CLM Claims & Litigation Management Alliance™
ADVANCING ETHICS, COOPERATION AND EDUCATION

CLM 2016 Midwest Conference
June 23, 2016 in Omaha, NE

Using Evidence Based Medicine to Facilitate Settlements and Improve Claims Outcomes

I. Evidence Based Medicine (EBM), ODG (Official Disability Guidelines) and Current State Formularies

Definition and Application of EBM and ODG

Evidence Based Medicine (EBM) was originally defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual client expertise with the best available external clinical evidence from systematic research. *Sackett et al, Evidence Based Medicine: What It Is and What It Isn't, BMJ 1996; 312: 71-2.*

ODG Treatment Guidelines:

ODG is designed for clinical practice as well as utilization review/management. The overall objectives of users of the treatment guidelines in ODG are:

- To improve outcomes and patient satisfaction by focusing on restoration of functional capacity through prompt, responsible delivery of healthcare based on the best medical evidence;
- To reduce excessive utilization of medical services (and corresponding medical costs);
- To identify and target ineffective and harmful procedures, thus reducing risk on injured workers;
- To reduce delayed recovery rates and indemnity costs with the concurrent management of treatment and time away from work;
- To improve clinical practice/utilization management by indexing procedures adjacent to a summary of their effectiveness based on supporting evidence, provided by way of link, in abstract form ;
- To automate approval for universally effective treatment methods, where appropriate, reducing friction and administrative delays on necessary medical care.
- To open the lines of communication among all parties in the return-to-work process by providing a common framework based on existing and emerging medical evidence
- To help injured workers get back on their feet in good time, safely, easily and effectively.

- To take evidence-based medicine to its logical endpoint – the convergence of health, wellness, productivity, efficiency and responsible, cost-effective medical care
- To use guidelines that have been accepted by the Federal Agency for Healthcare Research & Quality (AHRQ) for inclusion in the National Guidelines Clearinghouse www.guidelines.gov

Opioids, MSAs and the Newly Released *CDC Guidelines for Prescribing Opioids for Chronic Pain*

Application of Evidence Based Limits on Opioids for MSAs following newly released *CDC Guidelines for Prescribing Opioids for Chronic Pain* caps costs for future opioid expenditures, which facilitates settlements and enhances patient safety.

The new CDC guidelines provide recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.

Evidence based studies have long shown that long-term use of opioid medications for chronic, non-cancer pain is ineffective, counterproductive and if left unchecked, deadly. 90% of chronic pain is not effectively treated with opioids, and opioid use for chronic pain is not associated with any increase in function. Using opioids for more than seven days doubles the risk of disability at one year. Every patient who is chronically prescribed opioids will develop dependence, and 60% of those prescribed opioids for more than three months, will still be on opioids in five years. *Safely Prescribing Opioids in Practice. G. Franklin. American Academy of Neurology Course C 171-Opioids and Marijuana in Your Practice, April 19, 2015, Long Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study. B.C. Martin, et al. Journal of General Internal Medicine. (12): 1450-7. December 2011.*

The CDC, like CMS, is under the auspices of DHHS (Department of Health and Human Services). This begs the question that shouldn't the CMS (Center for Medicaid and Medicare Services), a sister agency of the CDC (Centers for Disease Control) follow the CDC guidelines in recommending and approving opioid allocations in MSAs?

Exploration of Current State Drug Formularies

Government officials at the national, state and local levels are grappling with various measures to eliminate prescription drug abuse and rein in pharmacy costs. A drug formulary is not a new concept to most players in administering workers' compensation claims. States' like Texas, Washington and Ohio have implemented closed formularies with many more states expected to follow suit.

California Governor Jerry Brown has signed Assembly Bill No. 1124, which mandates that the Division of Workers' Compensation (DWC) implement a prescription drug formulary by July 1, 2017. The bill, sponsored by Henry Perea (D-Fresno), makes California the fifth state—along with Texas, Oklahoma, Washington, and Ohio—to provide a closed pharmacy formulary for medications prescribed to injured workers.

A closed formulary is a predetermined list of prescription medications approved for certain medical conditions. Unapproved medications, commonly referred to as "N" drugs, will need prior authorization for payment. The law also requires the DWC to meet with stakeholders and publish interim reports describing the status of the formulary, provide quarterly updates, and create a Pharmacy and Therapeutics Committee to review and consult with the DWC regarding those updates. It's significant that the new law will enable the DWC to update the formulary without a formal administrative rule-making process (which would require a public comment period and a public hearing).

Proponents of the closed drug formulary concept laud its potential to reduce costs, improve predictability in provider behavior, and provide a seamless experience in medication delivery to injured workers. This change is particularly valuable because increases in medical costs and pharmacy spend can pose barriers to timely claim settlement and potentially delay an injured worker's return to employment.

