December 9, 2014

The California Applicants' Attorneys Association offers the following comments regarding the proposed Medical Treatment Utilization Schedule (MTUS) regulations that are currently posted on the DWC website for a second 15 day comment period.

The primary focus of our comments is with regard to proposed new section 9792.21.1 on the Medical Evidence Search Sequence and proposed amendments to section 9792.25.1 on the MTUS Methodology for Evaluating Medical Evidence.

However, as stated in our earlier comments, as the key principle underlying these guidelines is that clinical decisions are to be based on Evidence Based Medicine (EBM), we must continue to emphasize our strong support of the proposed definition of EBM contained in §9792.20(d): "'Evidence-Based Medicine (EBM)' means 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 cookie cutter approach to finding the treatment option supported by the highest level of medical evidence. An individualized approach is still 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 diabetes, obesity, and a smoking history.

In medicine, comorbidity, described as the effect all other diseases may have on an individual patient other than the primary medical condition, is a necessary evaluation tool. Comorbidity affects prognosis and the delivery of medical care. The presence of comorbid disorders increases disability, hinders rehabilitation, increases the number of complications after surgical procedures and enhances the chances of decline in aged people. It is well established in medicine that the presence of comorbidity must be taken into account when selecting a diagnosis and treatment plan for any given injury, disease, or medical condition.

Unfortunately, in reviewing the proposed modifications to the current draft of the MTUS regulations, we believe that "clinical expertise and patient values" are for the most part ignored in the Medical Evidence Search Sequence and MTUS Methodology for Evaluating Medical Evidence sections. Further, the application of the MTUS guidelines is set forth in a vacuum and fails to be integrated with the basic foundations of the practice of medicine, including how diagnoses and medical treatment plans are regularly formulated for patients based on individual factors. We believe that EBM can co-exist with these principles. We also believe that treatment

guidelines should be applied in the same manner to work injuries, as they are to medical conditions in Group Health, and Medicare, as an example.

By analogy, physicians have experience applying "guidelines" integrating their clinical judgment in another context for work injuries which can be applied here . When evaluating permanent disability under the AMA guidelines, Labor Code section 4660 permits reliance on the entire AMA Guides to the Evaluation of Permanent Impairment, including the instructions on the use of clinical judgment, in deriving an impairment rating in a particular case. In the *Guzman III* case, the DCA said on pages 14 -15, "...the *Guides* must be applied "as intended" and "as written," but we take a broader view of both its text and the statutory mandate. Section 4660,subdivision (b)(1), recognizes the variety and unpredictability of medical situations by requiring *incorporation* of the descriptions, measurements, and corresponding percentages in the *Guides* for each impairment, **not their mechanical application without regard to how accurately and completely they reflect the actual impairment sustained by the patient...** " (Emphasis added)

In *Guzman III,* the DCA concluded that the AMA *Guides* is an integrated document and its statements in Chapters 1 and 2 regarding physicians using their clinical judgment, training. experience and skill cannot be divorced from the balance of the Guides. The Court said at page 20 of the decision, "The failure to follow all of the instructions in the first two chapters could result in useless evidence, inadequate diagnostic reasoning, and inaccurate and inconsistent ratings. "

We suggest that to ignore two of the three prongs of the definition of EBM , clinical expertise and patient values, will have the same result here, i.e. evidence based decisions that are useless, diagnostic reasoning that is inadequate , and treatment decisions that are inaccurate and inconsistent. As in *Guzman III,* treating physicians should be allowed to utilize independent analysis to promote consistency in treatment decisions.

CAAA urges that "the integration of the best available research evidence with clinical expertise and patient values" must be the foundation for any further proposed modifications to the MTUS regulations to insure that injured workers have access to the highest quality and most effective medical treatment for their injury. Like impairment rating guidelines, treatment guidelines should also be applied to achieve treatment accuracy and to promote consistency in treatment decisions.

Section by Section comments follow.

**§9792.21.1. Medical Evidence Sequence Search**

Subdivision (a).

This subdivision establishes a mandatory medical evidence search sequence (a hierarchy) to be used by the treating, Utilization Review (UR), and Independent Medical Review (IMR) physicians. However, there is no authority in statute for establishing a mandatory hierarchy that is applicable to the treating physician. Thus, this subdivision must be significantly amended.

