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On behalf of Pacific Compensation Insurance Company, we appreciate the opportunity to provide the following comments on proposed regulations revising the Medical Treatment Utilization Schedule (MTUS).

With the enactment of Senate Bill 863 (De León), the MTUS takes on a significantly different role than what had existed previously before the adoption of independent medical review (IMR). There is no role for the MTUS to play in resolving *med-legal* disputes because there *are* no more med-legal disputes regarding medical treatment issues. (Labor Code § 4062) Consequently, the presumption of correctness still remaining in Labor Code § 4604.5(a) should no longer be a consideration in the application of the MTUS and all references to it in the proposed regulations should be eliminated.

As was stated in the legislative findings and declarations in SB 863:

“...the current system of resolving disputes over the medical necessity of requested treatment is costly, time consuming, and does not uniformly result in the provision of treatment that adheres to the highest standards of evidence-based medicine, adversely affecting the health and safety of workers injured in the course of employment.”

And:

“...having medical professionals ultimately determine the necessity of requested treatment furthers the social policy of this state in reference to using evidence-based medicine to provide injured workers with the highest quality of medical care and that the provision of the act establishing independent medical review are necessary to implement that policy.”

While Labor Code § 4604.5 was amended to reflect the current status of the MTUS and deleted outdated provisions transitioning from the ACOEM Guidelines to the MTUS, this section was not amended in regards to the presumption of correctness afforded the MTUS. [See: Labor Code § 4604.5(a)] That presumption, however, is an evidentiary presumption affecting the burden of proof (Evidence Code § 605) intended to be used in a judicial proceeding to resolve, in this specific instance, disputes before a WCALJ over the denial of a request for authorization by a claims administrator. In other words, Section 4604.5 was amended in Senate Bill 899 (Poochigian) to address the issue of how the Appeals Board would enforce the evidence based medicine mandate that was

added in Labor Code § 5307.27. Both Section 4604.5 and 5307.27 were enacted in prior legislation, Senate Bill 228 (Alarcon).

The Legislature has clearly expressed its intent that medical decisions are to be made by medical professionals. It would appear axiomatic that given the overall evidence based medicine mandate in the Labor Code these medical professionals should not be required to act as judges when making a determination of whether a disputed medical treatment is medically necessary.

The effect of a presumption affecting the burden of proof is to impose upon the party against whom it operates the burden of proof as to the nonexistence of the presumed fact. (Evidence Code § 606) The proceeding before an IRO, however, is to determine whether a requested treatment is medically necessary, in other words whether the request is for "...medical treatment that is reasonably required to cure or relieve the injured employee of the effects of his or her injury and based on the following standards, which shall be applied in the order listed, allowing reliance on a lower ranked standard only if every higher ranked standard is inapplicable to the employee's medical condition." [Labor Code § 4610.5(c)(2)] Interposing a presumption affecting the burden of proof into this deliberation would require the requesting physician to have to explain not only why the requested treatment is properly supported but also why the treatment in the MTUS is not as efficacious. This is a process that the Labor Code did not envision when the question of medical necessity is being reviewed through IMR rather than by the Appeals Board; where there is an opportunity for additional physical examinations and the examination and cross-examination of witnesses.

The proposed revisions to the MTUS would appear to view the changes in medical dispute resolution in SB 863 as a non-event. That is profoundly not the case. While the Legislature did not expressly amend the evidentiary language in Section 4604.5(a), the Division may nevertheless use its rulemaking authority to adopt regulations that are reasonably necessary to effectuate the purpose of statutes. (Government Code § 11342.2) The continued fixation on the presumption afforded the MTUS is, essentially, irrelevant to the process now in existence for resolving disputes over medical treatment and should be deleted in its entirety from the revised MTUS.

There is nothing in Labor Code § 4610.5 that requires or even allows an independent review organization (IRO) to apply a presumption affecting the burden of proof to its deliberations when there is a request for IMR. Indeed, Section 4610.5 gives specific guidance to the IRO on how to apply medical guidelines when reviewing a disputed medical treatment. These criteria and the order in which they are to be applied are replicated in 8 CCR § § 9792.10.1(a)(4).

There is also nothing in Labor Code § 4610.6 that authorizes an adjudication of conflicting guidelines for treatment of a condition or allows the Administrative Director to

review the quality of a particular guideline that was applied to resolve a dispute over medical treatment. Indeed, quite the opposite is the case:

“If the determination of the administrative director is reversed, the dispute shall be remanded to the administrative director to submit the dispute to independent medical review by a different independent review organization. In the event that a different independent medical review organization is not available after remand, the administrative director shall submit the dispute to the original medical review organization for review by a different reviewer in the organization. *In no event shall a workers’ compensation administrative law judge, the appeals board, or any higher court make a determination of medical necessity contrary to the determination of the independent medical review organization.*” (Emphasis added) Labor Code § 4610.6(i).

Consequently, at best proposed 8 CCR § 9792.21(d)(1) creates a conflict with Labor Code § 4610.5 because there is no opportunity for the IRO to do anything other than apply the MTUS when the disputed medical treatment [8 CCR § 9792.10.1(a)(2)] is covered by it. Far worse, in terms of unintended consequence, is if a provider challenges the MTUS through the mechanism of petitioning the Appeals Board to adjudicate the relative weight of evidence supporting the request for authorization compared to the MTUS [Labor Code § 5300(f)]. Such an action would be entirely inconsistent with both the intent and the express language of SB 863, undermine the authority of the Division to adopt an MTUS under Labor Code § 5307.27, and add yet another dimension of confusion to the utilization review process.¹

In addition, the regulations conflate the process of developing guidelines with the application of principles of evidence based medicine. While the words “medical necessity” appear in the Labor Code and a multitude of regulations from the Division, unlike group health the Legislature has decided to supply its own definition of “medical

¹ While well beyond the scope of this rule making proceeding, the Division should nevertheless acknowledge that the changes to the Labor Code in SB 863 have repealed by implication the presumption of correctness of the MTUS.

“The presumption against implied repeal is so strong that, ‘To overcome the presumption the two acts must be irreconcilable, clearly repugnant, and so inconsistent that the two cannot have concurrent operation. The courts are bound, if possible, to maintain the integrity of both statutes if the two may stand together.’” *Western Oil & Gas Assn. v. Monterey Bay Unified Air Pollution Control Dist.* (1989) 49 Cal.3d 408, 419- 20, 261 Cal.Rptr. 384; 777 P.2d 157.

In its findings, in the mandated use of the MTUS by the IRO, the limitation of the jurisdiction of the Administrative Director to overturn a decision of the IRO, and the express, clear, and unambiguous divesting of jurisdiction of the Appeals Board and the Courts to resolve issues of medical necessity contrary to the determination of the IRO, the Legislature under its plenary authority has rendered the presumption afforded the MTUS irrelevant and has impliedly repealed its application to procedures to determine medical necessity. To revive it through this regulation is beyond the Division’s authority.

necessity”. [See, e.g.: Labor Code §§ 4600(b), 4610(a), 4610(c), 4610.5(c)(2), 4610.5(c)(3), 4610.6(a), 4610.6(c)] Consequently, the focus of the MTUS should be as set forth in Labor Code § 5307.27 and address, “...at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.”

To meet the mandate of Labor Code § 5307.27 and to provide the clarity necessary to make IMR work where the med-legal process did not, the Division is charged not just with adopting guidelines, but to make sure those guidelines are “evidence-based, peer-reviewed, nationally recognized standards of care...”. In other words, the provenance of the guideline is critical to its development. But it is less critical to the IMR and UR processes tasked with making sure treatment in accordance with these guidelines is delivered to injured workers and for which the employer is liable per Section 4600 than it is to the development of these guidelines by the DWC.

Section 4604.5(b) goes further, stating that the MTUS shall, “...reflect practices that are evidence and scientifically based, nationally recognized, and peer reviewed. The guidelines shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Section 4600 for all injured workers diagnosed with industrial conditions.”

This latter requirement should not be confused with the methodology by which a guideline is developed and it meeting the criterion of highest evidence based. Instead, as the DWC has done, the “analytical framework” is provided either with the supporting document behind the guideline, as is the case with chronic pain or post-surgical treatment guidelines, or is incorporated by reference with the adoption of a guideline from ACOEM and the supporting guidance provided by that publisher. Over time, one would expect further use of already published guidelines that would incorporate by reference that publisher’s recommendations, instructions, and provenance into the MTUS.

Where treatment is not in accordance with the MTUS, Section 4610.5(c)(2) provides direction to the IRO about evaluating the efficacy of the treatment for which review is sought and, as set forth in Labor Code § 139.5(d)(3)(C), the IRO must have a quality assurance mechanism in place that: “Ensures that the method of selecting medical professionals for individual cases achieves a fair and impartial panel of medical professionals who are qualified to render recommendations regarding the clinical conditions and the medical necessity of treatments or therapies in question.”

The reviewing physician, furthermore, “...shall be a clinician knowledgeable in the treatment of the employee’s medical condition, knowledgeable about the proposed

treatment, and familiar with guidelines and protocols in the area of treatment under review.” Labor Code § 139.5(d)(4)(A).

For the URO, the mandate is direct:

“Each utilization review process shall be governed by written policies and procedures. These policies and procedures shall ensure that decisions based on the medical necessity to cure and relieve of proposed medical treatment services are consistent with the schedule for medical treatment utilization adopted pursuant to Section 5307.27. These policies and procedures, and a description of the utilization process, shall be filed with the administrative director and shall be disclosed by the employer to employees, physicians, and the public upon request.” Labor Code § 4610(c).

And the purpose of UR is defined as: “...utilization review or utilization management functions that prospectively, retrospectively, or concurrently review and approve, modify, delay, or deny, based in whole or in part on medical necessity to cure and relieve, treatment recommendations by physicians, as defined in Section 3209.3, prior to, retrospectively, or concurrent with the provision of medical treatment services pursuant to Section 4600.” Labor Code § 4610(a).

