March 10, 2017

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The California Applicants' Attorneys Association ("CAAA") offers the following comments regarding the proposed amendments to the Medical Treatment Utilization Schedule (MTUS) regulations that are currently posted on the DWC Forum for comment.

The key principle underlying these regulations is that clinical decisions are to be based on Evidence Based Medicine (EBM).

CAAA strongly supports the provision of the highest quality and most effective medical treatment for injured workers. However, the practice of medicine is an art, and determining the proper treatment for every patient and condition is not simply a matter of finding the treatment option supported by the highest level of medical evidence.

Reg §9792.20 (d) defines Evidence-Based Medicine (EBM) as "a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values".

This definition allows the integration of three things, best available research evidence, clinical expertise and patient values. It recognizes that determining the proper treatment for every patient and condition is not simply a matter of applying a generic approach to selecting the treatment option supported by the highest level of medical evidence. An individualized approach should still be sought to obtain the most effective and accurate treatment plan for each individual patient. A healthy twenty five year old worker with a back injury and no history of other medical problems is not going to need the same treatment as a sixty two year old worker with a back injury, and a history of diabetes, obesity, and smoking .

The primary focus of our comments will be with regard to proposed changes to § 9792.21 (e) keeping this definition of Evidence Based Medicine in mind.

Initially, the proposed modification to Reg § 9792.21 (e) which would eliminate language declaring that "treatment shall not be denied on the sole basis that the condition or injury is not addressed in the MTUS" is potentially problematic in light of the three principles noted

above. It is inconceivable that the MTUS will cover all treatment requests to be reviewed in the workers' compensation system. In fact we don't even know at this point if the MTUS will be adopting the ACOEM guidelines in their entirety or only selective provisions as the expedited process to update the evidence-based guidelines by Administrative Director order (now allowed per SB 1160) won't begin until after formal rulemaking. It is conceivable that the MTUS won't address many common medical conditions but nevertheless medical treatment will be needed by that worker who has that condition.

To honor the definition of Evidence Based Medicine and one of the few protections in these regulations for injured workers, CAAA recommends that the language "treatment shall not be denied on the sole basis that the condition or injury is not addressed in the MTUS" not be eliminated from Reg § 9792.21 (e). We believe that the elimination of this language would be inconsistent with the requirements of Labor Code 4600 and the mandates of the California Constitution. Additionally we are concerned that this recommended change to the MTUS guidelines may tempt overzealous UR reviewers to deny all treatment that is not included in the guidelines.

CAAA urges that "the integration of the best available research evidence **with** clinical expertise and patient values" must be the foundation of the MTUS regulations to insure that injured workers have access to the highest quality and most effective medical treatment for their injury. We believe allowing reviewers to ignore two of the three prongs of the definition of EBM , clinical expertise and patient values, and deny treatment on the sole basis that the condition or injury is not addressed in the MTUS is not the direction that the DWC should be heading if they want to ensure that the most effective medical treatment is being delivered to injured workers. Preserving this language will benefit both injured workers and employers by reducing delays and frictional costs in the delivery of medical care and getting employees back to work as quickly as possible after their injury.

Next, the proposed new language in § 9792.21(e)(2) which sets forth how the MTUS' presumption of correctness may be challenged using the Medical Evidence Search Sequence raises similar questions that CAAA tried to address in our prior comments on the MTUS regulations in 2014 and 2015. For example, why must the guideline or study to rebut the MTUS be of higher quality and strength of evidence? If of the same quality shouldn't it be resolved in favor of the worker? Should there be a different method for rebuttal of the MTUS if the treatment guideline itself is inconsistent with a patient's values or not recommended based on a clinician's individual expertise?

CAAA had previously objected to the mandatory hierarchy in the Medical Evidence Search Sequence as the treating physician is not conducting utilization review, and therefore the hierarchy established under Labor Code §4610.5(c)(2) does not apply to when the treating physician makes a treatment recommendation rebutting the MTUS.

Also based on the statutory language in Labor Code §4604.5(a) the treating physician is only required to rebut the MTUS based on "a preponderance of the scientific medical evidence establishing that a variance from the guidelines reasonably is required to cure or relieve the injured worker from the effects of his or her injury." We believe the proposed language in § 9792.21(e)(2) conflicts with Labor Code section 4604.5(a) because it establishes a different standard for rebuttal than is authorized by statute.

