not assessing out-of-state manufacturers.

To ensure that interstate compound manufacturing is consistently regulated, S. 959 would require these compounding manufacturers to register with the Food and Drug Administration (FDA), to disclose the registrant's compounding products, and to comply with certain manufacturing processes. The bill would also prohibit compounding of certain categories of drugs that the FDA considers unsafe. By clarifying oversight of compounding practices, the bill would presumably help prevent another public health crisis and erase the confusion over who has responsibility to regulate compounding pharmacies.

BY THE NUMBERS

OPIOIDS

WITHOUT EARLY CLINICAL INTERVENTION

15% OF PATIENTS USING **OPIOIDS**

↑INCREASE DOSE STRENGTH (MED) by **414%** WITHIN **1 YEAR**

— BASED ON HEALTHESYSTEMS DATA ANALYSIS

IN WASHINGTON STATE

42%

of workers with compensable back injuries **received an opioid Rx** in the first year after injury

— FRANKLIN, G.M, ET. AL. 2002-2005. CLINICAL JOURNAL OF PAIN, 2009

PHYSICIAN DISPENSED DRUGS

14 States Passed regulations to **CAP THE PRICE OF** physician-dispensed **DRUGS**

WCRI. THE PREVALENCE AND COSTS OF PHYSICIAN-DISPENSED DRUGS.

+2x

PHYSICIAN-DISPENSED AVERAGE DRUG COST PER CLAIM **MORE THAN DOUBLED** FROM 2007 -2011

NCCI. WORKERS COMPENSATION PRESCRIPTION DRUG STUDY: 2013 UPDATE.

COMPOUNDS

55 DEATHS attributed to a MENINGITIS OUTBREAK traced to **CONTAMINATED COMPOUNDED DRUGS** IN MASSACHUSETTS IN 2012

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