There is no shortage of guidelines for medical treatment. In order to have the IMR process meet expectations of all participants, there needs to be some acknowledgement that the requesting physician, URO, and IRO cannot be entirely bound by a cookbook approach to medical treatment and that the MTUS, within its statutory requirements, needs to foster a dialogue on the proper course of treatment for a particular individual and not be so rigid as to transform this into the same type of adversarial proceeding it was enacted to replace. (See: <http://www.guideline.gov/index.aspx>)

“Evidence based medicine is not “cookbook” medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied. Clinicians who fear top down cookbooks will find the advocates of evidence based medicine joining them at the barricades.

Some fear that evidence based medicine will be hijacked by purchasers and managers to cut the costs of health care. This would not only be a misuse of evidence based medicine but suggests a fundamental misunderstanding of its financial consequences. Doctors practicing evidence based medicine will identify and apply the most efficacious interventions to maximize the quality and quantity of life for individual patients; this may raise rather than lower the cost of their care.” (Sackett, et al, Evidence based medicine: what it is and what it isn't, BMJ 1996; 312:71)

The proposed regulations do not foster this process. And yet, this process is critical to the effective functioning of IMR. The Division would serve the community well to allow medical professionals to work with other medical professionals within the broad framework established in over a decade of changes to the workers' compensation system and not adopt a rigid regulatory structure that if relevant at all is truly only relevant to the decision making process of the Division.

The Division's resources would be far better served by continuing to develop guidelines that are based on the best and most current medical evidence, adopt these guidelines through a transparent regulatory process, and for each recommended guideline demonstrate to the community that it meets the requirements of Section 5307.27, including a thorough documentation of the provenance of each guideline.

It is not in the best interests of any stakeholder in the system to simply update a cookbook.

As part of the process of developing the MTUS, we also strongly recommend a revisiting of the Medical Evidence Evaluation Advisory Committee (MEEAC), if for no other reason that the acronym sounds like a parrot with indigestion. But beyond the name, there needs to be a more transparent and more focused role of an advisory board or committee to assist in the implementation and ongoing improvement of medical care within the workers' compensation system. One example is from the State of Washington and its Industrial Insurance Medical Advisory Committee established in RCW 51.36.140². A copy of the By-Laws of the Committee is attached [copy available upon request].

The State of Oregon has adopted a similar structure³. According to their Division of Workers' Compensation:

"ORS 656.794 established the Medical Advisory Committee in 1965. The committee members are appointed by the Director of the Department of Consumer and Business Services. The committee meets regularly with Workers Compensation Division management to provide advice to the director on matters relating to the provision of

² (See: <http://www.lni.wa.gov/ClaimsIns/Providers/ProjResearchComm/PAC/default.asp>)

³ (See: <http://www.cbs.state.or.us/external/wcd/rdrs/mac/mac.html>)

medical care to workers. Members of the committee include representatives of the types of health care providers that are most representative of those providing medical care services to injured workers. The committee also includes one insurer representative, one employer representative, one worker representative, and one managed-care organization representative. The director may appoint other persons as may be determined necessary to carry out the purpose of the committee."

It is important to note when reviewing the Oregon process that their operative statutes state:

"Notwithstanding any other provision of this chapter, the director, by rule, upon the advice of the committee created by ORS 656.794 and upon the advice of the professional licensing boards of practitioners affected by the rule, may exclude from compensability any medical treatment the director finds to be unscientific, unproven, outmoded or experimental. The decision of the director is subject to review under ORS 656.704." [ORS 656.245(3)]

Obviously such a structure could not be adopted through a regulatory process given the current state of California law, but the Medical Advisory Committee also provides a better template for dialogue on medical treatment issues than currently exists in California.

Regardless of how it is named or how it is configured, we do want to emphasize once again, as we have in other rule making proceedings with the Division, the importance of having an ongoing dialogue between the Medical Director of the DWC and the medical directors of IROs and UROs. This should not be ad hoc.

Steven Suchil, Assistant Vice President/Counsel
American Insurance Association

August 30, 2013

These comments are in response to the DWC Forum regarding the revisions to the Medical Treatment Utilization Schedule rules, Title 8 C.C.R. Section 9792.20 et seq., and are submitted on behalf of the members of the American Insurance Association (AIA).

AIA is the leading property-casualty insurance trade organization, representing approximately 300 insurers that write more than \$100 billion in premiums each year. AIA member companies offer all types of property - casualty insurance, including personal and commercial auto insurance, commercial property and liability coverage for small businesses, workers'

compensation, homeowners' insurance, medical malpractice coverage, and product liability insurance.

Introduction

We believe the proposed changes make complicated regulations even more cumbersome and will have the effect of creating more ambiguity, disputes, and delays for care to injured workers while increasing the costs of Utilization Review. Such costs could become so onerous that Utilization Review would rarely be used. As an example, these proposed regulations would allow a single study published within the last three years to outweigh any of our current ACOEM guidelines and most of the ODG guidelines.

It appears that the proposed revisions dilute the original social policy decision that led to the effort to move toward Evidence Based Medicine while, at the same time, make the process more complex, cumbersome and open to dispute, which will inevitably create delays in the decision making necessary for the timely provision of care. We are sure this was not the intent behind the proposal, but there can be no doubt that delays occur.

Lastly, we recommend a longer time period within which to review and respond to the regulations and the issues presented. The time period for the DWC Forum comments did not provide us with sufficient time to even look at anything beyond the superficial.

Set forth below are comments on specific sections.

Suggestions for added language are in italics, highlighted and shown with underline and deletions with ~~strikethrough~~.

Section 9792.20 Definitions

Subsection (e), should be amended as follows:

(e) "Evidence Based Medicine" means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.

The phrase "clinical expertise and patient or community values" dilutes the definition of Evidence Based Medicine, and would include subjective factors, leading to disagreements and delays. This phrase should be removed to maintain a reliance on true evidence based medicine, and exclude personal opinion or unproven community supposition.

We are concerned about the deletion of the subsection (f) definition of "Functional Improvement". In the MTUS functional improvement is used to determine the appropriateness

of ongoing treatment. We believe that the definition should remain in the regulations because it is intrinsic to continuing treatment requests for authorization.

Subsection (l), as proposed to be amended states:

(l) “Scientifically based” means based on scientific literature, wherein the body of literature is identified through performance of a literature search, the identified literature is evaluated, and then used as the basis for the guideline.

This definition is circular and unclear. The lack of clarity will lead to disagreements and disputes as to what is scientifically based, resulting in delays and needless costs. We recommend adoption of a more specific and definitive definition as to what is to be considered scientifically based.

Section 9792.21 Medical Treatment Utilization Schedule

We recommend amending subsection (b) as follows:

(b) The MTUS provides a framework for the most effective treatment of injured and ill workers and is based on the principles of Evidence Based Medicine (EBM). EBM is a systematic approach to making clinical decisions which allows the integration of the best available research evidence ~~with clinical expertise and patient or community values.~~

The phrase “clinical expertise and patient or community values” dilutes the definition of Evidence Based Medicine, and would include subjective factors, leading to disagreements and delays. As above, the italicized phrase should be deleted in order to maintain a purer evidence base.

Subsection (d) provides:

(d) The MTUS is inapplicable in the following two situations. First, the MTUS is inapplicable when the MTUS’ presumption of correctness is successfully rebutted. Second, the MTUS is inapplicable when the MTUS is silent and does not address a medical condition or diagnostic test.

(1) The MTUS’ presumption of correctness may be rebutted if medical evidence is cited that contains a recommendation directly applicable to the specific medical condition or diagnostic test requested by the injured worker and is supported by a higher level of evidence than the medical evidence used to support the MTUS’ recommendation.

This provision discusses the ability of the MTUS to be rebutted and appears, in a worst case scenario, to allow a rebuttal to occur with a single journal article.

The statutory requirement for rebuttal, in Labor Code Section 4604.5(a), is "...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."

We recommend that the statutory presumption and the proposed rule be harmonized.

Section 9792.25 Definitions

Subsection (a)(14) defines expert opinion:

(14) "Expert opinion" means a determination by an expert, through a process of evidenced-based thinking that a given practice should or should not be labeled evidenced based, and published in a peer-reviewed medical journal."

Under this definition, an opinion piece or letter to the editor of a peer reviewed medical journal could qualify as an expert opinion. The definition should be clarified to state that the specific piece of "expert opinion" was peer-reviewed before publishing.

Section 9792.25.1. Process to Determine When Medical Care is Reasonable and Necessary

Subsection (f) provides:

(f) In the interest of efficiency and consistency, when conducting the medical literature search of the large body of available medical evidence, the following search sequence shall be followed:

- (1) Search the most current version of ACOEM and/or ODG and choose the recommendation that is supported by the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.3; if no relevant recommendations are found or if the current version is more than three years old then,
- (2) Search the most current version of workers' compensation medical guidelines established by one or more US state governments or by the US federal government; if no relevant recommendations are found or if the current version is more than three years old then,
- (3) Search other evidenced based medical treatment guidelines that are recognized by the national medical community and are scientifically based. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/; if no relevant recommendations are found or if the current version is more than three years old then,...

The three year time limit in subsection (f)(1) effectively obviates all ACOEM guidelines and the majority of ODG guidelines currently in the MTUS, creating a scenario where any given study can be used to refute the MTUS guideline. It is unclear whether the three year time limit also applies to subsection (f)(2), and an explanation of why there is no limitation would be helpful. Lastly, with respect to subsection (f)(3), in the past there were complaints that there was insufficient rigor in some of the guidelines published National Guideline Clearinghouse.

Section 9792.25.2 Strength of Evidence - Method for Evaluating the quality of Medical Treatment Guidelines

While the AGREE II system is comprehensive, it is also complex, overly time consuming and burdensome for the volume of requests that this system receives on a daily basis. We are also very concerned about its subjective elements.

Evaluation of nearly every request using AGREE II, which will be necessary with the three year time limit on the bulk of the MTUS guidelines, will result in the system being gridlocked, delaying care, and increasing penalties and litigation. We are concerned that such a result could easily consume a very large portion of the savings intended to offset the benefit increases provided for injured workers in SB 863.

