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Dialogue

California Closed Formulary - benefit or detriment?

Introducing a closed pharmaceutical formulary into California workers' compensation identifies two main benefits. The first is to further lower the cost of pharmaceuticals by either restricting or eliminating certain medications and the second is to reduce the possibility of drug addiction, as opposed to having a physical dependence on a medication.

An October 2014 California Workers' Compensation Institute ("CWCI") report titled, "*Are Formularies a Viable Solution for Controlling Prescription Drug Utilization and Cost in California Workers' Compensation*", states that pharmaceutical costs could be reduced by 12 percent or $124 million by introducing the Texas workers' compensation pharmaceutical formulary, achieving the first benefit.

Can the aims of Group Healths' Closed Pharmacy Formularies be achieved in California Workers' Compensation?

To achieve the second benefit, Assembly-Member Perea introduced AB1124 to establish an evidence-based medication formulary and made the following statement on his website, "*The central purpose of our workers' comp system is to ensure injured workers regain health and get back to work. When workers get addicted to dangerous medications, goals of the program are not met. An evidence based formulary has proven to be an effective tool in other states and should be considered in California.*" To confirm whether these benefits could be achieved through the introduction of the Texas formulary, a review of the CWCI study and the opioid medications available under the Texas formulary was conducted. The findings are summarized below.

Although California does not restrict or limit medications in treating injured workers, it does limit the prices paid and provides an opportunity to question prescribed medications that appear out of the ordinary. Medi-Cal prices (California's Medicaid health care program) are used for establishing the maximum prices for workers' compensation medications in contrast to states such as Texas which use the Average Wholesale Price ("AWP") as the pricing point for determining maximum price.

A review of two cost saving examples which referenced specific medications calculated projected savings based on CWCI's ICIS payment data for prescriptions paid between January 1, 2012 and June 30, 2013.

The first example compared 50mg Tramadol prices between five different suppliers with the highest being $190 followed by $23, $18, $12 and $8 per script. Here CWCI suggested that the manufacturer of the highest priced script be removed from the California formulary saving up to $182 per script. From mid 2009 through 2013 however, the unit price for 50mg Tramadol from the supplier of brand name "Ultram" and at least 10 other suppliers in California was 9 cents (AWP $2). A script price of $190 results in a quantity of approximately 2,000 tablets being dispensed, which is unlikely and strongly questions whether overpaying for medications is an issue.

The Workers' Compensation Research Institute ("WCRI") also reported that California claims administrators paid a unit price of between 35 and 70 cents for 5mg and 10mg Cyclobenzaprine respectively, while at that time, the unit price from Californian suppliers was 10 cents for 10mg and 15 cents for 5mg, suggesting again that California claims administrators were paying more than the maximum prices.

Based on randomly selected manufacturers and strengths of the top twenty medications identified in the 2013 NCCI prescription drug study, California's prices were on average 20% lower than the AWP and in some cases up to 24 times lower. California prices were also found to be at the lowest retail price range compared to lowest and highest retail prices published on goodrx.com. Pharmacies located in Los Angeles, Miami and Dallas were used for comparison. Findings suggested employers in California workers' compensation are paying no more than the general public for medications whereas in Texas, employers are paying more by using the AWP.

The second example compared script prices of seven opioid agonists including Tramadol and Oxymorphone. Oxymorphone was the highest priced script at $600 and Tramadol the lowest at $60 per script, suggesting a saving of up to $540 if Tramadol were to be prescribed instead of Oxymorphone.

On the World Health ("WHO") Analgesic ladder, tramadol and codeine are weak opioids regarded as "step two" while acetaminophen and NSAIDs are "step one". "Step three" opioids include medications such as morphine, oxycodone and oxymorphone which all differ in their pharmacodynamics and pharmacokinetics so choosing one or more to treat pain becomes a balance between possible adverse effects and the desired analgesic effect. Oxymorphone (stronger than morphine or oxycodone) is recommended for use only when a person has not responded to or cannot tolerate morphine or other analgesics to control their pain. Prescribing oxymorphone when tramadol could suffice or vice versa could be regarded as an act of gross negligence by the physician.

A list of opioid medications published by Purdue Pharma ("Purdue") was used to identify which opioids were excluded from the Texas formulary. The list of over 1,000 opioid analgesics was prepared by Purdue to comply with the state of Vermont law 33 V.S.A. section 2005a, requiring pharmaceutical manufacturers to provide physicians with a list of all drugs available in the same therapeutic class. Being in the same class however, does not necessarily mean they are interchangeable or have the same efficacy or safety.

The list showed available strengths and included (1) immediate and extended release, (2) agonists such as fentanyl, oxycodone, hydrocodone, oxymorphone, tramadol, codeine, hydromorphone, methadone, morphine, tapentadol, and levorphanol and (3) combinations such as acetaminophen with codeine, oxycodone with acetaminophen, oxycodone with asprin, oxycodone with ibuprofen, hydrocodone with acetaminophen, hydrocodone with ibuprofen, acetaminophen-caffeine with dihydrocodeine, aspirin-caffeine with dihydrocodeine and tramadol with acetaminophen.