Labor Code §4610.5(c)(2) defines "medically necessary" and "medical necessity" based on a defined ranking of standards, starting with the MTUS. However, as set forth in Labor Code §4610.5(c) that definition applies only "for the purposes of this section and Section 4610.6." Labor Code §§ 4610.5 and 4610.6 set forth the rules and procedures to be followed in making UR determinations of disputed medical treatment requests. Consequently, the definition of "medically necessary" and "medical necessity," and the hierarchy of standards established under §4610.5(c)(2), apply only to the UR process.

The treating physician is not conducting UR, and therefore the hierarchy established under Labor Code §4610.5(c)(2) is not applicable when the treating physician makes a treatment recommendation rebutting the MTUS. Instead, based on the statutory language in Labor Code §4604.5 the treating physician can 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."

In order to bring subdivision (a) into compliance with these governing statutes, all references to the "treating physician" must be deleted. The statutory rule governing rebuttal of the MTUS by the treating physician as set forth under Labor Code §4604.5 is already incorporated in these draft regulations (§9792.21(c)(2)) and therefore, any reference to the treating physician in subdivision (a) is both inappropriate and would only lead to unnecessary disputes and higher costs.

In addition, the provisions applicable to UR and IMR physicians in subdivision (a) must be amended. As noted, Labor Code §4610.5(c)(2) does include a hierarchy of standards to be applied in determining medical necessity in the UR process. However, the search sequence established in subdivision (a) goes far beyond that statutory hierarchy.

Paragraph (a)(2) requires that "where a medical condition or injury is not addressed by the MTUS or if the MTUS' presumption of correctness is being challenged" the UR or IMR physician must first review "the most current version of ACOEM or ODG." The governing statute, Labor Code §4610.5(c)(2), however, provides only that where the MTUS is inapplicable the reviewer shall rely upon "peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service." Limiting the reviewing physician to two specific guidelines does not conform to this statute because it impermissibly restricts the ability of the reviewing physician to utilize any other "peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed treatment."

Consequently, we recommend that the provisions in subdivision (a) applicable to UR and IMR physicians be amended to conform to the hierarchy as set forth in Labor Code §4610.5(c)(2).

Alternatively, as we have previously recommended, this section could be brought into compliance with the governing statute by changing the search sequence for UR and IMR physicians to a recommended sequence, rather than a mandated sequence.

Subdivision (b).

First, to conform to the above changes, the introductory sentence must be amended to delete the requirement that the treating physician must follow a specific hierarchy of standards.

In addition, this subdivision sets forth very detailed requirements for the treating, UR, and IMR physicians as to what must be cited to support the recommendation for the treatment, or rationale for modifying, delaying, or denying the treatment.

We support the proposed amendments that require UR and IMR physicians to clearly document the level of evidence being applied to deny the treatment or diagnostic services being requested . Adding this requirement will allow all parties to easily determine the "highest level of evidence" applied to the treatment request, which will eliminate potential disputes. The result will be to speed up the final determination where there are competing recommendations between the treating physician and UR and IMR Physicians.

However, we are concerned that placing further mandates on treating physicians to provide specific documentation with their RFAs places an additional burden that may have serious impacts on the system. Under the current fee schedule treating physicians are not paid for doing this work. Further, physicians don't have to provide this level of documentation when requesting medical treatment for their patients under Medicare, Kaiser, or Blue Cross Health Plans. Placing added burdens on treating physicians, without providing reasonable reimbursement, will place a burden on MPN doctors in an already strained MPN process and may drive doctors out of the Workers' Compensation System. CAAA members report that a number of physicians have already stopped accepting new workers' compensation patients. We urge the Division to consider, at the earliest possible time, recommended amendments to the physician fee schedule to provide a reasonable payment for preparation of the RFA and supporting documentation. Although we recognize that this would cause a slight increase in paid fees, we believe the net impact would be a savings for the system as it will facilitate compliance with the requirements of this new section. With an increase in properly supported RFAs it would reduce the number of treatment requests that go through the dispute resolution process. We believe that one explanation for the high rate of UR denials and IMR appeals in the system is in part due to the extra burdens placed upon physicians with the use of the MTUS guidelines, and the requirement to support their RFAs with additional documentation. Therefore, we urge that our request for reconsideration of the physician fee schedule be considered .

Subdivision (c).

