Mitigating Fraud, Waste, and Abuse of Prescription Medication

There's a fine line between instances of fraud, waste, and abuse. One of the key differences is intent and knowledge. Fraud is knowingly and willfully defrauding a health care benefit program for personal gain or profit, and each of the parties to a claim have opportunity and motive to commit fraud. For example, an injured worker might fill a prescription for pain medication only to sell it to a third party for profit. A prescriber might knowingly write prescriptions for certain medications or products in order to receive a "bonus" or "kickback" by the manufacturer. A pharmacy might alter a prescription by adding Dispense as Written (DAW) codes in order to fill, and therefore bill, for, a more expensive brand name medication.

Waste is overuse of services and misuse of resources resulting in unnecessary costs, whereas abuse is practices that are inconsistent with professional standards of care, leading to avoidable costs. In both waste and abuse situations, the wrongdoer may not realize that they are causing an increase in costs and/or risks. Examples of waste include under-utilization of generics, either because of an injured worker's request for brand name medication, or the prescriber writing for such. An injured worker who continually receives supplies for durable medical equipment that he or she rarely uses is another situation of waste, as is an injured worker filling a prescription for a medication he or she does not intend to take. Examples of abusive behavior is an injured worker requesting refills too soon, and a prescriber or pharmacy billing for services that were not medically necessary or charging excessively for services or supplies, i.e. a compounded medication.

The challenge for the workers' compensation industry is to identify claims that are at risk for fraud, waste, and abuse as early as possible so that intervention may occur to ensure that injured workers receive safe and effective care. This requires a multi-dimensional perspective, looking at the separate, yet connected, parties involved. Injured workers are not the only party to fraudulent or abusive behavior. Rather, it is a concern for all stakeholders of a claim and requires all to participate in limiting the potential impact. Therefore, carefully monitoring the behavior of the injured worker, prescriber, and pharmacy can mitigate potential fraud, waste, and abuse situations.

Fraud, Waste, and Abuse in Workers' Compensation

In workers' compensation, injured workers do not have to meet a deductible or pay a co-pay for prescription medication. Therefore, they are more likely to fill a prescription even if they have no intention of using it, which can mean more prescription medications on the streets. According to National Institute on Drug Abuse (NIDA), more than half of those who take prescription medications got them from a friend or relative. [1]

Over the last 15 years, the use of prescription medications has surged, prompting federal officials to warn of an "epidemic" of addiction to the medications and increased risk of fraudulent and abusive

[1] Popping Pills, Prescription Drug Abuse in America. National Institute of Drug Abuse, http://www.drugabuse.gov/related-topics/trends-statistics/infographics/popping-pills-prescription-drug-abuse-in-america

behaviors. Most problematic are prescription pain medications. According to data from the Centers for Disease Control and Prevention (CDC), there were 259 million prescriptions for pain medications written in 2012—enough for every American adult to have a bottle of pills. The CDC also reports that nearly 17,000 people in the U.S. die every year because of overdoses involving prescription pain medication—outnumbering overdose deaths involving all illicit drugs such as heroin and cocaine combined. Additionally, for every opioid-related death, the CDC says more than 150 people abuse or are dependent on opioids.[2]

In workers' compensation, the treatment of pain is a prominent factor in treating the injury. Common medications used to treat pain include non-opioid analgesics, (such as Tylenol®, Motrin®, Aleve®, and Celebrex®), opioid analgesics (such as Percocet®, Vicodin®, OxyContin®, and Duragesic®, and adjuvants (such as Cymbalta®, Effexor XR®, Lyrica®, and Lidoderm®). The challenge for the workers' compensation industry is to balance the need for pain relief with proper medication. However, pain is very subjective; it varies from person to person, injury to injury. It is up to the injured person to relay to their doctor their level of pain, and then up to the doctor to address that.

