CLM CLAIMS & LITIGATION MANAGEMENT ALLIANCE™

ADVANCING ETHICS, COOPERATION AND EDUCATION

CLM 2015 Medical Legal Summit
June 3, 2015 in Chicago, IL

The Prescription Drug War: A Medical/Legal/Claims Perspective on the National Painkiller Crackdown

1. Focus on Supply- The "Hassle Factor"

Two perspectives have arisen around battling prescription drug abuse. One outlook focuses on curbing the supply of prescription drugs and the FDA's recent rescheduling of certain controversial opioids.

The battle continues to rage over Zohydro. More informally called "heroin in a capsule", Zohydro is a pure hydrocodone product whose approval by the FDA in 2013 created a firestorm of complaints around the country. Further complicating the debate was the back story of the FDA approving Zohydro despite the FDA's own advisors' recommendations. This was a very public fight between governments (responsible for the health and safety of their citizens) and Big Pharma, which is not only a harbinger of things to come but a sign that sensitivity to the overuse of these drugs has reached a tipping point.

Rescheduling of Hydrocodone products has also been extremely controversial. Hydrocodone is the most prescribed opioid in the U.S. In fact, the U.S. uses 99% of all hydrocodone in the world. Two HCPs, Vicodin and Norco, are heavily used ("handed out like candy") despite their dangers. The FDA's rescheduling of HCPs from Schedule III to Schedule II in 2014 (now at the same level of OxyContin) was a realization of those dynamics, but there was protracted lobbying against it which explains in some part the various motivations associated with the U.S. epidemic.

Likewise, the scheduling of Tramadol has been the subject of debate. The historical argument for Tramadol not being a controlled substance was that it is only "narcotic-like". But evidence showed the same level of withdrawal symptoms and potential for dependence/addiction existed for Tramadol as with opioids. If it walks like a duck and quacks like a duck … After years of consideration, in 2014, the FDA changed Tramadol

to a Schedule IV drug to add more controls over its use and, more importantly, to change the perception Tramadol was not very dangerous.

Prescription Drug Monitoring Programs

Every state except Missouri has a PDMP, which are aggregate databases of every single drug dispensed by a pharmacy regardless of payer. That holistic view (compared to a work comp PBM who only has access to the drugs filled thru their network) provides great visibility into the overall drug regimen, dosage/pill count, multiple prescribers and/or pharmacies, and a host of other very important information. The trick now is to share data across state boundaries (and nationally) and to require prescribers and pharmacists to access a PDMP before writing/dispensing a drug.

Workers' Compensation Drug Formularies

Drug formularies have been used everywhere except in workers' compensation claims for many years. However, the experience from the Texas closed formulary, implemented in stages in 2011 and 2013, has piqued the interest of the workers' compensation industry. With the decline of 'N' drug costs by 82% and the number of prescriptions by 74%, prescribing behavior has changed by increasing the hassle factor. There are a number of states considering drug formularies in 2015, and this trend will continue into the foreseeable future.

2. Focus on Demand and The Need for Education

The second way to address the prescription drug epidemic is to focus on the demand for opioids, versus cutting drug supply. Groups of medical care professionals and other educational forums have mobilized to focus on identifying why certain individuals become dependent upon opioids and what can be done to curb this demand.

Physicians for Responsible Opioid Prescribing (PROP)

This group of physicians has been outspoken in their belief that physicians need to change their understanding for when and how opioids (and other dangerous drugs) should be used. This means overcoming two decades of training at medical schools and education from Big Pharma marketing that the U.S. was under-treating pain and the appropriate and compassionate act was to alleviate that pain.

National Prescription Rx Drug Abuse Summit

The fourth annual conference is being held in Atlanta on April 6-9. This Summit brings together every potential constituent touched by the prescription drug epidemic, including physicians, patients, insurance companies, government and law enforcement. In recognition of the issue's scope, workers' compensation is only one track amongst many.