We recommend the following deletion in subsection (b)(3) as follows:

(b) (3) The guideline with the highest percentage score shall be used as the source to approve or deny a treatment or diagnostic service recommendation.

~~(A) Although the application of the AGREE II medical guideline evaluation tool leads to a percentage score, the figure may slightly vary between reviewers because individual judgments are still required. Therefore, the percentage scores calculated by any reviewer shall remain confidential and will not be disclosed in the decision.~~

It is unclear how disputes will be resolved among the parties - whether provider and payer, URO, IMRO or WCAB if the evaluation result is confidential.

Subsection (d)(2) should be amended as follows:

(d) (2) the second step in the assessment is the recommendation regarding using the guideline and will result in one of three possibilities:

- (A) Recommending the guideline for use as it is;
- ~~(B) Recommending the guideline for use with modifications; or~~
- (C) Not recommending the guideline for use.

After the very laborious assessment process we believe the result should be a simple yes or no. To include “yes with modifications” adds more complexity, subjectivity, and areas for dispute. Recommendation of a guideline with modifications has the potential for great harm. This option should also be removed from the Appendix A Form.

The following amendment should be made to subsection (h):

(h) If a guideline is recommended as a “no” it should not be used as the source to approve or deny a medical treatment recommendation. ~~However, the individual recommendations in this guideline may still be used as the source to approve or deny a medical treatment recommendation. The original studies supporting the individual recommendation must be evaluated using the process described in section 9792.25.3.~~

The piece meal approach reflected in the above adds another needless level of complexity, requiring starting all over again with AGREE II for each study that may apply, resulting in increased costs, more delays in the provision of care and more disputes.

Section 9792.25.3 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support Studies Published in the Medical and Scientific Literature

Subsection (a)(1) should be amended as follows:

(a) (1) Determine if the study is directly applicable to the specific medical condition or diagnostic test requested by the injured worker. Direct applicability refers to the extent to which the individual patients, workers, or subjects, interventions, and outcome measures are similar to the injured worker and his or her specific medical condition or diagnostic service request. A study published in the medical or scientific literature that is not directly applicable to the specific medical condition or diagnostic test requested by the injured worker if it evaluates a different population, setting, or intervention should not be used as the source to approve or deny a medical treatment recommendation ~~unless a directly applicable study is not available. If directly applicable studies are not available, the population most similar to the injured worker should be used and the reasoning documented~~

The use of studies that are not directly applicable is problematic and a rich field for dispute.

For subsection Section (a) (2)(C) we recommend a description of what an Uncontrolled or Observational study entails.

Subsection (a)(3) should be amended as follows:

(a) (3) Determine the study quality used to support the original study. Factors to consider include, ~~but are not limited to~~, the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective

outcome reporting, early stopping, and intention to treat. A study that is determined to be of poor quality due to the presence of these factors shall not be used as justification for a medical treatment decision.

DWC should provide listing of specific factors to be considered to determine study quality. A rule that states “include, but are not limited to” is unclear and will provide yet more fodder for disputes.

Mark Gerlach
California Applicants’ Attorneys Association

August 30, 2013

The California Applicants’ Attorneys Association offers the following comments regarding the Medical Treatment Utilization Schedule (MTUS) regulations currently posted on the DWC Forum.

It was our understanding that the primary purpose of these proposed changes to the MTUS was to revise the strength of evidence standards that are currently set forth in §9792.25. Although we would support changes that simplify this process, we believe the proposed changes do little to make the rebuttal process either more understandable or more accessible to treating physicians. Consequently, we do not believe these changes will result in any meaningful improvement over the current expensive and delay-prone system for determining the appropriateness of medical treatment requests.

In addition, one proposed change is clearly in contravention of the authorizing statute and must be deleted. Specifically, proposed §9792.21(d)(1) imposes a more restrictive standard for rebutting the MTUS than is authorized in statute. Labor code §4604.5(a) reads as follows:

"(a) 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 important to note that §4604.5(a) was amended in SB 863 but the highlighted language was not revised. That sentence defines the standard by which the MTUS may be rebutted. The

Administrative Director has no authority to adopt a different standard than the standard specifically set forth in statute. Accordingly, proposed §9792.21(d)(1) should be deleted. Instead, the current language in §9792.25(a) correctly implements the statutory standard and should be retained.

Section 9792.20: Definitions

1. Subdivision (f). It is not clear why the definition of "functional improvement" is deleted in this proposal. A number of treatment guidelines call for evidence of functional improvement, and the proper implementation and regulation of the MTUS requires that a clear and precise definition of this term be included in the regulations.

Therefore, we suggest that this subdivision be retained. However, we also recommend that the definition be amended to recognize that it is just as important to prevent a decline in functional abilities as it is to promote an improvement. The current definition can be interpreted to require a continued reduction in the worker's functional limitations. This ignores the reality of many medical conditions. In some cases continued treatment may not result in a further reduction in limitations, but such treatment may be necessary for a worker to maintain his or her ability to continue working and perform everyday tasks. We recommend that this definition be amended to recognize this situation and provide that functional improvement also includes the prevention of a decline in functional abilities.

2. Subdivision (j). This new subdivision adds a definition of the Official Disability Guidelines published by the Work Loss Data Institute. Although we have no objection to adding this definition we do not believe it is necessary, as explained in the discussion regarding proposed §9792.25.1. At this point, however, we would like to call the Division's attention to the 2006 RAND study prepared for the Commission on Health and Safety and Workers' Compensation (CHSWC) entitled "*Evaluating Medical Treatment Guideline Sets for Injured Workers in California.*" [See http://www.dir.ca.gov/CHSWC/Reports/Evaluating_med_tx_guideline.pdf]

The RAND study surveyed and evaluated medical treatment guidelines for injured workers in California pursuant to the mandate in Labor Code §77.5. The study included a comparative evaluation of five sets of guidelines, including the ACOEM Practice Guidelines and the ODG Guidelines. The study used the AGREE instrument to evaluate the technical quality of these guidelines. Although all five of the guidelines did "reasonably well in the technical quality evaluation," a subsequent evaluation by a multidisciplinary clinical panel of 11 national experts concluded that none of the evaluated guidelines "meet or exceed standards; they barely meet standards" and that "California could do a lot better by starting from scratch." The conclusion of RAND was that "All five guideline sets appear far less than ideal – in the words of the panelists, they barely meet standards." The study also notes that a survey of system participants found that "A commonly held viewpoint among the participants was that the longer-term goal should be to take the best guideline available for each topic area and patch these guidelines together into a single cohesive set...."

Section 9792.21

1. Subdivision (b). In order to help the parties understand their rights and responsibilities under the Labor Code, regulatory language must be clear and precise. Unfortunately much of the proposed new language in this subdivision is ambiguous and lacks focus; in fact most of it appears to be merely a series of statements justifying the use of evidence based medicine. This language is better suited for inclusion in a Statement of Reasons to be issued when the Division starts the formal rulemaking process. The adoption of these conclusory statements as regulatory language could inadvertently be interpreted as establishing a set of ill-defined standards that would only lead to more disputes and delay. This subdivision also includes numerous vague and confusing terms. For example, what does the phrase "practices that work" mean? What is "unsystematic clinical experience?" And what is "pathophysiologic rationale?" We recommend that the Division maintain the current language of this subdivision (some of which mirrors the statutory language in Labor Code §4604.5(b)) and either delete or extensively revise the newly proposed language.

2. Subdivision (d). As noted above, paragraph (1) establishes a rebuttal standard that is contradictory to statute and must be deleted. The statutory rebuttal standard as set forth in Labor Code §4604.5(a), quoted above, should be adopted in this subdivision.

3. Subdivision (f). See later comments on the rebuttal process provisions in §9792.25.1 *et seq.*

Section 9792.25

1. Current Subdivision (a). As noted above, we recommend that the language of this subdivision not be deleted as it correctly interprets the statutory standard for rebuttal of the MTUS as set forth in Labor Code §4604.5(a).

Sections 9792.25.1, 9792.25.2, and 9792.25.3

CAAA strongly supports the provision of the highest quality and most effective medical treatment for injured workers. The Legislature has mandated that the Administrative Director adopt a MTUS that incorporates evidence-based, peer-reviewed, nationally recognized standards of care, and has further provided that medical care that is reasonably required to cure or relieve the injured worker from the effects of a work injury means treatment that is based upon the MTUS.

However, as noted above the Legislature has also declared that the guidelines in the MTUS are rebuttable. This right to rebut the MTUS is critically important. It recognizes that injured workers should not be treated with "cookbook medicine." However, the establishment of improper standards or unworkable procedures for rebutting the MTUS can eviscerate this right. As noted earlier, the standard established in the proposed language of §9792.21(d)(1) conflicts with the statutory language of Labor Code §4604.5(a) and must be deleted.

In addition, we believe the processes set forth in this proposal for ranking the strength of medical evidence is unworkable as a method to evaluate an individual treatment request. There are several problems with this approach.

First, according to proposed §9792.25.2, the physician is to use the AGREE II evaluation tool to develop a percentage score, and pursuant to subdivision (b)(3) "the guideline with the highest percentage score shall be used as the source to approve or deny a treatment or diagnostic service recommendation." However, this rule directly contradicts instructions for use of the AGREE methodology, which state that "Although the domain scores may be useful for comparing guidelines and will inform the decision as to whether or not to use or to recommend a guideline, it is not possible to set thresholds for the domain scores to mark a 'good' or 'bad' guideline." [http://www.cebm.net/mod_product/design/files/worksheet-guideline-appraisal-sheet.pdf, AGREE Appraisal Instrument, page 5]

In addition, we believe it is unlikely that most treating physicians, who are paid \$11.78 for submission of a PR-2, with no additional compensation for attaching an RFA, will be able to spend the literally hours it may take to research medical guidelines or journals / studies, then apply the AGREE II methodology to determine which guideline / article has the highest percentage score, and then document that analysis as an attachment to the RFA. And even if the treating physician does calculate an AGREE II score for a rebuttal guideline or article, that exercise is likely to be fruitless because the proposed regulation does not specify how the "highest percentage score" is to be determined. Is it the highest percentage score as determined by the treating physician? What if the UR physician disputes the score assigned by the treating physician? Is that an issue that can be resolved through IMR? Does this require the IMR physician to determine a possible third percentage score?