Treatment Guidelines

A tool that can help physicians better understand the level of pain based on the injury is treatment guidelines, such as those developed by the American College of Occupational and Environmental Medicine (ACOEM) and Work Loss Data Institute, which publishes the Official Disability Guidelines (ODG). Specific to the workers' compensation industry, these treatment guidelines provide evidence-based, integrated medical treatment and disability duration guidelines and a drug formulary which promotes the use of first-line agents. They provide recommendations and strategies to help doctors make decisions about appropriate treatment, with a focus on functional restoration.

Treatment guidelines include recommendations for managing different types of pain (chronic pain, neuropathic pain, somatic pain, muscle pain, and mechanical pain), and how to assess the injured worker. Additionally, these treatment guidelines provide appropriate prescribing for different drug classes, including anticonvulsants, antidepressants, sedatives, stimulants, anti-anxiety agents, muscle relaxants, and anti-emetics, and provide instructions for weaning protocols if available.

Treatment guidelines promote responsible prescribing by providing tools to;

- Screen for substance abuse and mental health problems
- Avoid dangerous combinations of opioids and sedatives
- Prescribe the lowest effective dose needed
- Provide recommended frequency and duration of treatment

[2] Centers for Disease Control and Prevention (CDC). *CDC Vital Signs: Opioid Painkiller Prescribing*. CDC Vital Signs; July 2014.

Additionally, treatment guidelines recommend the use of other tools which can help reduce instances of fraud, waste, and abuse, including:

- Use of random urine drug screens
- Patient medication agreements
- Functional status assessments to help determine if continued treatment is necessary
- Weaning protocols if they are available

A team approach is optimal when implementing these guidelines so that the prescriber, pharmacist, Pharmacy Benefit Manager (PBM) and case manager all work together to improve patient outcomes, through the use of best practices. Treatment guidelines help the doctor assess the injured person's injury in many different ways to best treat the injury and its accompanying pain.

Opioid Medications

While skeletal muscle relaxants, non-narcotic pain medication, and sleep aids are examples of classes of medications often misused or abused, opioids are the leading driver of fraudulent and abusive activities in workers' compensation simply because of their addictive and euphoric properties.

Opioid analgesics are used for moderate to severe pain. They are useful in somatic and visceral pain and are thought to have some benefits in neuropathic pain. Opioids are classified according to their actions on the opioid receptor and their duration of action. They are also classified as either long-acting or short-acting.

- Long-acting opioids are used to provide baseline pain control. Duration of action ranges from 8-72 hours. Many have no specific dose limits but there are a few exceptions.
- Short-acting opioids are used in the management of acute, intermittent or breakthrough pain. These are referred to as immediate-release or normal-release. The duration of action ranges from 4-6 hours (some less). They are available as single ingredients and combination products. Combination products have dose limits based on the non-opioid component (acetaminophen, ibuprofen, or aspirin).

When treating chronic, severe pain, it is typically recommended to use a combination of a long-acting and a short-acting analgesic in order to provide adequate pain control and improved functional status.

All opioid analgesics produce common adverse effects including tolerance, sedation, nausea/vomiting, respiratory depression, itching, and constipation. Physical dependence and addiction are also possible. Therefore, there is heightened risk for fraud, waste, and abuse.

In order to promote more rational prescribing of opioids, organizations publish guidelines for the use of opioid analgesics, measured in terms of morphine equivalent dose or MED. Most of the pure opioid agonists such as morphine or oxycodone have no ceiling dose. One of the first suggestions of an "upper limit of range" of opioid use occurred in 2007 in the guidelines published by the Washington State

Department of Labor and Industries. When an injured worker reached an oral MED of 120mg, it was suggested that the individual undergo an evaluation with a pain specialist to determine continuation of treatment, escalation of dose, or possible weaning. The value was based on evidence of increased risk of alcohol- or drug-related encounters (alcohol or drug intoxication, alcohol or drug withdrawal, or alcohol or drug overdose) at higher doses, and increased with a history of previous or ongoing substance abuse and concurrent use of habit-forming drugs (opioids with sedative hypnotics and/or benzodiazepines).

