September 22, 2017

The California Applicants' Attorneys Association ("CAAA") appreciates the opportunity to provide written comments on the proposed revisions to the MTUS Drug Formulary currently posted on the DWC website for a second 15 day comment period ending September 22.

Our specific comments pertain to **Section 9792.27.3** which relates to the MTUS drug formulary transition and the proposed revision in (b)(2)(A) deleting the word" **safe**" and adding the words "**medically appropriate**". In the context of the required progress report to address the injured worker's ongoing drug treatment plan, the report must now set forth a "**medically appropriate**" weaning, tapering or transitioning of the worker to a drug on the MTUS drug list(if the doctor can't otherwise provide supporting documentation to substantiate the medical necessity of the continuation of the non-exempt or unlisted drug) . This section applies if an injured worker, with a date of injury prior to January 1, 2018, is receiving a course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug.

First, and foremost, as we have stated in previous comments, the proposed formulary must comply with the authorizing statutes, including Labor Code 5307.27(a) which states in relevant part:

"The administrative director, in consultation with the Commission on Health and Safety and Workers Compensation, shall adopt, after public hearings, a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care recommended by the commission pursuant to Section 77.5....."

The proposed revision to **Section 9792.27.3** does not appear to honor this legislative mandate and additionally it omits a basic premise. A previously prescribed drug, whether or not it is on the new MTUS Drug Formulary List, is by definition "**medically appropriate**" as it was previously recommended by the treating physician and authorized by the carrier! Truly the only question to be addressed in this section on the MTUS Drug Formulary Transition is how to **safely** wean and taper the worker off a previously prescribed and approved drug if a

transition to a listed formulary drug is considered appropriate by the treating physician. Removing the word "**safe**" seems to suggest that an unsafe but somehow "medically appropriate" weaning protocol would be contemplated by this revision to the regulation! "**Safe**" is defined as "protected from or not exposed to danger or risk; not likely to be harmed or lost; uninjured." Clearly, there is no sound rationale or public policy argument for removing the word "**safe**" from **Section 9792.27.3.** For these reasons**,** we urge that the word "safe" remain in **9792.27.3** (b)(2)(A)**.**

Also, in implementing the new formulary for dates of injury prior to January 1, 2018, we must make certain that the treating physician's duty of care to his or her patient is made a priority. This duty or standard of care is defined as "…using the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful medical practitioners in the same specialty would use in the same or similar circumstances. "It should be noted that both UR and IMR reviewers routinely attempt to disclaim all liability for weaning and abrupt cessation of medications. As the new formulary is being applied retroactively to patients with chronic pain on an existing treatment plan with opioid medications, caution must be exercised in how these patients are weaned or transitioned off these medications. We must also assure that all involved medical practitioners remain accountable to the patient, and the patient's safety.

While the recently revised ACOEM guidelines for Opioids (effective April 20,2017) set forth recommendations for discontinuation and tapering of opioids (pp. 32-36), we strongly believe that the nationally recognized CDC Guidelines for Tapering Opioids for Chronic Pain will better serve medical practitioners in meeting this duty or standard of care, as set forth below:

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

HOW TO TAPER

- Tapering plans should be individualized and should minimize symptoms of opioid withdrawal while maximizing pain treatment with non-pharmacologic therapies and non-opioid medications.

- Go Slow.

- A decrease of 10% of the original dose per week is a reasonable starting point.

- Some patients who have taken opioids for a long time might find even slower tapers (e.g., 10% per month) easier.

- Discuss the increased risk for overdose if patients quickly return to a previously prescribed higher dose.

- Coordinate with specialists and treatment experts as needed—especially for patients at high risk of harm such as pregnant women or patients with an opioid use disorder.

- Make sure patients receive appropriate psychosocial support.

- If needed, work with mental health providers, arrange for treatment of opioid use disorder, and offer naloxone for overdose prevention.

- Watch for signs of anxiety, depression, and opioid use disorder during the taper and offer support or referral as needed.

- Let patients know that most people have improved function without worse pain after tapering opioids.

- Adjust the rate and duration of the taper according to the patient's response.

- Don't reverse the taper; however, the rate may be slowed or paused while monitoring and managing withdrawal symptoms.

- Once the smallest available dose is reached, the interval between doses can be extended and opioids may be stopped when taken less than once a day.

We are quite concerned that the ACOEM Guidelines for Opioids suggestion that tapering may occur as swiftly as a 20 to 50% reduction in dosage per day may cause significant harm to many workers , and while they recognize a taper of 10 % per week(as recommended by the CDC) they emphasize faster tapering as the preferred option. This may work for some, but not for most chronic pain patients. Safe weaning and tapering needs to be built into the regulations for all the reasons stated above. If the slower taper of 10 % per week recommended by the CDC is followed, the worker will still be transitioned to a MTUS formulary drug in a very short time, i.e. 10 weeks. Therefore, we urge that the CDC Guidelines for Tapering Opioids for Chronic Pain as set forth above be referenced in **Section 9792.27.3 (b) (2)(A)** to best serve medical practitioners in meeting the standard of care in safely treating their patients. Here is proposed language (new language double underlined):

(2) If the injured worker with a date of injury prior to January 1, 2018 is receiving a course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug, the physician shall submit a progress report issued pursuant to section 9785 and a Request for Authorization that shall address the injured worker's ongoing drug treatment plan. The report shall either:

(A) Include a treatment plan setting forth a safe medically appropriate weaning, tapering, or transitioning of the worker to a drug pursuant to the MTUS in the timeframe recommended by the CDC Guidelines for Tapering Opioids for Chronic Pain https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf , or

(B) Provide supporting documentation, as appropriate, to substantiate the medical necessity of, and to obtain authorization for, the Non-Exempt drug, unlisted drug, or

compounded drug, pursuant to the MTUS (via guidelines, Medical Evidence Search Sequence, and/or Methodology for Evaluating Medical Evidence.)

Lastly, CAAA had recommended in our written comments for the 1st 15 day comment period that the language from LC 4616.2 (d) (3) (B) regarding continuity of care for serious and chronic conditions serve as an established model for a safe transition period to formulary drugs. We continue to recommend this statutory language be modified to replace proposed Section 9792.27.3 (b) (4) as follows: "Previously approved drug treatment shall not be terminated or denied for a period of time necessary to complete a course of treatment and to arrange for a safe tapering and weaning plan as recommended by the treating physician. Drug treatment approved before implementation of the MTUS drug formulary may not be terminated based on the MTUS or in accordance with applicable utilization review and independent medical review regulations until a safe tapering and weaning treatment plan has been in effect for 12 months."

CAAA strongly supports the provision of the highest quality and most effective medical treatment for injured workers. We believe these recommended changes are essential for the safety and protection of injured workers lives.

CAAA commends the DWC staff for the considerable work and effort which went into the drafting of these regulations. We thank you for considering these comments.