Under the right circumstances we concur that the use of the AGREE methodology is useful in evaluating medical treatment guidelines. For example, as proposed in §9792.26(b) this methodology can be used by the Medical Evidence Evaluation Advisory Committee to evaluate various guidelines for inclusion in the MTUS. However, mandating the use of this complicated, time consuming, and inherently subjective process by treating physicians as proposed in these rules will only, in our opinion, increase disputes over medical necessity, increase delays in receiving appropriate treatment, further delay workers return to work, and increase costs.

We also object to the methodology outlined in §9792.25.1(f) which establishes a rigid hierarchy for conducting a medical literature search. The Administrative Director has no authority to limit the research areas reviewed by a physician. The regulation could set forth a recommended sequence, but it cannot proscribe the analysis of any valid medical literature. We believe it is particularly objectionable to propose a rule that could limit a physician's search of medical literature to only the ACOEM and ODG Guidelines, two treatment guidelines that were judged to "barely meet standards."

We strongly recommend that the Division begin the overdue process of expanding the MTUS to include the best guidelines for each topic area. We believe this change, which was the consensus recommendation of system participants in the 2006 RAND study, would significantly reduce disputes over medical necessity, reduce delays in the provision of medical treatment and reduce overall costs. We recognize that a possible criticism of an expanded MTUS is that the adoption of guidelines from multiple sources could introduce conflicting standards. We do not believe this is a significant problem. The use of multiple guidelines is common in health insurance and presents no problem to health insurers.

Furthermore, if there is a difference between two evidence-based treatment guidelines, we believe it is the treating physician's role – not the regulator's – to select the guideline that best meets the needs of his or her patient. EBM should be used as a tool to determine the best treatment option, not simply as a sword to deny treatment requests. This point was discussed in an article published by several of the originators of EBM, including Professor David Sackett, entitled *"Evidence based medicine: what it is and what it isn't; It's about integrating individual clinical expertise and the best external evidence."* A copy of this article, available on the website of the Center for Evidence Based Medicine (<http://www.cebm.net/?o=1014>) which is affiliated with the University of Oxford, is attached to this letter for your reference. In the article, Professor Sackett notes that "Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient."

It has been almost ten years since adoption of the MTUS and the Schedule has been greatly improved by the addition of guidelines for acupuncture, post-surgical treatment, and chronic pain. However, the Schedule is still much too reliant on the use of the ACOEM Guidelines, a guideline that "barely meets standards." We urge the Division to re-analyze the findings in the 2006 RAND study of treatment guidelines cited earlier, and to work with the Medical Evidence Evaluation Advisory Committee to expand the MTUS to include the best guidelines for each topic area.

Peggy Thill, Claims Operations Manager
State Compensation Insurance Fund

August 30, 2013

State Compensation Insurance Fund appreciates the time and effort the Division of Workers' Compensation (DWC) has put into revising the Medical Treatment Utilization Schedule (MTUS) regulations. We offer the following comments regarding the proposed changes.

§9792.20. Medical Treatment Utilization Schedule – Definitions

1) This section defines *evidence based medicine* as, “a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.”

It is unclear what “patient or community values” means, as this term is not commonly used in medical literature.

Recommendation

State Fund respectfully requests that the DWC clarify the meaning of the term “patient or community values.”

2) The draft regulations propose striking “functional improvement” from the MTUS definitions; however, the existence or absence of functional improvement is used in ACOEM and other medical treatment guidelines to measure treatment efficacy. In addition, the term “functional improvement” is specifically used in the existing MTUS sections related to acupuncture (§9792.24.1) and postsurgical treatment (§9792.24.3).

Absent a clear definition of this term, the consistent and effective application of the MTUS, ACOEM and other treatment guidelines that take functional improvement into consideration when determining medical necessity would be difficult, if not impossible.

Recommendation

State Fund recommends restoring the definition of functional improvement to §9792.20.

§9792.25.2. Strength of Evidence – Method for Evaluating the quality of Medical Treatment Guidelines

This section proposes replacing the current strength of evidence rating methodology in the MTUS regulations with a modified Appraisal of Guideline for Research & Evaluation (AGREE II) tool to assess the quality of medical guidelines. While AGREE II appears to be widely accepted by the medical community as a valid and reliable assessment instrument, the extensive structure of the modified tool proposed by the DWC (i.e. rating 27 individual items on a 7-point scale, calculating a scaled score for 8 domains and then providing 2 global ratings) may be burdensome for treating physicians as well as UR and IMR physicians – especially those currently unfamiliar with AGREE II. With already heavy workloads and a limited amount of time to spend per case, adoption of a complex new assessment instrument may result in confusion and disputes, which will in turn create delays and increase costs.

Recommendation

State Fund recommends that the DWC consider less cumbersome alternatives to address the issue of variability in guideline quality. However, if the DWC chooses to adopt the modified AGREE II instrument outlined in the proposed regulations, we strongly recommend that the DWC develop an implementation plan to ensure a smooth transition and compliance with the new methodology.

Jason Schmelzer
California Coalition on Workers' Compensation

August 30, 2013

Jeremy Merz
CalChamber

The MTUS is a vitally important component in the machinery that makes up California's workers' compensation system. The effectiveness of Utilization Review and Independent Medical Review are directly linked to the quality of the guidelines in the MTUS and the strength of evidence regulations. Considering the importance of the MTUS, we offer the following comments:

Functional Restoration

The draft regulations strike the definition of "functional improvement" which, because there is no explanation such as the one that would typically be included in an ISOR, is concerning to our coalition members.

In fact, in June 2007, in the Final Statement of Reasons (FSOR) for revisions to the MTUS Regulations, the DWC included the following reasons for including a definition for functional restoration:

The definition of "functional improvement" was adapted from the medical treatment philosophy that is incorporated in the ACOEM Practice Guidelines. For example, the ACOEM Practice Guidelines state at page 77:

In order for an injured worker to stay at or return successfully to work, he or she must be physically able to perform some necessary job duties. This does not necessarily mean that the worker has fully recovered from the injury, or is pain-free: it means that the worker has sufficient capacity to safely perform some job duties. Known as functional recovery, this concept defines the point at which the worker has regained specific physical functions necessary for reemployment. (See, ACOEM Practice Guidelines, at p. 77.)

The next ACOEM quote included in that 2007 FSOR specifically addresses over-treating pain, and over-medicating with Opioids and Pain Meds.

Another example is contained at ACOEM Practice Guidelines, page 106:

Pain in today's work place presents a challenge to the occupational physician. Although mistreating or undertreating pain is of concern, an even greater risk for the physician is overtreating the chronic pain patient, especially with opioids and other medications. Overtreatment often results in irreparable harm to the patient's socioeconomic status, home life, personal relationships, and quality of life in general. However, because opioids are "easy" and represent a path of little resistance, they may prevent the patient, the physician, or both from vesting in a difficult and uncomfortable rehabilitation course. A physician's choice to palliate and not rehabilitate is a profound clinical, ethical, and medico-economic decision not to be taken lightly or be based on unfounded dogma. A patient's complaints of pain should be acknowledged. Patient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization. (See, ACOEM Practice Guidelines, at p. 106.)

In 2007, the prescience to recognize the possibility of over-medicating was evident. Now in 2013, when we recognize there exists an epidemic of over-medicating, we should not eliminate one of the definitions that will give us a tool to guide treatment to recovery of function as opposed to "treatment" to addiction.

Is "functional improvement" and the elimination of disability and barriers to return to work not the entire point of the Work Comp System? Unfortunately, we know in some cases, we may never make someone pain-free, but we can allow them to return to work. Further, functional improvement is also a criterion in many sections of the MTUS used to determine whether ongoing treatment is appropriate. Without the definition of functional improvement, when should treatment stop, or go into "maintenance mode?"

RECOMMENDATION: *Maintain the definition of functional improvement in the regulations to ensure that proper consideration is given to the restoration of functionality.*

Definition of "Evidence Based Medicine"

The definition of "Evidence Based Medicine" contained in § 9792.20(e) of the draft regulations is problematic because it expands the scope of what can be considered as "evidence based" to include subjective factors into what should be a purely objective decision-making process. The inclusion of "patient and community standards" in the definition of "evidence based medicine" is a significant diversion away from the objective evaluation of medical treatment and opens the door to virtually any kind of treatment.

RECOMMENDATION: *Remove references to "patient and community standards" from the definition of "evidence based medicine".*

MEEAC Process

Our coalition would respectfully request that the DWC reconsider the current MEEAC process, which unfortunately provides very little opportunity for input from stakeholders. We understand that the MEEAC was intentionally designed to be private in order to provide doctors with an opportunity to provide the unvarnished truth that may not be appreciated by their colleagues; however, we believe that a more open and inclusive process would yield better results. Consider, for example, the [Oregon Medical Advisory Committee](#) that has been in existence since 1965. This body has by-laws, established processes, and public meeting schedules, agendas, and notes.

RECOMMENDATION: The DWC should consider modifications to the MEEAC process that increases transparency, accountability, and stakeholder involvement.

MTUS and Independent Medical Review

The draft regulations would create an odd interaction between the Medical Treatment Utilization Schedule (established by the DWC under authority granted in LC Section 5307.27) and the Independent Medical Review (IMR) process established pursuant to LC Section 4610.5. LC Section 4610.5(c)(2) contains a definition for the term “medically necessary” that creates a hierarchy of medical evidence to be used when making decisions about medical treatment. The hierarchy, in which standards must be applied in order and reliance on a lower-ranked standard is only applicable when every higher-ranked standard is inapplicable, is as follows:

1. The guidelines adopted by the administrative director pursuant to Section 5307.27 (MTUS).
2. Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service.
3. Nationally recognized professional standards.
4. Expert opinion.
5. Generally accepted standards of medical practice.