After this was introduced, there was a 27% decrease in the average morphine equivalents per day dispensed and, by 2009-2010, a 50% decrease in number of unintentional opioid deaths. As a result, by 2012, Washington State began to recognize that the range for risk was lower (in the 100-120mg MED range), although the official value remained 120mg/day. Subsequent research now indicates that adverse effects secondary to opioid use occur in the range of 50mg to 100mg MED (and in some studies, at lower ranges), and increase significantly at doses greater than 100mg MED (NEED CITATION FOR THIS. THIS IS FROM PAGE 31 of the FWA PART II CE WEBINAR).

ACOEM recently changed their recommendations in an effort to curb inappropriate prescribing of opioids, stating that MED should be limited to 50mg in most acute cases, although sub-acute and chronic pain patients may require higher doses. Additionally, ODG now recommends that dosing should not exceed 100mg MED, with increased caution for dosing over 50mg MED, and only under the care of specialists.

SIDEBAR:

What is Morphine Equivalent Dose (MED)

- MED is used to estimate the dose of each opioid received over a 24-hour period
- Morphine is considered the 'gold standard'
- Knowing the MED helps determine if the patient's opioid doses are excessive; also useful if converting from one opioid to another
- Standard conversion tables are used to convert opioid doses to an equianalgesic dose of morphine
- It is important to enter all opioid doses (short-acting and long-acting opioids) to generate the total MED
- One method provides multiplication 'factors' for converting easily to morphine
    - EXAMPLE:
        - MED factor for oxycodone is 1.5.

- If a patient is taking OxyContin 40mg twice daily this equates to 80mg of Oxycodone.
- Multiple that by 1.5 and the total MED = 120mg

– These tables are available in the ODG and other websites such as globalrph

MED for Selected Opioids		
Opioid	**Approximate Equianalgesic Dose (oral & transdermal)**	**MED Factor**
Morphine (reference)	**30 mg**	**1**
Codeine	200 mg	0.15
Fentanyl transdermal	12.5 mcg/hr	2.4
Hydrocodone	30 mg	1
Hydromorphone	7.5 mg	4
Oxycodone	20 mg	1.5
Oxymorphone	10 mg	3

**list not all inclusive*
Source: Work Loss Data Institute ODG Opioid MED Calculator

END OF SIDEBAR (taken from page 33-34 of FWA part 2 CE presentation deck)

Anti-Anxiety Agents

Injured persons with traumatic injuries or with chronic pain can have anxiety associated with their injury. In these cases, their anxiety may stem from the fear of the next painful episode, or associated with anxiety of not being able to provide for their family due to the injury. Overall, anxiety is more common in those also reporting depression.

There are multiple drug classes that can be used for the treatment of anxiety, including benzodiazepines (e.g., alprazolam, clonazepam, lorazepam, and diazepam), non-benzodiazepines (e.g., buspirone), antihistamines (e.g., hydroxyzine), and antidepressants (e.g., sertraline and paroxetine). Many of them also have several indications, such as diazepam (Valium), which can also be used for the acute treatment of muscle spasm.

Benzodiazepines are controlled substances and are not recommended for long term use due to their potential for physical dependence and risk for abuse or addiction. Most concerning is their effects can be enhanced when combined with other medications that depress the central nervous system. Instead, chronic anxiety is better treated with other medication classes such as antidepressants (sertraline or

paroxetine). The most common adverse effects of benzodiazepines include drowsiness, dizziness, confusion, anorexia, nausea and vomiting, as well as physical dependence and tolerance.

Although the use of anxiolytic agents can be key to treatment of anxiety, non-pharmacologic therapy such as psychological counseling can be an integral part of the treatment in these patients so they can learn coping mechanisms in order to deal with the stress of chronic pain.