The dialogue at the conference, and before/after the conference, furthers the general education of the dangers of these drugs.

State-level educational campaigns

Various states, including most recently Colorado, have launched educational campaigns for their citizens on the dangers of the misuse and abuse of prescription drugs. These efforts, combined with mainstream media documenting statistics and telling personal stories, heighten the awareness of the issue so that no one- not physicians nor patients – has the excuse of ignorance any longer.

3. A Case Handler's Perspective

Historically, in the context of claims handling, management of prescription drug issues has been primarily the nurse case manager's duty. Today, however, every case handler must recognize effective prescription drug management is not just the nurse's problem anymore. For effective medical case management, a team approach is needed to win!

Case handlers must have a more thorough understanding of how prescription drugs affect the outcome of their claims and work diligently "early on in the life of the claim" with the treating physician, Nurse case managers, the injured worker's representative, and the insured must work in tandem to ensure a successful outcome.

For example, expectations must be set early. There are many strategies and tools case handlers and nurse case managers can use to reduce narcotic usage. During the initial contacts with the treating physician and injured worker there must be dialogue regarding current/past narcotic use. Moreover, the case handler must set expectations with all parties that the current use will need to end at some point. It is extremely important to obtain target dates from the treating physician on when he/she will initiate a taper plan.

With respect to tapering and management of chronic pain, treatment for patients in chronic pain often evolves into a mixture of opioids, NSAIDs, benzodiazepines, muscle relaxants, and antidepressants. Over time, a simple drug regimen with a single opioid can expand into five, eight, 12 or more drugs in multiple classifications.

To increase function, patients often need to be tapered, not just from a single drug or classification, but from multiples of each. Unfortunately, there is little clinical support available to physicians who want to manage a tapering process according to PRIUM's white paper, "An Analysis of Drug Therapy Tapering Guidelines."

Drugs in different classifications have different tapering protocols. While some medications, such as Celebrex, an NSAID, or the muscle relaxant Zanaflex, do not require a gradual decline in dosage and can be discontinued fairly quickly, while others cannot. Opioids like Oxycontin and benzodiazepines like Xanax require careful tapering, which is even more complicated when they are taken with other medications in multiple drug classifications.

Decisions should be made about what medication to reduce first, how it should be reduced and the duration for tapering. However, the intersection of polypharmacy and tapering is not well documented.

PRIUM examined 257 medical guidelines containing keywords such as "opioids" and "chronic pain" and applied filtering criteria like updates since 2009 and systemic review of medical literature and found 18 guidelines that discussed initiating and maintaining opioid therapy. Only seven of the 18 discussed discontinuing opioid therapy and those focused exclusively on tapering individual drug classifications, i.e., how to taper a single opioid, with none providing any information on the duration of tapering.
Amazingly, none of the clinical guidelines addressed tapering opioids in a polypharmacy environment. The clinical reality is that most chronic pain patients have a polypharmacy regimen.

Physicians need to answer a number of questions when creating a polypharmacy tapering plan, including:

- Which drug should be discontinued first?
- What drugs can be discontinued concurrently?
- What thresholds should be reached before addressing the next drug?
- What drugs cannot start discontinuance until other drug(s) have been fully/partially tapered?
- What drug should be discontinued last?

Another interesting finding from the white paper's analysis was that 13 of the 18 opioid guidelines address psychosocial issues. Historically health care in workers' compensation has focused on the biomedical model, seeking a physical solution to pain. However, experience indicates that psychosocial issues often play a major role in the proper management of chronic pain. Catastrophizing, perceived injustice, fear avoidance and low self-esteem contribute to both pain and drug abuse. Other potential complications include personal discipline, depression, anxiety, and enabling environments at home. If not identified and addressed, these conditions can sabotage the tapering process and result in relapse.

In addition, physical therapy, yoga, Pilates, stretching, along with appropriate doses of medication can relieve musculoskeletal pain. Finding the most effective tools to facilitate an individual's ability to manage pain, such as cognitive behavioral therapy or psychotherapy, exercise, proper nutrition, and good sleep habits, should be a major component of the tapering process.