It appears that extended-release medications used for around-the-clock treatment of severe chronic pain have been excluded or are not listed in the Texas formulary with a few exceptions. For example 80mg OxyContin (Oxycodone) ER 12 hour (AWP $18, Medi-Cal $15) is excluded. 120mg Hysingla

(Hydrocodone) ER 24 hour (AWP $41, Medi-Cal $34) is not listed. However, 200mg MS Contin (Morphine) ER 12 hour (AWP $31, Medi-Cal $26) and 100mcg Fentanyl 72 hour transdermal patch in both brand name and generic forms are approved under the Texas formulary. Immediate release generic medications such as oxycodone, hydromorphone and hydrocodone with acetaminophen in all strengths are approved however, immediate release hydrocodone with ibuprofen and oxymorphone in either immediate or extended release are excluded.

Is the objective of AB1124 being achieved by utilizing the Texas formulary? From the above review, it would suggest not. All the opioid medications available through the Texas formulary have the potential to cause addiction and be abused, possibly leading to death either accidentally or intentionally. As an example, the Executive Director of the Medical Board of California has filed accusations against Henri Eugene Montandon MD for Unprofessional Conduct including Gross Negligence. His patient was found dead with three 100mcg fentanyl patches on his upper chest. The autopsy revealed he potentially had toxic levels of fentanyl, codeine and morphine in his bloodstream at time of death. These three opioids are available under the Texas formulary. An article published on the website www.startribune.com described the challenges in treating returning soldiers from combat duty. The article discusses Zach Williams, decorated with two purple hearts who was found dead in his home from a fatal combination of fentanyl and venlafaxine, an antidepressant. Venlafaxine in both immediate and extended release form is approved in the Texas formulary. In addition, the following statement was made in a 2011 CWCI study into fentanyl, "… *of the schedule II opioids included in the Institute's study, the most potent is fentanyl, which is 75 to 100 times more powerful than oral morphine.*"

The top twenty medications identified by the 2013 NCCI prescription drug study were also compared to the Texas formulary and six medications were found to be excluded from the formulary including three extended release opioids, OxyContin (Oxycodone), Opana ER (Oxymorphone) and the once daily Kadian ER (Morphine). The twice daily extended release morphine MS Contin however, was approved. Flector, a non-steroidal anti-inflammatory transdermal patch used for acute pain from minor strains and sprains was excluded as was carisoprodol a muscle relaxant, classified by the DEA as a Schedule IV medication (the same as Tramadol). The Lidocaine transdermal patch, which is a local anesthetic available in both brand name and generic was also excluded. Lidocaine patches have been found to assist in controlling pain associated with carpal tunnel syndrome, lower back pain and sore muscles. Apart from carisoprodol, it would appear the remaining five were excluded from the Texas formulary due to their high price rather than concerns regarding their safety or potential for abuse.

The U.S. Food and Drug Administration (FDA) is responsible for the approval of all medications in the United States. Their approved list is the United States Pharmacy Formulary (or Closed Formulary). California workers' compensation utilizes this list for treatment and the Medi-Cal formulary for medication pricing. In comparison, Texas workers' compensation utilizes their own formulary, which is a restricted list of FDA approved medications and pay a higher price for their approved medications than California.

Implementing an evidence-based formulary such as Texas may result in an injured worker not having the same choice of medications as a patient being treated for pain under California's Medicaid health care program. How can this be morally justified? Will we see injured workers paying out-of-pocket to receive the medications necessary to control their pain?

Claims administrators can greatly reduce pharmaceutical costs through their own initiatives by (1) ensuring they pay no more than the Department of Industrial Relations ("DIR") published price for a medication, (2) ensuring physicians within their Medical Provider Network ("MPN") treat pain using the established pharmacological frameworks such as the WHO Analgesic ladder, (3) ensuring quantities and medication strengths are monitored along with how a person has responded to or tolerated analgesics, (4) when controlling pain with opioids, ensuring there is a heightened awareness for potential abuse, misuse and addiction, (5) establishing a multimodal pain management regimen including non-pharmacological therapies such as acupuncture, aerobics, pilates, chiropractic and physical therapy tailored to a person's medical condition and (6) for chronic pain, consider introducing an internet-delivered pain management program based on the principles of cognitive behavioral therapy. Many of these initiatives along with their progress can be automatically monitored through a claims administrator's technology solution where a yellow or red flag is raised when prices paid exceed the legislated maximum amounts, when a pharmacological step therapy or progressive

plan has been breached or when non-pharmacological therapy goals have not been achieved.

Using these proactive initiatives as opposed to restricting specific manufacturers or medications through a closed formulary, will undoubtedly yield a far better outcome for the injured worker and lower the cost to the employer benefitting all involved.

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