Sedatives

Sedatives are commonly used in workers' compensation due to an injured worker's inability to get a restful night sleep because of chronic pain. Unfortunately, this can also lead to a vicious cycle of pain-insomnia -increased pain. Because of this, it is important to emphasize good sleep hygiene to chronic pain patients. When these practices do not result in a restful night sleep, it may result in the need of a sedative. However, medications should be used as needed. Some agents may cause residual sedative effects the next morning and there have been reports of next-day driving impairment. This is more often seen in the longer-acting formulations, if taking higher doses, and if the patient does not get an adequate amount of sleep. Some may experience amnesia, confusion, hallucinations and nightmares while under the influence of this medication class. These agents can also worsen depression.

One of the therapeutic concerns with sedatives is duration of therapy. Until recently, there were no studies demonstrating that there was a benefit to chronic sedative use. These agents are habit-forming and may impair function and memory more so than opioids. In workers' compensation, providing effective pain relief may mitigate the need for long term use of sedatives.

Stimulants

Stimulants have FDA indications for the management of conditions such as narcolepsy and attention-deficit hyperactivity disorder (ADHD). Stimulants have a high potential for abuse, especially for those who have a history of drug abuse. These agents are often used in an off-label manner to counteract the sedative effects of other medications, especially high dose opioid therapy. However, this may be a concern as the need for a stimulant may indicate that the dose of the opioid, or sedative, may be too strong.

Psychostimulants affect the central nervous system (CNS) and produce increased alertness, decreased sense of fatigue, and increased motor activity. Because of this, the most common adverse effects for the CNS stimulants include abdominal pain, decreased appetite, weight loss, dry mouth, constipation, restlessness, anxiety, chest pain, heart attack, increased heart rate, increased blood pressure, insomnia, irritability, and headache. These agents can also result in physiological dependence, psychological dependence, tolerance, abuse, addiction, and withdrawal.

According to the ODG, stimulants are not recommended solely to counteract sedation effects of opioids until AFTER first considering dose reduction of excessive opioid use. If prescribed, these agents should also be taken in the morning to reduce the risk of insomnia.

Muscle Relaxants

Muscle relaxants are typically used for painful musculoskeletal conditions such as low back pain, neck pain, and spasticity due to spinal cord injury. The most commonly prescribed agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol. However, muscle relaxants are highly abused and are often used to augment or alter the effects of other drugs. Soma (carisoprodol), for example, is the most highly abused muscle relaxant. Abusers will often use it to augment or alter effects of other drugs. It is often used in combination with hydrocodone, tramadol, and codeine. It can also be used to increase sedation of benzodiazepines or alcohol and prevent side effects of cocaine.

There are some therapeutic concerns with this drug class, as long-term efficacy appears to diminish over time. In general, these agents are often prescribed much longer than required, and typically have no direct effect on muscles. Due to their CNS-depressing effects, these agents help to reduce muscle tone and tension by producing a generalized sensation of relaxation, leading to the perception of decreased muscle tension and pain.

Intoxification signs include decreased cognitive function, altered gait and motor function, and subdued consciousness.

Actions that Interfere with Prescription Medication Management

Early intervention of potential situations of fraud, waste, and abuse situations is the best way to mitigate its effects. By considering the total pharmacotherapy program of an injured worker, prescribing behaviors of physicians, and pharmacy dispensing patterns, opportunities to intervene, control, and correct behaviors that are counterproductive to treatment and increase costs become possible. Certain behaviors in each community are indicative of potential fraud, waste, and abuse situations. Through their identification, early intervention can begin.

<u>Injured workers</u>

- Prescriber/Pharmacy Shopping – By going to different prescribers or pharmacies, under the same or other identities, an injured worker can acquire multiple prescriptions. They may be able to obtain “legitimate” prescriptions, as well as find those physicians who aren't so diligent in their prescribing practices. Shoppers often work in groups and track where they had successes and failures.
- Utilizing Pill Mills – Pain clinics or pill mills are typically cash-only facilities that only treat pain with prescription painkillers. Likely, there are no physical exams, medical records, or x-rays required in order for anyone to receive any pain medication desired—no questions asked. Security guards and long lines of people are usual sights at these storefront clinics.
- Beating the Urine Test – Injured workers can beat the in-office urine test by using any of the multiple commercial products available in an attempt to mask results of urine tests, or declaring religious/moral grounds as a refusal for taking the test. They may also take certain products known to deliver a false positive in order to show compliance. For example, using the over-the-counter Vicks® inhaler will show positive for amphetamines in an in-office test.