Our coalition believes that the scope of the draft MTUS regulations essentially integrates all of the lower-ranked standards in the hierarchy established in LC Section 4610.5. The result, as far as we can tell, is to consolidate the entire decision-making process inside of the MTUS. If this was the intent of the draft MTUS regulations, then the DWC should make that clear and ensure that the decision-making processes established in the draft MTUS regulations are consistent with the hierarchy established in 4610.5(c)(2).

RECOMMENDATION: Clarify the intent of the approach being taken by the MEEAC and the DWC with respect to the draft MTUS regulations. If the MTUS is now a substitute for the hierarchy established in LC Section 4610.5(c)(2) then that should be clearly stated.

AGREE II Process

Our coalition is unified in our concern that the Appraisal of Guideline for Research & Evaluation (AGREE) II medical guideline evaluation tool is too complex and cumbersome. We do not believe that a process that requires a ten page worksheet and requires that 27 “key items” be scored from 1 to 7 and then plugged into a complex calculation is conducive to dispute-free and timely decision-making.

RECOMMENDATION: Identify and pursue alternative decision-making processes that are less cumbersome and more conducive to dispute-free and timely medical treatment decisions.

Application of Guidelines to all Providers

For maximum effectiveness, the ODG guidelines must apply to all providers. All entities including physician dispensers, clinics, pharmacies, and mail order pharmacies must be held to the same standard under the guidelines. This includes enforcing prospective and retrospective review guidelines across all providers.

RECOMMENDATION: Require all providers handling a claimant’s prescription drug treatment program to follow the ODG guidelines.

Treatment Guidelines as Presumptively Correct

We are supportive of language identifying the MTUS as presumptively correct, meaning in order to treat outside the guidelines, clinically compelling evidence must be provided. Considering the guidelines presumptively correct places the burden on the provider to justify treating outside of evidenced-based medicine, which is considered the best pathway for positive outcomes for claimants.

RECOMMENDATION: Maintain the language identifying the MTUS as presumptively correct.

Adoption of Nationally Accepted Treatment Guidelines

We urge adoption of nationally accepted guidelines that are evidence-based. The Official Disability Guidelines (ODG) are robust and have been adopted by a majority of states that utilize treatment guidelines. There are two significant advantages of adopting nationally accepted guidelines versus state-specific guidelines. First, there are no administrative costs for creating or maintaining the guidelines. Second, it circumvents political pressure to modify guidelines for special interest groups.

RECOMMENDATION: Replace the current California-specific MTUS guidelines with the Official Disability Guidelines (ODG)

Mandatory Pre-Authorization and/or Utilization Review

Pre-authorization and/or utilization review must be mandatory. Mandating pre-authorization and/or utilization review on certain procedures and/or medications is a valuable tool to assist in the improvement of medical outcomes for injured workers. Utilization review should occur prior to the procedure or dispensing of medication in order to achieve the best results. Mandatory pre-authorization on specific medications or combinations of medications would be beneficial in the following situations:

- a) Any non-FDA approved medication, including compounds;
- b) Opioids over 120 mg/day morphine equivalents; and,
- c) ODG N-Drugs. (These are not considered first line medications)

RECOMMENDATION: Mandate pre-authorization and/or utilization review for certain procedures and/or dispensations of medication.

Tim East
Director, Corporate Risk Management
The Walt Disney Company

August 30, 2013

I agree with you (CWCI) that I am very concerned about treatment guidelines that, regarding definitions, include the language “clinical expertise and patient or community values.”

Bret Graham, President
LatinoComp

August 30, 2013

On behalf of LatinoComp I wanted to comment on the proposed regulations related to the MTUS. SB 863 adopted new definitions and criteria for reviewing medical treatment and resolving medical treatment disputes. Specifically, LC 4610.5(c) defines what is “medically necessary” and what is a “medical necessity” and established an order and hierarchy of standards to be followed in reviewing medical treatment requests:

(2) "Medically necessary" and "medical necessity" mean medical treatment that is reasonably required to cure or relieve the injured employee of the effects of his or her injury and based on the

following standards, which shall be applied in the order listed, allowing reliance on a lower ranked standard only if every higher ranked standard is inapplicable to the employee's medical condition:

(A) The guidelines adopted by the administrative director pursuant to Section 5307.27.

(B) Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service.

(C) Nationally recognized professional standards.

(D) Expert opinion.

(E) Generally accepted standards of medical practice.

(F) Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious.

For reasons unknown and unstated, the proposed MTUS regulations do NOT follow this hierarchy. Rather, items (B) "Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service" and (C) "Nationally recognized professional standards" are now given equal weight when in fact the Legislature already determined that the "Nationally recognized professional standards" such as ODG, other states' treatment guideline standards and other employer/insurance or government treatment standards are NOT to be considered unless (1) MTUS not applicable; AND (2) there is no applicable "Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service". Cf. Labor Code 4610.5(c)(2)(A-F).

ODG, other states' treatment guideline standards and other employer/insurance or government treatment standards do NOT fit in LC 4601.5(c)(2)(B) but instead are "Nationally recognized professional standards" of the lower standard LC 4610.5(c)(2)(C). We know this since, as with ACOEM Guides, many of their treatment recommendations are NOT based on peer-reviewed scientific evidence but rather on based on group-think: "D = Panel interpretation of information not meeting inclusion criteria for research-based [scientific] evidence." See ACOEM 2d Ed., summary of treatment recommendations.

Since the proposed regulations on the MTUS are contrary to the very clearly defined system created in SB 863, they should be withdrawn or amended to conform to the statute. In fact, as written, these regulations will only serve to confuse the treating doctors. In fact, the treatment they recommend based on non-MTUS treatment guidelines (as opposed to peer-reviewed scientific articles) may very well be denied by IMR due to the doctors' application of the wrong, lower ranked standard.

Lastly, the deletion of the definition of "functional impairment" does a great disservice to the community. Virtually every UR denial I have seen considers the "lack of functional improvement" and UR approvals cite "functional improvement" for the requested treatment. It is unclear in the regulations how a doctor is to assess the effectiveness of the treatment to date and

when to move on to a different or more invasive or alternate treatment or surgery without at least considering functional improvement. In fact, isn't the entire function and goal of the workers' compensation system's medical treatment to achieve functional improvement in work restrictions and activities of daily living as part of the overall mandate to "cure or relieve"? One can only assume that the intent of these regulations is to have the doctors apply treatment guidelines (and treatment) by rote without considering either functional improvement or lack thereof. In other words, the injured worker's response to the treatment apparently just doesn't matter anymore. That cannot be the basis of an acceptable medical treatment delivery system.

Hopefully, revised regulations on the MTUS can follow the intent and language of LC 4610.5 and give doctors clearer guidance on what evidence based treatment they should be providing and what standards and other factors (such as functional improvement) to consider when recommending treatment to help the injured workers get better so they can return to work.

Robert C. Blink, MD
Co-Chair, WOEMA Legislative Committee
Western Occupational & Environmental Medical Association

August 30, 2013

The Western Occupational & Environmental Medical Association (WOEMA) is pleased to respond to the recent request by the California Division of Workers' Compensation (DWC) for comments on the subject of the proposed Medical Treatment Utilization Schedule (MTUS) regulation changes. Below we have excerpted various sections as identified, which are quoted in italics followed by our comments in bold non-italicized font.

*TITLE 8. INDUSTRIAL RELATIONS
DIVISION 1. DEPARTMENT OF INDUSTRIAL RELATIONS
CHAPTER 4.5. DIVISION OF WORKERS' COMPENSATION
SUBCHAPTER 1. ADMINISTRATIVE DIRECTOR -- ADMINISTRATIVE RULES
ARTICLE 5.5.2 MEDICAL TREATMENT UTILIZATION SCHEDULE*

§ 9792.20. Medical Treatment Utilization Schedule—Definition (b) “ACOEM Practice Guidelines” means the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2nd Edition (2004). A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org).

COMMENT: We strongly recommend that the Third Edition of the ACOEM Guidelines be specified rather than the Second Edition. It is scientifically stronger and covers more

conditions and situations. Furthermore, as noted in section (g), renumbered from (h), resources should have been written within the past five years; the Second Edition was not but the Third Edition does qualify.

(e) ~~“Evidence-based Evidence Based Medicine”~~ means ~~based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.~~ means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.

COMMENT: We recommend eliminating the mention of community values, as this may introduce non-scientific influences such as political factors into what should as much as possible be an objective endeavor. A preferred approach would be to use the definition in 9792.21 (b).

(f) ~~“Functional improvement” means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment.~~

COMMENT: We strongly recommend keeping “functional improvement” as a ecified goal and value for treatment outcomes; it is a cornerstone of Evidence Based Medicine. Moreover, it is used in the acupuncture guidelines and is integrated throughout the ACOEM and other guidelines as well.

(k) ~~“Peer reviewed” means that a medical study’s content, methodology and results have been evaluated and approved prior to publication by an editorial board of qualified experts.~~

COMMENT: The phrase “peer-reviewed medical journal” itself should be defined as it has meaning beyond the shorter phrase, “peer-reviewed.” A peer-reviewed journal only derives proper authority when the journal as a whole is edited and published without serious commercial bias toward specific medical products or procedures and this should be recognized by the regulation. Such an approach is evidenced in 9792.25.2 (Strength of Evidence), and we recommend that a similar approach be included here as a separate definition.

§ 9792.21. Medical Treatment Utilization Schedule

(b) The best available evidence is then used to guide clinical decision making. In order to effectively promote health and well-being, health care professionals shall base clinical decisions on evidenced based medicine.

COMMENT: The final sentence in this paragraph should be modified to recognize that there are situations where Evidence-Based Medicine cannot be used as there is no published data on which to base an opinion; in such cases determining the best approach requires knowledge of basic medical science and analogy to other situations. If this language is required by statute then we recommend some recognition that such situations do arise, as is done in (e) below from the same section:

(e) When the MTUS is inapplicable, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and/or peer-reviewed published studies that are nationally recognized by the medical community.