While some workers' compensation payers shrink from any "psyche" diagnosis, addressing psychosocial issues and helping patients develop coping skills costs much less than years of an inappropriate drug regimen. A multi-disciplinary approach of medical and psychological treatment with physical fitness can equip patients to manage pain and lead functional, productive lives.

Narcotic Contracts are also an effective way for the treating physician to set expectations with the injured worker. The contract outlines the following: the injured worker is taking a controlled II or III substance and if they abuse or do not take it accordingly, he/she will be immediately terminated from treatment.

Urinary drug screens/pill counts are also extremely helpful in determining if the injured worker is taking the prescribed medication as it is prescribed and if there are any non-work related/recreational drugs being taken at the same time. IL, MA, TX, CA have developed utilization guidelines for prescription drugs. This is a useful tool in opening the door to meaningful dialogue with the treating physician on creating a taper plan or alternatives to chronic pain.

Changing prescription drugs from brand to generic will not only assist in lowering the cost of the file but also create an environment ripe for final resolution.

For example:

- Brand-Ultram 50 mg-Average wholesale price= 2.9585
- Current dose is 6 tabs/day = $17.51/day x 365 = $6479/year x 12 = $77,749
- Compared to the generic equivalent (Tramadol) 50 mg- Average wholesale price 0.0863 x 6 = 0.52/day x 365 = $190/year x 12 = $2280 over the NLE
- If the primary care physician will make this switch from Ultram to Tramadol, a savings will result of approximately $75,469

Detox and Interdisciplinary Pain Programs

Other tools available to the claims handler for reduction of prescription drug abuse include detox and interdisciplinary pain programs. Detox programs focus on the narcotic

usage through use of other drugs such as Methadone/Suboxone and focus on coping skills. Interdisciplinary Pain Programs focus on the triggers for pain as well as showing the injured worker how to be functional again through exercise and alternatives to pain.

4. **Prescription Drug Rescheduling and CMS Submission**

An issue related to prescription drug abuse and claims handling involves prescription drug allocations in Medicare Set Asides. The Centers for Medicare and Medicaid Services (CMS) has announced a new policy starting January 1, 2015 regarding hydrocodone combination products and other controlled substances in relation to WCMSA proposals.

As part of this new policy, CMS will require a minimum number of healthcare provider visits per year in situations where the claimant's prescription regimen includes hydrocodone combination products or other controlled substances. CMS' notice announcing this new policy can be obtained **here**.
This new policy can be outlined as follows:

Background
This policy change comes in direct response to the Drug Enforcement Administration's (DEA) recent rescheduling of hydrocodone combination products. Specifically, as outlined in CMS' notice, the DEA in October, 2014 rescheduled all hydrocodone combination products from C-III controlled substances to C-II controlled substances.

In accordance therewith, CMS notes that this may result in more frequent provider visits for beneficiaries to obtain prescriptions for hydrocodone combination products, as refills are now prohibited. CMS further notes that C-IIIs required a new prescription after five refills or after six months, whichever occurs first. C-IIs require new prescriptions at intervals no greater than 30 days; however, a practitioner may issue up to three consecutive prescriptions in one visit authorizing the patient to receive a total of up to a 90 day supply of a C-II.

What is CMS' New Policy?
In light of these updates, CMS has announced the following changes for all WCMSAs proposals submitted on or after January 1, 2015:

- At a minimum, CMS will require that 4 healthcare provider visits be allocated per year when schedule II controlled substances (including hydrocodone combination

products) are used continuously unless healthcare provider visits are more frequent per medical documentation.

- WCMSA cases submitted to CMS *before* January 1, 2015, closed due to missing, incomplete and/or inadequate supporting documentation (or any other reason), and subsequently re-opened after January 1, 2015, will also be subject to a review that includes the C-III controlled substances changes due to rescheduling by the DEA.