Therefore CAAA strongly objects to the addition of language in § 9792.21(e)(2) which states <u>"To rebut the MTUS' presumption of correctness, apply the Medical Evidence Search Sequence and provide a citation to a medical treatment guideline or peer-reviewed study which contains recommendations supported by a higher quality and strength of evidence than the recommendations in the MTUS Treatment Guidelines"</u> .

Another problem with this subdivision is that it assumes that there are scientific, evidence-based studies supporting every possible medical treatment recommendation. In fact, although there appears to be a broad range of evidence available to a physician, the actual number of medical procedures for which high level medical evidence is available is limited. This is demonstrated by reviewing the 2011 version of the ACOEM Guidelines.

ACOEM cites the level of evidence supporting its recommendations using four alphabet grades:
A represents a "Strong evidence base"
B represents a "Moderate evidence base"
C represents a "Limited evidence base"
I represents "Insufficient" or" Irreconcilable" evidence.

Table 1 in the ACOEM chapter on Shoulder Disorders includes recommendations for diagnostic testing , covering 10 diagnostic categories with 30 separate treatment recommendations. Of the 30 recommendations, one is based on strong evidence/ Category A while the remaining 29 are based on insufficient evidence/Category I.

Table 2 summarizes recommendations for treatment, separated into three categories: (1) Recommended; (2) No Recommendation; and (3) Not Recommended. There are 99 treatment options in Table 2 for which there is "No Recommendation" because there is insufficient

evidence/Category I, and 65 treatment options that are "Not Recommended" of which 54 – 7 out of every 8 – are based on insufficient evidence/Category I!

This is not an isolated example and can be found in other chapters of the ACOEM guidelines. Few chapters in ACOEM have a higher level of evidence supporting the "Not Recommended" treatment options, but in most Chapters the majority of "Not Recommended" treatment options are based on insufficient evidence/Category I. Furthermore, the same is true of "Recommended" treatment options – the majority are based on insufficient evidence/ Category I.

Given the fact that most treatment recommendations in ACOEM are based on insufficient or irreconcilable evidence, a comprehensive medical literature search will not locate a "higher" level of medical evidence unless a new study is published. In essence, the proposed rules require the treating physician to cite evidence that ACOEM has already determined is not available. The end result is that these rules could significantly hamper the ability of the treating physician to rebut the MTUS, which is specifically authorized by Labor Code § 4604.5(a).

Further Labor Code §4610.6(e) requires that if medical professionals reviewing the case for Independent Medical Review are evenly split on whether the disputed medical treatment should be provided, the decision shall be in favor of providing the services. The same should be applied when rebutting the MTUS. If treatment guidelines or studies are of equal quality then they should carry equal weight when rebutting an MTUS treatment guideline .

To achieve this, we recommend that proposed §9792.21(e) (2) be amended to read:
"To rebut the MTUS' presumption of correctness, medical evidence must be cited that contains a recommendation applicable to the specific medical condition or diagnostic test requested by the injured worker. The recommendation must be the same level **or** a higher quality of evidence as the medical evidence used to support the MTUS's recommendation and the requesting physician must document the clinical justification for the treatment for this patient."

We believe that amending §9792.21(e) (2) with this suggested language will provide needed clarity in the MTUS on how the presumption of correctness may be rebutted.

In closing, we continue to be concerned that these proposed regulations do not adequately account for the need to recognize that EBM is not simply a process of looking up the "best

available medical evidence” and blindly following that guideline or study.
The goal of all stakeholders should be to get the most appropriate treatment to the worker as quickly as possible. However, we believe this goal will be reached only if the regulations establish a process that truly "allows the integration of the best available research evidence with clinical expertise and patient values.”

Even ACOEM states in its treatment guidelines that "decisions to adopt particular courses of actions must be made by trained practitioners on the basis of the available resources and the particular circumstances presented by the individual patient." The clinical expertise of a physician is an indispensable component of appropriate medical outcomes. A “strict” application of the MTUS guidelines harkens back to previous attempts to mandate a “strict” application of the AMA Guides to evaluate work impairment. This was rejected by the courts and the wisdom of those decisions is no less true here.