(1) The MTUS' presumption of correctness may be rebutted if medical evidence is cited that contains a recommendation directly applicable to the specific medical condition or diagnostic test requested by the injured worker and is supported by a higher level of evidence than the medical evidence used to support the MTUS' recommendation.

COMMENT: We recommend that the word “higher” be defined in this context so as to clarify its intent.

§ 9792.25. Presumption of Correctness, Burden of Proof and Strength of Evidence Definitions.

(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:

(1) “Bias” means any tendency to influence the results of a trial (or their interpretation) other than the experimental intervention. Biases include inadequate generation of the randomization sequence, inadequate concealment of allocation, selection, confounding, lack of blinding, selective outcome reporting, failure to do intention-to-treat analysis, early stopping, selection, and publication.

COMMENT: In order to recognize the many kinds of serious bias that may be present in a study, we recommend that the phrase “among other types of bias” be appended to the last sentence.

(14) “Expert opinion” means a determination by an expert, through a process of evidenced-based thinking that a given practice should or should not be labeled evidenced based, and published in a peer-reviewed medical journal.

COMMENT: The phrase “evidence-based thinking” should either be defined or replaced. Also, again we recommend that the phrase “peer-reviewed medical journal” be defined as in our previous comment.

(26) “Selective outcome reporting” means the failure to report all of the outcomes that are assessed in a trial, including a post hoc change in the primary outcome.

COMMENT: We recommend adding the phrase “or group of trials” after the word “trial” in this sentence, to address the problem of non-publication of trials that don’t support the desires of a biased funding source.

§ 9792.25.1. Process to Determine When Medical Care is Reasonable and Necessary

(f) In the interest of efficiency and consistency, when conducting the medical literature search of the large body of available medical evidence, the following search sequence shall be followed:

(2) Search the most current version of workers’ compensation medical guidelines established by one or more US state governments or by the US federal government; if no relevant recommendations are found or if the current version is more than three years old then.

(3) Search other evidenced based medical treatment guidelines that are recognized by the national medical community and are scientifically based. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/; if no relevant recommendations are found or if the current version is more than three years old then.

(4) Search for studies that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community. A search for peer-reviewed published studies may be conducted by accessing the U.S. National Library of Medicine’s database of biomedical citations and abstracts that is searchable at the following website: www.ncbi.nlm.nih.gov/pubmed. Other searchable databases may also be used.

COMMENT: In all three paragraphs above, instructions are needed as to what action to take if a recommendation is found, not just if one is not found.

§ 9792.25.2 Strength of Evidence - Method for Evaluating the quality of Medical Treatment Guidelines

COMMENT: We believe that this section is most appropriate for Medical Evidence Evaluation Advisory Committee (MEEAC), use, but it does not determine if an individual recommendation is valid in a guideline. We suggest that outside of MEEAC, any dispute between recommendations in different guidelines should be settled by the strength of evidence for that one recommendation using the strength of evidence laid out in 9792.25.3.

Brenda Ramirez, Claims and Medical Director
California Workers' Compensation Institute

August 31, 2013

The Institute offers these general recommendations, followed by recommendations for specific modifications to the proposed regulations.

General Recommendations

Introduction

The Institute strongly supported the Administrative Director's (AD) original decision to anchor the statutory definition of medical care with the ACOEM guidelines. That policy decision followed both the spirit and the letter of SB 899 in establishing evidence based medicine as the cornerstone of proper medical care in the California workers' compensation system.

The consequence of that social policy decision by the Legislature was to require reliance on evidence-based medicine and the ACOEM guidelines at every level of the workers' compensation system. The Supreme Court affirmed that determination in SCIF v WCAB (Sandhagen) (2008) 73 CCC 981 stating, in essence, that reasonable and necessary medical care under section 4600 is any treatment provided in accordance with the medical treatment utilization schedule. We are disappointed to see that the proposed regulations for revising the Medical Utilization Treatment Schedule (MTUS) have significantly diluted the standard of medical care established by the Legislature with the adoption of evidence based medicine.

The regulations must be very clear that treating physicians, claims administrators, medical treatment evaluators for utilization review and independent medical review, and adjudicators have to apply the hierarchy of scientific medical evidence, the ACOEM guidelines, and other evidence based, peer-reviewed, nationally recognized treatment guidelines that meet similar high-grade standards to determine whether any proposed treatment is safe, efficacious and therefore presumed to be appropriate under the statute. The regulations supporting that determination must strengthen, not dilute the statutory foundation of high-grade evidence-based medicine and the ACOEM guidelines.

The Statutory Mandate

The statutory scheme adopted by the Legislature in 2004 made fundamental changes to the provision of medical care to injured workers. The amendments to section 4600 and the addition of section 5307.27 defined the employer's liability to provide all medical care "reasonably

required to cure or relieve the injured worker from the effects of his or her injury.” Section 4600 now states:

(b) 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 or, prior to the adoption of those guidelines, the updated American College of Occupational and Environmental Medicine's. (Emphasis added)

Section 5307.27, therefore, defines medical care as follows:

5307.27. On or before December 1, 2004, the administrative director shall adopt ... 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, and that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. (Emphasis added)

To the extent that the proposed regulation to revise the MTUS repeatedly includes references to “best available research evidence with clinical expertise and patient or community values”, they violate the statutory mandate established by the Legislature. The DWC should be strengthening the treatment guidelines by restricting the use of low level, unsupported, or unsubstantiated modalities of medical care, not authorizing them.

Eliminate the Acupuncture Guidelines

The most obvious example of treatment guidelines that violate the evidentiary standard of care established by the Legislature are the Acupuncture Guidelines, as they have no evidence base and are not nationally recognized standards of care. The AD in order to bolster the standard of care for injured workers should eliminate these guidelines from the schedule.

The MTUS established both the preeminence of the ACOEM methodology and philosophy and the process to review and adopt guidelines of comparable quality. When the acupuncture guidelines were included in the schedule, they constituted an independent set of guidelines that supersede ACOEM and were not vetted by the established methodology or the hierarchy of evidence. Labor Code section 4600 includes acupuncture as a legitimate form of treatment for injured workers; it does not endorse acupuncture as a system of medicine.

Hierarchy of Scientific Medical Evidence

“Hierarchy of evidence” should be strengthened in order to more clearly establish the relative weight to be given to scientifically based medical evidence. Guidelines that do not meet the standards of evidence based medicine or are not supported within a meaningful hierarchy of evidence should not be included. Within the hierarchy of evidence, only research of greater scientific reliability on the scale should be afforded the presumption under section 4604.5.

The hierarchy of scientific medical evidence is the yardstick by which all medical evidence relating to the nature, scope, duration, and intensity of treatment are judged. The social policy decision has been made by the Legislature and the regulations must unambiguously reflect the paramount importance of this scale and the ACOEM guidelines in the prompt and definitive resolution of treatment issues. In this way, the hierarchy and the treatment guidelines will provide predictability and stability and will facilitate the delivery of consistent, high quality medical care, which is the goal of the legislative mandate. It should be clear in the regulations that guidelines, which do not measure up to the standard of scientific reliability cannot be used to counter the recommendations of the ACOEM guidelines.

Under SB 863, the MTUS will be used by treating physicians, utilization reviewers, and the independent medical reviewers to determine the most appropriate modalities of treatment and whether untested, unreliably treatment should be eliminated. All of these users should be able to rely on the credibility and consistency of the schedule. The use of the AGREE II protocol as proposed will only dilute the statutory standard and create inconsistency among reviewers that will result in contradictory, unpredictable decisions – all of which will be presumed “correct” under the MTUS. The regulations, as proposed, give greater weight to a single study published within the past three years than to relevant ACOEM or ODG guidelines in the schedule. In some areas “expert opinion” carries greater weight. These vague, subjective standards must be eliminated.

The Institute believes that it is appropriate for the Administrative Director and the Medical Director to use the AGREE II protocol to evaluate guidelines to determine and adopt the most effective guidelines, but that its use by reviewers as proposed is impractical at best.

Recommendations

Section 9792.20(e) Definitions, section 9792, 21(b) Medical Utilization Treatment Schedule

Recommendation

Delete “with clinical expertise and patient or community values.”

Discussion

These sections use the phrase “clinical expertise and patient or community values” to serve as a basis for medical treatment guidelines and are an example of how far the proposed schedule has drifted away from the statutory standard of “evidence based, peer-reviewed, nationally recognized treatment guidelines” to determine whether any proposed treatment is safe, efficacious and presumed to be appropriate under the statute. Clinical expertise, patient values, or community values as standards to assess the appropriateness of medical care are wholly subjective and meaningless. The MTUS has to be definitive and the statutes provide ample direction for establishing useful, clear, and scientific treatment guidelines.

Section 9792.20(f) Definitions**Recommendation**

Restore the definition of functional improvement.

Discussion

The elimination of the concept of functional improvement as a means of determining whether proposed treatment is or will be effective is inappropriate. In practice this definition is often used in UR decisions to evaluate a treatment plan. If the treatment plan fails to discuss functional improvement as a benchmark, then the plan is unjustified. This definition should be retained.

Section 9792.25(a)(14) Definitions**Recommendation**

Delete this definition of expert opinion.

Discussion

As drafted “expert opinion” is similarly ineffective as it is defined as “evidence based thinking” by “an expert”. Medical treatment guidelines are controversial, as evidenced recently by the publication of the DSM-V-R. There will always be experts who disagree

with any guideline regarding the practice of medicine and to permit a minority opinion to trump other evidence based medical guidelines is to make the MTUS, which is now the definition of reasonable and necessary medical care, worthless. Therefore, this empty language must be eliminated from the schedule.

Section 9792.25.1(f) Determining Reasonable and Necessary Medical Care

Recommendation

Delete this search sequence requirement.