- Renting Pills – When prescribers demand an injured worker submit to drug counts (random or not), he or she must bring in their prescription bottles. The quantity remaining should match up to the prescribed dose. Rent-a-pill operations have supplies of various products from multiple manufacturers. An injured worker can pay a fee to rent the pills needed for their upcoming office visit.
- Forging or Altering Prescriptions – With today's technology, there are multiple ways to create and edit prescription pads. The phone number of the prescriber is easily replaced with that of a friend should a pharmacy call to verify the prescription. It's also possible for injured workers to take sheets from a prescription pad while at the physician's office.

Physicians

- Over-Prescribing of Controlled Substances – By prescribing high amounts and dosages of controlled medications, a physician quickly becomes a go-to physician for injured workers seeking these particular prescription medications.
- Physician dispensing and compounded medication– By dispensing prescription medications from their office, a physician may benefit from the revenue generated by these medications, and may be prone to higher prescribing of these particular medications for that reason. Additionally, a physician who prescribes compounded medications before a commercially available product is tried may have a financial relationship with a compounding pharmacy.
- Historical Non-Compliance – Physicians who have exhibited potentially high-risk behavior in the past (e.g., sanctions, outlier prescribing patterns compared to their peers, reluctance or refusal to engage in peer-to-peer outreach) are likely to continue aberrant behavior.
- Unnecessary Brand Utilization – Writing prescriptions for brand medication when a generic is available may be an indicator of potential fraud, waste, or abuse.
- Unnecessary Diagnostic Procedures or Surgeries – A physician may require or recommend tests or procedures that are not typical or necessary for the treatment of the injury, which can be wasteful.
- Billing for Services Not Provided – Since the injured worker is not financially responsible for his or her treatment, a physician may mistakenly or knowingly bill a payer for services not provided.

Pharmacies

- Compounded Medications – Compounded medications are often very costly, more so than other treatments. A pharmacy that dispenses compound medications may have a financial arrangement with a prescriber.
- Historical Non-Compliance – Like physicians, pharmacies with a history of non-compliance raise a red flag. In states with Prescription Drug Monitoring Programs (PDMPs), pharmacies who fail to consult this database prior to dispensing are not compliant with the processes put in place by lawmakers to help control the prescription medication abuse problem. They may be turning a blind eye to injured workers filling multiple prescriptions from multiple physicians.

- Excessive Dispensing of Controlled Substances – Dispensing of a high number of controlled substances could be a sign of aberrant behavior, either on behalf of the pharmacy itself or that injured workers have found this pharmacy to be lenient in its processes.

Clinical Tools

Once identified, acting on the potential situations of fraud, waste, and abuse should leverage all key stakeholders, including the payer, healthcare professionals, PBM, and state regulatory agencies. Intervention approaches include notifying claims professionals, sending letters to prescribing physicians, performing urine drug testing, reviewing full medical records with peer-to-peer outreach, and referring to payer special investigative unit (SIU) resources. Many tools can assist with monitoring and managing prescription medication use, providing opportunities for intervention and mitigating the potential for fraud, waste, and/or abuse.

