May 1, 2017

The California Applicants' Attorneys Association ("CAAA") appreciates the opportunity to provide written comments on the proposed MTUS Drug Formulary currently posted on the DWC website for a 45 day comment period ending May 1.

CAAA strongly supports the provision of the highest quality and most effective medical treatment for injured workers. We recognize that considerable work went into the drafting of these regulations by DWC staff and we commend them for their work and tremendous efforts. However, we continue to have concerns about whether this proposed Formulary meets the objectives of AB1124 to adopt a formulary which is based on nationally recognized evidence based guidelines. Specifically, the Preferred Drug List in the proposed formulary is restricted to only low cost, non-opioid prescriptions. While public policy may dictate the benefit of reducing drug costs for carriers and opioid dependency for injured workers, the Preferred Drug List does not meet any evidence based medicine standard. It is neither linked to evidence based treatment guidelines nor any scientific literature or studies recommending these preferred drugs over others as an efficacious means of treatment for a particular medical condition or injury.

While there does not seem to be any advantage to designating a very limited number of consumer-type drugs as "Preferred," there does seem to be a clear disadvantage in designating a large number of drugs as "Non- Preferred." Undoubtedly many employers would prefer not to provide the drugs on the "Non-Preferred" list, but if a drug is medically appropriate under the MTUS, what basis is there for designating that drug as "Non-Preferred?" Unfortunately assigning the "non-preferred" label to so many drugs appears to be based solely on financial considerations and will undoubtedly result in a stigmatization of those drugs by many carriers in their utilization review practices.

Our specific comments follow.

Section 9792.27.3. MTUS Drug Formulary Transition.

Labor Code section 5307.27 requires the formulary to include a phased implementation for workers injured prior to July 1, 2017.

Regulation 9792.27.3 was changed from the first draft posted on the DWC Forum to the current draft and it now contains no timeframe for a worker to be allowed to transition from a non- formulary drug to a formulary drug .

When implementing its' formulary, Texas set a two-year deadline for transitioning patients into their formulary . On one hand this gives physicians a clear timeline for weaning patients who have been on a non -formulary drug for an extended period, but it also protects workers from being abruptly cut off their medications.

While the removal of a deadline is viewed by the DWC as allowing doctors flexibility in shaping a treatment plan, it also provides little protection to workers who may need time to transition to a new drug. The language "The claims administrator shall not unilaterally terminate or deny previously

approved drug treatment" provides little to no protections to the worker because the claims administrator can send the request for a renewal of a previously authorized prescription drug to utilization review where it may be promptly denied if a non-formulary drug!

As the statute mandates a phased implementation for workers injured prior to July 1, 2017, it is recommended that a two year timeline be added to Section 9792.27.3 for "legacy" workers to be covered by the formulary.

Additionally the lack of a transition timeframe presents a risk for workers as ACOEM does not appear to have a multidisciplinary approach to weaning that is evidence-based similar to that provided for in the ODG guidelines which were incorporated into the Chronic Pain and Opioid Guidelines approved last year.

Therefore it is further recommended that until such time as ACOEM updates their Opioid Guidelines that the administrative director adopts regulations for weaning which are evidence-based which may include the weaning protocols followed by ODG and implemented last year.

Additional treatment guidelines for tapering opioids which may be used include:

CDC Guideline for Tapering Opioids for Chronic Pain

https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

Washington State Opioid Taper Plan Calculator
www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

Tapering Long-Term Opioid Therapy in Chronic Noncancer Pain
www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext

Section 9792.27.10. MTUS Drug List; Preferred Drugs, Non-Preferred Drugs, Unlisted Drugs, Prospective Review.

Unfortunately, as currently drafted the formulary will have minimal impact on reducing frictional costs of utilization review and Independent Medical Review because there is such a small number of preferred drugs on the list which are not subject to prospective review.

The CWCI reports that 78% of prescription drug payments in California will continue to require preauthorization under the proposed MTUS Formulary. In other words three of every four medications prescribed will still be subject to pre-authorization. With such a highly restrictive formulary, there will be no positive impact on or reduction of UR and IMR costs in the system. As a result, delays will continue for injured workers in accessing appropriate medications while recovering from their work injuries. While a formulary might be expected to decrease the amount of utilization review for drug

prescriptions, as providers are steered toward preferred drugs that don't require preauthorization, the amount of payer scrutiny of non-preferred drugs or medications not listed in the formulary will most likely increase when a formulary is adopted.

It is possible the adoption of the formulary, and specifically the "first fill" exception, could result in a quicker delivery of those prescriptions on the preferred list. However, if the purpose of the formulary proposal is to designate a limited number of drugs as "Preferred" this will have little to no impact on how fast injured workers receive prescribed medications. Looking at the top 20 drugs that will be in the Preferred category, the list includes a number of drugs, such as Advil, Tylenol, Prilosec, Zantac, Nexium, Prevacid, and Pepcid, that are readily available over-the-counter.

Designating these drugs as "Preferred" will speed up delivery only if requests for these drugs are currently being sent to formal Utilization Review. An earlier CWCI study found that approximately 85% of medical treatment is approved and paid without a Request for Authorization (RFA) being filed. If that is anywhere near correct, then it is likely that requests for Tylenol and Pepcid are not currently going to formal UR (or at least they shouldn't be). Consequently, designating these drugs as Preferred and exempting them from formal UR will not change anything.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

Perioperative medication management can be complicated in high risk patients. A 4 day fill following surgery is not going to be adequate for many patients in controlling pain and can ensure a trip to the emergency room if the 4th day falls on a weekend. Therefore, to avoid these risks it is recommended the length of a perioperative drug fill be 7 days. Most patients will have the ability to follow up with their doctor following surgery in a 7 day time period, which would include monitoring of the medications that have been prescribed and management of perioperative pain levels.

Conclusion: ACOEM Says Doctors Should Be Paid for Dealing With Utilization Review

As a growing number of states adopt workers' compensation drug formularies, ACOEM released a position paper on formularies in August 2016 that includes a recommendation to pay physicians for time they spend dealing with utilization review.

"Policies for the implementation of a formulary should aim to pay providers for the extra time required for documenting medical necessity, following step-care procedures, and communicating with (pharmacy benefit managers) and UR agents," according to the position paper, authored by a six-member task force.

For example, in Arizona billing codes have been approved for reimbursing doctors $75 to $100 for the time spent on discussing medical necessity issues with utilization reviewers.

ACOEM further noted in this paper that while a formulary gives greater clarification on a drug-by-drug basis resulting in fewer disputes, it can also delay the filling of prescriptions, to the detriment of the injured worker. The delay might arise because the formulary is "silent" as to whether a particular drug is recommended or not.

CAAA urges the DWC to heed ACOEM's recommendations when finalizing the regulatory process for the implementation of the MTUS drug formulary.