Discussion

The proposed “search sequence” defines a medical literature search that ignores the time restraints of medical reviewers. The 3-year limitation effectively nullifies the ACOEM guidelines, ODG, and the MTUS. It is the function of the MTUS to establish evidence based medical treatment guidelines for reviewers and physicians to apply in the real world. This process should be eliminated and the AD should reconsider how the MTUS can be structured to apply scientific evidence promptly to specific treatment issues.

The ACOEM Practice Guidelines

The Institute supports returning to the use of the ACOEM Practice Guidelines and updating them to the most current version, and eliminating from the MTUS the ODG pain management guidelines. ACOEM Guidelines are nationally recognized, evidence based, and comprehensive. The use of a single treatment guideline will improve the consistency of application, improve timely decision making, and reduce disputes. It is essential that all medical care reviewers apply the same rules, so that effective treatment is provided in a timely manner and disputes are kept to a minimum.

Simply stated, the ODG guidelines use ungraded medical evidence, often fail to provide specific recommendations, include vague, ambiguous language to qualify their conclusions, and fail to follow the Strength of Evidence and Rating methodology in the schedule. Yet, by including them in the MTUS, they will be afforded the legal presumption of correctness contained in Labor Code section 4604.5.

Needless ambiguity in the treatment schedule serves no one. Guidelines with ungraded evidence or that offer contradictory or conditional recommendations do not facilitate the legislative goal of identifying the best medical care for injured workers. Where guidelines are not clear, reviewers may be powerless to prevent injured workers from receiving inappropriate or unnecessary care.

It is important to eliminate medical care that does no harm but does no good when ensuring high quality treatment. If the MTUS is so open to interpretation and so subjective that no decision by a utilization reviewer (or the IMR) is sustainable, then the treatment guidelines will fail to effectuate the Legislature's social policy and the statutes will be rendered meaningless.

Robert Ward, Clinical Director
CID Management

August 27, 2013

The care, consideration and effort that has gone into the proposed revision is readily apparent, and to be congratulated.

Unfortunately, the proposed amendments to the MTUS represent an excellent conceptual framework that is likely to be unusable by the constituents who actually need to follow the MTUS. There are two major issues with the current proposal.

Issue #1: Treatment outcomes have been removed from consideration.

The highest form of evidence regarding appropriateness of medical care is not found in guidelines or publications; but is obtained from objective observation of the specific patient. The most appropriate use of population-based evidence (guidelines and publications) is when there is no meaningful evidence about the specific patient. This would be true prior to a trial of therapy; or for ongoing care where the quality of medical assessment and/or documentation is poor. However, when patient outcome evidence is available with regard to the specific patient and the specific treatment modality, that becomes the highest form of evidence on which to base decisions of medical necessity. It is contrary to the interests of the patient to deny a form of care that has been effective for the specific patient but not in studied populations. It is equally contrary to the interests of the patient to continue care that has been demonstrated as ineffective for the specific patient, as this can delay alternative and potentially more successful modes of treatment.

It is recommended that there be consideration of adding patient outcomes for continuing care to the hierarchy of evidence discussed in the MTUS.

It is recommended that the proposed elimination of 8CCR9792.20(f) not be enacted; and that the present or a modified version of this regulation be retained.

The current operational definition of functional improvement is the only consideration of patient outcomes in the MTUS. Additionally, a simple, objective and operational definition of functional improvement is required for triers of fact attempting to settle disputes as to whether continuation of a specific form of care is necessary for a specific injured worker; and would be of substantial benefit to physicians (treating, UR and IMR) attempting to serve the injured worker.

Issue #2: The evidence rating scheme is fine for academia; unsuitable for work comp

With very rare exceptions, the persons who would need to use the MTUS will be unable to conduct a meaningful assessment of contrasting guidelines with the AGREE II instrument; and will be unable to successfully classify the level of evidence represented by a peer-reviewed publication. Most stakeholders in the workers compensation system simply lack the background in academia.

Physicians (treating, reviewing and IMR) will be unable and/or unwilling to engage in the rating process. It is incompatible with their professional skills and unfavorable to their schedules and their success in generating personal income.

Applicant and defense attorneys will be ill-equipped to understand or use the rating systems; and will be forced to rely on dueling expert witnesses to settle disputes of medical necessity. WCAB judges will likewise be unable to follow the rating process, and will have no more than their "gut" to decide between the opinions of the opposing parties.

It is recommended that if the proposed evidence rating system is adopted, that there be a rating score through the AGREE II instrument made for common guidelines by an impartial group or committee.

It is recommended that if the proposed evidence rating system is adopted, that there be established a mechanism for conducting an impartial comparison of competing scientific evidence as a component of dispute resolution process, in cases where the question of medical necessity is based on such evidence.

Comments and suggested changes are as follows:

TITLE 8. INDUSTRIAL RELATIONS

DIVISION 1. DEPARTMENT OF INDUSTRIAL RELATIONS

CHAPTER 4.5. DIVISION OF WORKERS' COMPENSATION

SUBCHAPTER 1. ADMINISTRATIVE DIRECTOR -- ADMINISTRATIVE RULES

ARTICLE 5.5.2 MEDICAL TREATMENT UTILIZATION SCHEDULE

§ 9792.20. Medical Treatment Utilization Schedule—Definitions

As used in this Article:

(a) “American College of Occupational and Environmental Medicine (ACOEM)” is a medical society of physicians and other health care professionals specializing in the field of occupational and environmental medicine, dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education.

(b) “ACOEM Practice Guidelines” means the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2nd Edition (2004). A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org).

Comment [RW1]: The specific reference to the 2004 edition here is inconsistent with other sections of the

(c) “Chronic pain” means any pain that persists beyond the anticipated time of healing.

(d) “Claims administrator” is a self-administered workers' compensation insurer, a self-administered self-insured employer, a self-administered legally uninsured employer, a self-administered joint powers authority, a third-party claims administrator, or the California Insurance Guarantee Association.

(e) ~~“Evidence-based Evidence Based Medicine” means based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.~~ means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.

~~(f) “Functional improvement” means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment.~~

Comment [RW2]: This definition should not be omitted.

There are a great many forms of continued treatment discussed within the OMFS which require evidence of functional improvement as a criterion for continuation. Likewise, there are times when an invasive therapy is based on the absence of functional improvement from conservative care.

There must be an objective operational definition of functional improvement. Without it, any unqualified statement that there was or was not functional improvement is as valid as any other; and finders of fact will have difficulty resolving the issue.

(gf) “Medical treatment” is care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20-9792.26.

(hg) “Medical treatment guidelines” means the most current version of written recommendations revised within the last five years which are systematically developed by a multidisciplinary process through a comprehensive literature search to assist in decision-making about the appropriate medical treatment for specific clinical circumstances.

(ih) “MEDLINE” is the largest component of PubMed, the U.S. National Library of Medicine’s database of biomedical citations and abstracts that is searchable on the Web. Its website address is www.pubmed.gov.

(ji) “Nationally recognized” means published in a peer-reviewed medical journal; or developed, endorsed and disseminated by a national organization with affiliates based in two or more U.S. states; or currently adopted for use by one or more U.S. state governments or by the U.S. federal government; and is the most current version.

(kj) “ODG” means the Official Disability Guidelines published by the Work Loss Data Institute containing evidenced-based medical treatment guidelines for conditions commonly associated with the workplace. ODG guidelines may be obtained from the Work Loss Data Institute, 169 Saxony, #101, Encinitas, California 92024 (www.ODG@worklossdata.com).

(k) “Peer reviewed” means that a ~~medical~~ study’s content, methodology and results have been evaluated and approved prior to publication by an editorial board of qualified experts.

(l) “Scientifically based” means based on scientific literature, wherein the body of literature is identified through performance of a literature search in MEDLINE, the identified literature is evaluated, and then used as the basis for the guideline.

(m) “Strength of Evidence” establishes the relative weight that shall be given to scientifically based evidence.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.21. Medical Treatment Utilization Schedule

(a) The Administrative Director adopts the Medical Treatment Utilization Schedule (MTUS) consisting of section 9792.20 through section 9792.26.

~~(b) The MTUS is intended to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers and to help those who make decisions regarding the medical treatment of injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers, in accordance with section 4600 of the Labor Code. The MTUS provides a framework for the most effective treatment of injured and ill workers and is based on the principles of Evidence Based Medicine (EBM). EBM is a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values. EBM is a method of improving the quality of care by encouraging practices that work, and discouraging those that are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions. Instead, EBM requires the evaluation of medical evidence by applying an explicit systematic methodology to determine the strength of evidence used to support the recommendations of a medical condition. The best available evidence is then used to guide~~

clinical decision making. In order to effectively promote health and well-being, health care professionals shall base clinical decisions on evidenced based medicine.

(c) Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence based, peer reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10. The MTUS shall constitute best practice guidelines for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions. The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition.

(d) The MTUS is inapplicable in the following two situations. First, the MTUS is inapplicable when the MTUS' presumption of correctness is successfully rebutted. Second, the MTUS is inapplicable when the MTUS is silent and does not address a medical condition or diagnostic test.

(1) The MTUS' presumption of correctness may be rebutted if medical evidence is cited that contains a recommendation directly applicable to the specific medical condition or diagnostic test requested by the injured worker and is supported by a higher level of evidence than the medical evidence used to support the MTUS' recommendation.

(e) When the MTUS is inapplicable, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and/or peer-reviewed published studies that are nationally recognized by the medical community.

(f) To determine the best available medical evidence, the strength of evidence methodologies set forth in sections 9792.25.2 and 9792.25.3 shall apply.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.25. ~~Presumption of Correctness, Burden of Proof and Strength of Evidence~~ Definitions.