- Formularies - A formulary is a list of medications that may or may not require prior authorization before being prescribed and/or dispensed by a pharmacy. Several states have active workers' compensation formularies, including Texas, Oklahoma, Ohio, and Wyoming. Additionally, PBMs often utilize formularies based on treatment guidelines for the specific injury. The application of a clinically-based, workers' compensation-specific formulary that proactively evaluates medication appropriateness and cost-effectiveness at the point of service can reduce opioid utilization and pharmacy spend.
- Medication Agreements – A medication agreement outlines the patient's rights and responsibilities of his or her therapy, and clearly sets the expectations for both the injured worker and physician.
- Documentation of Care – Documenting the injured worker's progress is an important part of the treatment plan, including outcomes of drug testing, improvement in functionality and pain, and other factors. However, equally as important is follow-through on these tests and milestones. This is an area where PBM oversight can provide a valuable checks-and-balances relationship to improve medication-related outcomes.
- Medication Monitoring - Drug testing and monitoring of high-risk injured workers, combined with proactive interventions ensures effective pain control and helps prevent situations of abuse. Testing can detect prescribed medications, illicit substances, and/or non-prescribed medications. Pill counts are also useful in monitoring adherence to the therapy regimen.
- Medication Review - A clinical pharmacist who specializes in pain management for occupational injuries does a comprehensive assessment of the injured worker's medication therapy, checks for appropriate therapies, and develops an action plan for optimal pain management.
- Peer-to-Peer Outreach – In suspected situations of abuse, physicians with experience in pain management engage the prescriber of record in a discussion that facilitates change to a more appropriate therapy.
- PDMPs – These state-based databases provide prescription information from pharmacies, outpatient clinics, and prescriber offices in order to monitor prescription information of

individuals. Healthcare practitioners can access it to see the injured worker's past and present prescriptions as a means to identify, deter, or prevent drug abuse and diversion.

Industry Tools

In addition to the clinical tools that can be used to mitigate fraud, waste, and abuse situations, several other initiatives are helping with the effort.

- Abuse Deterrent Formulations – Abuse-deterrent formulations are designed to discourage medication misuse and abuse. Such formulations are intended to prevent the product from being cut, broken, chewed, crushed, or dissolved to release more medication, with the hope that it will lessen abuse by snorting or injection. Data shows that an abuse-deterrent formulation can successfully reduce abuse of a specific drug but could lead to an increase in use of an alternative medication and/or heroin. Thus, abuse-deterrent formulations may not be the "magic bullets" that many have hoped for.
- Detox Medications - An antagonist interferes with, reduces, or defeats the euphoria associated with prescription medication and thus, reduces its abuse. Such formulations include Buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®, Zubsolv®, Bunavail™). Administered in the outpatient treatment of opioid dependence, these medications can help detoxify a patient, with the goal of eliminating all opioid use, and not substituting one medication for another.
- Risk Evaluation and Mitigation Strategy (REMS) – The Food and Drug Administration (FDA) requires a manufacturer of any medication to submit documentation to illustrate the benefits and risks of the medication. Manufacturers must prove that the benefits outweigh the risks by sending a medication guide, communication plan, details on elements to assure safe use, an implementation plan, and a timetable for submission of assessments.
- Regulatory Actions – Several states have taken regulatory actions, including the removal of propoxyphene products from the market, dose limitations for acetaminophen products, and rescheduling of medications to more restrictive classes. Additionally, some states require pre-authorization or a step process for opioids, and restrict physician dispensing of opioids and other highly abused medications.

Proactive Prescription Medication Management Mitigates Fraud, Waste, and Abuse

Prescription medication, including opioid analgesics, can be used safely when monitored and controlled according to clinical goals that focus on function restoration. A program that integrates clinical strategies to identify aberrant behavior, alert stakeholders of potential issues, act through intervention, and monitor progress with the injured worker, prescriber, and pharmacy communities can prevent and resolve potential fraud, waste, and abuse situations.

Additionally, a vital (but often overlooked) component of successful prescription medication management is education. It is important that all stakeholders not only stay abreast of current issues and advancements in pain and medication management, new developments and methods for

prevention and management of fraud, waste, and abuse, but also share this information with injured workers, their families, and their caregivers.

Prescription medication will continue to play a role in treating injured workers. While the industry and lawmakers make strides in increasing monitoring, oversight, and education, it is important that workers' compensation payers take proactive measures to reduce fraud, waste, and abuse of prescription medications. In doing so, payers improve injured worker safety and obtain more control over medication expenses. A PBM can offer payers an effective prescription utilization strategy to identify, alert, intervene upon, and monitor potential aberrant behavior, providing a path to brighter outcomes for all.