Perea's office referenced a study published by the California Workers' Compensation Institute (CWCI), indicating that a closed drug formulary in the state based on the Washington state formulary and the current Texas ODG (Official Disability Guidelines) model could lead to a savings of up to $420 million annually.[i] The Texas model, adopted in 2011, distinguishes between new and legacy claims. The Texas Department of Insurance released a report early this year finding that the cost of "N" drugs in new claims fell by 83 percent and the average pharmacy cost in legacy claims dropped 18 percent in the first month they became subject to the formulary.[ii] The study also revealed the generic substitution rate for "N" drugs increased, leading to lower costs.

When the new law goes into effect, the potential costs savings may have a direct impact on premium costs in California. In addition, a CWCI study indicates that 44 percent of utilization reviews and 35 percent of independent medical reviews involved disputes over pharmaceuticals.[iii] When providers adhere to a list of approved medications for specific conditions, the number of disputes and reviews filed should decrease, thereby leading to reduced administrative costs and faster delivery of medications for treatment.

Formularies are likely to remain a hot topic over the next five years. Almost a dozen other jurisdictions are currently considering drug formularies in their workers compensation system. California's implementation of AB 1124 will be closely watched across the country as lawmakers seek to reduce opioid access and addiction and insurers seek to rein in skyrocketing medical costs while maintaining the integrity of patient care. [i] Swedlow, Alex, MHSA, Steve Hayes, MHSA, and Rena David, MBA, MPH. *Are Formularies a Viable Solution for Controlling Prescription Drug Utilization and Cost in California Workers' Compensation*. Rep. Oakland: California Workers' Compensation Institute, 2014. Web 21 Oct. 2015.[ii] Impact of the Texas Pharmacy Closed Formulary. Rep. Texas Department of Insurance Workers' Compensation Research and Evaluation Group, Feb. 2015. Web 22 Oct. 2015.

Jurisdictional Challenges and Legal/Medical Defenses for CMS Submission

CMS' policy with respect to the effect of state statutes on MSA determinations is contained in Section 9.4.5 of the CMS WCMSA (Workers' Compensation Medicare Set Aside) Reference Guide:

"*The WCRC (Workers' Compensation Review Contractor's) review of state-specific statutes is limited to the guidance provided by CMS. CMS will recognize or honor any state-mandated, non-compensable medical services and will separately evaluate any special situations regarding WC cases. A submitter requesting that CMS review the applicability of a state WC statute must include a copy of the statute with the submission and indicate to which topic in the submission the statute applies."*

CA IMR (Independent Medical Review) Statute *8 CCR Section 9792.10.7(a)(2)*

"As of July 1, 2013, medical treatment disputes for all dates of injury will be resolved by physicians through an efficient process known as IMR, rather than through the often cumbersome and costly court system." CA.gov (Division of Workers' Compensation)(DWC)

CA Legal Standard: Employers must pay for all medical treatment that is reasonable and necessary to cure or relieve the effects of a work-related injury.

The California IMR process involves several steps:

- **First Step:** UR to confirm medical treatment is medically necessary
- **Second Step:** UR denies, delays or modifies the treating physician's request for medical treatment
- **Third Step:** Applicant may ask for review of UR decision through IMR (Maximus)

The decision issued by Maximus is deemed to be the determination of the Administrative Director and it is binding on all parties, **except in the event of an appeal**. The grounds for an appeal of an IMR decision are:

- AD acted without or in excess of her powers
- The final determination was procured by fraud
- The medical reviewer was subject to a material conflict of interest
- The final determination was the result of bias on the basis of race, national origin, ethnic origin, religion, age, sex, color, disability
- The final determination was the result of a plainly erroneous mistake of fact.

When IMR decisions conflict with the treating provider, the WCMSA must clearly exclude the treatment consistent with the IMR decision, contain an explanation of the basis for excluding treatment and contain a copy of the IMR decision (the final decision, not just a peer review report). The WCMSA must also contain a copy of the CA statute, address whether the IMR was appealed, and the refill records and pay history post IMR date must show the carrier did not pay for the medication or treatment.

Common CMS Review Obstacles-The Volatility Challenge

Given CMS may or may not recognize state law in its MSA determinations, a practical strategy needs to be developed for MSA submission designed to counterbalance CMS' lack of understanding of state law. In addition, the Workers' Compensation Review contractor will use AWP (average wholesale pricing) to calculate the prescription drug allocation amount and may allocate prescriptions based on the life-expectancy of the claimant despite evidence based medical contraindications for long-term dosage and frequency. CMS may also fail to recognize recommended treatment weaning programs.

Consequently, the MSA submission must be explicit in its reliance on a state statute, with a copy of the statute included with the submission. Also, pricing information (including generic pricing) must be provided to CMS in order to avoid CMS pricing prescriptions using the AWP. The submission should also very clearly spell out the IMR decision and include a copy of the IMR with the MSA submission. If CMS refuses to recognize this, or other evidence based medicine supporting an allocation, a reconsideration request may be appropriate.

The WCRC relies on evidence-based guidelines for prescription medication and medical treatment allocations; however, these are guidelines, not rules. The final determination is also based on the claimant's past use and future recommended treatment as supported by the medical records and by current peer-reviewed medical literature.