Implications

The drugs related to CMS' new policy (hydrocodone and other schedule II controlled substances) are typically seen in cases involving orthopedic injuries. In terms of policy, CMS' upcoming changes are relatively straightforward as the agency is basically setting a minimum allocation standard for healthcare provider visits in certain situations regarding schedule II controlled substances. From a more practical perspective, CMS' upcoming changes will likely have minimal impact on WCMSA allocation costs in most instances since the minimum healthcare provider visits standard being established by CMS is essentially in line with typical allocation practices in these situations.

5. CMS Requirements for Prescription Drugs and the Workers' Compensation Medicare Set Aside Portal (WCMSAP)

The Centers for Medicare and Medicaid Services (CMS) has released a training document regarding its upcoming plans to allow prescription drug information to be entered directly into the WCMSA Portal (WCMSAP).

A copy of CMS' new training document can be obtained **here**.
This article outlines this new development as follows:

Background

By Alert dated August 19, 2014 CMS announced that beginning October 6, 2014 WCMSA submitters will be able to enter prescription drug information directly into CMS' WCMSA Portal.

As outlined in this prior Alert, some of the features related to this planned WCMSAP expansion include: *new data entry pages to enter prescription drug information; a drug "look up" feature; and the ability to calculate expected drug costs.*

For a more in-depth summary of CMS' August 19th Alert, see ISO CP's August Bulletin **here**.

In conjunction with this Alert, CMS advised that it would be releasing subsequent information sometime prior to the October 6, 2014 start date. Accordingly, CMS has now released its new training document.

CMS' New Training Document
CMS released its new training document via PowerPoint format.

In terms of its set up, the training document provides information on the following features:

- Prescription drug page
- Redbook RX search page
- Redbook RX detail page
- RX historical detail
- Revised case summary page

CMS explains how each of these features will work, what information will be provided, and provides other important details.

Highlights & Considerations
While CMS' training document does not contain page numbers, as part of the below discussion the authors have assigned "slide numbers" to provide a more orderly discussion.

In assessing the actual content of the training document, several questions and considerations surface:

1. To start, the training document states that submitters choosing to use the portal will be "*required, when applicable*" to directly enter prescription drug information into the portal "*prior to submission of a case using the portal*." (Slide 3). This reference seems to suggest the submitters wishing to use the portal will have no choice but to utilize CMS' new RX portal process.

2. The training document further suggests that submitters will have no discretion in terms of limiting the number of years for calculating the costs of a specific drug. (Slide 9)

Specifically, it is indicated that submitters will only be able to choose the frequency of prescription drug use (i.e. one pill per day, week, etc.). As such, it appears that the portal will automatically default to calculating the drug costs over the claimant's lifetime.

Assuming that this will be the case, this restriction could prove problematic in that it would apparently prevent submitters from utilizing the WCMSAP in situations where the submitter believes a more limited calculation is appropriate; such as the case where prescription drug weaning is occurring or is recommended, or for other valid reasons.

3. With respect to what CMS refers to as the "look up" feature, it appears that this will not be accessible until the process for interaction with the portal is initiated relative to a specific settlement. That is, this feature would not appear to serve as a tool for the purpose of simply checking, or "looking up," drug pricing short of actually submitting a WCMSA proposal.

Nevertheless, assuming that CMS' overall goal in adding this new feature is to improve the efficiency of the WCMSA review process, the above considerations (especially points #1 and #2 above) could ultimately cause submitters to reconsider using the portal in certain situations if the new process ends up limiting the flexibility to submit realistic assessments of a person's expected post settlement prescription drug usage, or limits the ability to submit certain evidence or arguments in support thereof.

Lastly, assuming the "look up" tool will be limited as noted in point #3 above, this would appear to be a missed opportunity for CMS to provide parties with a tool allowing them to proactively identify the anticipated drug pricing that CMS would approve.