Labor Code §4610.6(e) requires that if the medical professionals reviewing the case are evenly split on whether the disputed medical treatment should be provided, the decision shall be in favor of providing the services. In order to implement this statutory provision, we recommend that §9792.21.1 (c) be amended to add the following language:

If the medical professionals reviewing the case are evenly split on whether the disputed medical treatment should be provided, the decision shall be in favor of providing the services.

Subdivision (e).

We support the addition of this subdivision which reminds employers that they may approve "medical treatment beyond what is covered in the MTUS or supported by the best available medical evidence in order to account for unique medical circumstances warranting an exception."

However, we recommend that the second sentence of this subdivision, which reads: "The treating physician should provide clear documentation of the clinical rationale focusing on expected objective functional gains afforded by the requested treatment and impact upon prognosis," be deleted. This sentence does not conform to the "cure or relieve" standard of care which is to be used to determine what is reasonable and medically necessary treatment. As we have noted in previous comments regarding the adopted treatment guidelines, the MTUS focuses too much on "cure," but says little about medical treatment that will "relieve" the injured worker of the effects of the injury.

Labor Code Section 4600(b) states:

"As used in this division and notwithstanding any other provision of law, medical treatment that is reasonably required **to cure or relieve** the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27." (Emphasis added)

Labor Code Section 4604.5(a) states:

"The recommended guidelines set forth in the medical treatment utilization schedule adopted by the administrative director pursuant to Section 5307.27 shall be presumptively correct on the issue of extent and scope of medical treatment. The presumption is rebuttable and may be controverted by 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. The presumption created is one affecting the burden of proof." [Emphasis added.]

It is clear upon a review of these statutes that the standard of care for California's injured workers remains a two pronged test as to what is reasonable and medically necessary. That is an injured worker has the right to medical care that either will cure **OR** relieve the effects of the injury.

The MTUS is replete with the phrase "functional improvement," as a prerequisite to approving the treatment request, which is analogous to treatment that leads to a cure of the injury or illness. This is an incorrect standard of review for determining if a treatment request is reasonable and medically necessary based on the statutes cited above.

The Workers' Compensation Appeals Board has overturned the application of this incorrect standard (see Loynachan v. Co. of Los Angeles, Case No. ADJ7144283). Forcing workers through the dispute process by ignoring the statutory standard, and requiring "functional improvement" is wasteful and harmful to both employers and workers. Consequently, we strongly urge the Division to not only amend this subdivision to conform to the proper "cure or

relieve" standard, but to also revise other sections of the MTUS to incorporate this statutory standard.

**§ 9792.25.1 MTUS Methodology for Evaluating Medical Evidence**

The modifications to section 9792.25.1 provide a methodology for reviewers to evaluate studies including the "quality" of studies. While determining if the study supports the treatment recommendation is appropriate, this section also allows the UR and IMR reviewer to conduct an evaluation of whether there was "bias" in the study including factors such as financial interests, academic interests, and industry influence.

We believe this section introduces a subjective analysis to an otherwise objective evidence based system. It gives authority to the UR and IMR reviewer to weigh evidence way beyond the statutory authority given them to determine only issues of medical necessity applying the MTUS guidelines. Further, if the UR or IMR reviewer is incorrect in determining there is bias in a study, there is no remedy for the injured worker in the current regulatory and statutory scheme. Therefore, we recommend that section 9792.25.1, subdivision (3), and subparagraph (A), be deleted in its' entirety, as it exceeds statutory authority, and is not within the purview of the regulatory process. We further recommend that subdivision (4) be renumbered to (3), and that it be amended as follows:

**( 3 ~~4~~) If the guidelines or studies cited contain recommendations supported by studies applicable to the worker and his or her medical condition or injury ~~and if the recommendations are supported by studies that are determined to be of good quality due to the absence of bias,~~ then the reviewing physician shall determine the strength of evidence used to support the differing recommendations by applying the Hierarchy of Evidence for Different Clinical Questions set forth in 9792.25.1(b). If the studies are of equal strength after applying the questions in 9792.25.1(b) , the decision shall be in favor of providing the services. To apply the Hierarchy of Evidence for Different Clinical Questions, the following steps shall be taken:**

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. EBM requires that the best available evidence be integrated with the clinical expertise of the treating physician and with patient and community values. As we have previously noted, The Center for Evidence Based Medicine states on its' website that "even excellent external evidence may be inapplicable to or inappropriate for an individual patient." The goal of all parties 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." .