~~(a) The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the MTUS for the duration of the medical condition. The presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably 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.~~

~~(b) For all conditions or injuries not addressed by the MTUS, authorized treatment and diagnostic services shall be in accordance with other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community.~~

~~(c)(1) For conditions or injuries not addressed by either subdivisions (a) or (b) above; for medical treatment and diagnostic services at variance with both subdivisions (a) and (b) above; or where a recommended medical treatment or diagnostic service covered under subdivision (b) is at variance with another treatment guideline also covered under subdivision (b), the following ACOEM's strength of evidence rating methodology is adopted and incorporated as set forth below, and shall be used to evaluate scientifically based evidence published in peer-reviewed, nationally recognized journals to recommend specific medical treatment or diagnostic services:~~

~~(A) Table A — Criteria Used to Rate Randomized Controlled Trials~~

~~Studies shall be rated using the following 11 criteria. Each criterion shall be rated 0, 0.5, or 1.0, thus the overall ratings range from 0-11. A study is considered low quality if the composite rating was 3.5 or less, intermediate quality if rated 4-7.5, and high quality if rated 8-11.~~

Criteria	Rating Explanation
<p>Randomization:</p> <p>Assessment of the degree that randomization was both reported to have been performed and successfully* achieved through analyses of comparisons of variables between the two groups.</p> <p>*Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful.</p>	<p>Rating is "0" if the study is not randomized or reports that it was and subsequent analyses of the data/tables suggest it either was not randomized or was unsuccessful.</p> <p>Rating is "0.5" if there is mention of randomization and it appears as if it was performed, however there are no data on the success of randomization, it appears incomplete, or other questions about randomization cannot be adequately addressed.</p> <p>Rating is "1.0" if randomization is specifically stated and data reported on subgroups suggests that the study did achieve successful randomization.</p>
<p>Treatment Allocation Concealed:</p> <p>Concealment of the allocation scheme from all involved, not just the patient.</p>	<p>Rating is "0" if there is no description of how members of the research team or subjects would have not been able to know how they were going to receive a particular treatment, or the process used would not be concealed.</p> <p>Rating is "0.5" if the article mentions how allocation was concealed, but the concealment was either partial involving only some of those involved or other questions about it are unable to</p>

	<p>be completely addressed.</p> <p>Rating is "1.0" if there is a concealment process described that would conceal the treatment allocation to all those involved.</p>
<p>Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).</p>	<p>Rating is "0" if analyses show that the groups were dissimilar at baseline or it cannot be assessed.</p> <p>Rating is "0.5" if there is general comparability, though one variable may not be comparable.</p> <p>Rating is "1.0" if there is good comparability for all variables between the groups at baseline.</p>
<p>Patient Blinded</p>	<p>Rating is "0" if there is no mention of blinding of the patient.</p> <p>Rating is "0.5" if it mentions blinding, but the methods are unclear.</p> <p>Rating is "1.0" if the study reports blinding, describes how that was carried out, and would plausibly blind the patient.</p>

<p>Provider Blinded</p>	<p>Rating is "0" if there is no mention of blinding of the provider.</p> <p>Rating is "0.5" if it mentions blinding, but the methods are unclear.</p> <p>Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the provider.</p>
<p>Assessor Blinded</p>	<p>Rating is "0" if there is no mention of blinding of the assessor.</p> <p>Rating is "0.5" if it mentions blinding, but the methods are unclear.</p> <p>Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the assessor.</p>
<p>Controlled for Co-interventions: The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during</p>	<p>Rating is "0" if there are multiple interventions or no description of how this was avoided.</p> <p>Rating is "0.5" if there is brief mention of this potential problem.</p> <p>Rating is "1.0" if there is a detailed description of how co-</p>

the study).	interventions were avoided.
<p>Compliance Acceptable: Measures the degree of non-compliance.</p>	<p>Rating is "0" if there is no mention of non-compliance.</p> <p>Rating is "0.5" if non-compliance is briefly addressed and the description suggests that there was compliance, but a complete assessment is not possible.</p> <p>Rating is "1.0" if there are specific data and the non-compliance rate is less than 20%.</p>
<p>Dropout Rate: Measures the drop-out rate.</p>	<p>Rating is "0" if there is no mention of drop-outs or it cannot be inferred from the data presented.</p> <p>Rating is "0.5" if the drop-out issue is briefly addressed and the description suggests that there were few drop-outs, but a complete assessment is not possible.</p> <p>Rating is "1.0" if there are specific data and the drop-out rate is under 20%.</p>
<p>Timing of Assessments: Timing rates the timeframe for the assessments between the</p>	<p>Rating is "0" if the timing of the evaluations is different between the groups.</p> <p>Rating is "0.5" if the timing is nearly identical (e.g., one day</p>

<p>study groups.</p>	<p>apart).</p> <p>Rating is "1.0" if the timing of the assessments between the groups is identical.</p>
<p>Analyzed by Intention to Treat: This rating is for whether the study was analyzed with an intent to treat analysis.</p>	<p>Rating is "0" if it was not analyzed by intent to treat.</p> <p>Rating is "0.5" if there is not mention of intent to treat analysis, but the results would not have been different (e.g., there was nearly 100% compliance and no drop-outs).</p> <p>Rating is "1.0" if the study specifies analyses by intention to treat.</p>
<p>Lack of Bias: This rating does not enter into the overall rating of an article. This is an overall indication of the degree to which biases are felt to be present in the study.</p>	<p>Rating is "0" if there are felt to be significant biases that are uncontrolled in the study and may have influenced the study's results.</p> <p>Rating is "0.5" if there are felt to be some biases present, but the results are less likely to have been influenced by those biases.</p> <p>Rating is "1.0" if there are few biases, or those are well controlled and unlikely to have influenced the study's results.</p>

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(B) Table B—Strength of Evidence Ratings

Levels of evidence shall be used to rate the quality of the body of evidence. The body of evidence shall consist of all studies on a given topic that are used to develop evidence-based recommendations. Levels of evidence shall be applied when studies are relevant to the topic and study working populations. Study outcomes shall be consistent and study data shall be homogeneous.

A	Strong evidence base: One or more well-conducted systematic reviews or meta-analyses, or two or more high-quality studies.
B	Moderate evidence base: At least one high-quality study, a well-conducted systematic review or meta-analysis of lower-quality studies or multiple lower-quality studies relevant to the topic and the working population.
C	Limited evidence base: At least one study of intermediate quality.
D	Insufficient Evidence: Evidence is insufficient or irreconcilable.

~~(2) Evidence shall be given the highest weight in the order of the strength of evidence.~~

(a) For purposes of sections 9792.25-9792.26, the following definitions shall apply:

(1) "Bias" means any tendency to influence the results of a trial (or their interpretation) other than the experimental intervention. Biases include inadequate generation of the randomization sequence, inadequate concealment of allocation, selection, confounding, lack of blinding, selective outcome reporting, failure to do intention-to-treat analysis, early stopping, selection, and publication.

(2) "Blinding" means a technique used in research to eliminate bias by hiding the intervention from the patient, clinician, and/or any others who are interpreting results.

(3) "Biologic plausibility" means the likelihood that existing biological, medical, and toxicological knowledge explains observed effect.

(4) "Case-control study" means a retrospective observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups.

(5) "Case-series" means a group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment. This may be done prospectively or retrospectively.

(6) "Case report" means a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. Case reports usually describe an unusual or novel occurrence.

(7) "Cohort study" (also known as Follow-up or Prospective study) means an epidemiologic study in which two or more groups of people that are free of disease and that differ according to the extent of exposure to a potential cause of the disease are compared with respect to the incidence (occurrence of the disease) in each of the groups. This may include a comparison of treated and non-treated patients. The main feature of cohort study is observation of large numbers of people over a long period of time (commonly years) with comparison of incidence rates in groups that differ in exposure levels.

(8) "Concealment of allocation" means precautions taken to ensure that the groups to which patients or subjects are assigned as part of a study are not revealed prior to definitively allocating them to their respective groups.

(9) "Confounding variable" means extrinsic factor associated with the exposure under study and cause of the outcome.

(10) "Cross-sectional study" means a study that examines the relationship between diseases (or other health-related characteristics) and other variables of interest as they exist in a defined population at one particular time. Note that disease prevalence rather than disease incidence is normally recorded in a cross-sectional study. The temporal sequence of cause and effect cannot necessarily be determined in a cross-sectional study.

(11) "Diagnostic test" means any medical test performed to confirm, or determine the presence of disease in an individual suspected of having the disease, usually following the report of symptoms, or based on the results of other medical tests. Some examples of diagnostic tests include performing a chest x-ray to diagnose pneumonia, and taking skin biopsy to detect cancerous cells.

(12) "Disease prevalence" means rate of a disease or condition at any particular point in time.

(13) "Disease incidence" means new cases of disease or condition over a period of time.

(14) “Expert opinion” means a determination by an expert, through a process of evidenced-based thinking that a given practice should or should not be labeled evidenced based, and published in a peer-reviewed medical journal.

(15) “Index test” means the diagnostic procedure or test that is being evaluated in a study.

(16) “Inception cohort study” means a group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition, or before the condition develops.

(17) “Intention to treat” means a procedure in the conduct and analysis of randomized controlled trials. All patients allocated to a given arm of the treatment regimen are analyzed together as representing that treatment arm, whether or not they received or completed the prescribed regimen. Failure to follow this step defeats the main purpose of random allocation and can invalidate the results.

(18) “Low risk of bias” means those trials or studies that contain methodological safeguards to protect against biases related to generation of the randomization sequence, concealment of allocation, selection, blinding, selective outcome reporting, early stopping, and intention to treat.

(19) “Meta-analysis” means a mathematical process whereby results from two or more studies are combined using a method that provides a weight to each study that reflects the statistical likelihood (variance) that its results are more likely than not to be true. A meta-analysis may be part of a systematic review or may be performed in the absence of a systematic review.

(20) “Post-marketing surveillance” means a procedure implemented after a drug has been licensed for public use, designed to provide information on the actual use of the drug for a given indication and on the occurrence of side effects, adverse reactions, etc. This is a method for identifying adverse drug reactions, especially rare (< 1% incidence) ones.

(21) “Prognosis” means the prospect of survival and recovery from a disease as anticipated from the usual course of that disease or indicated by special features of the case.

(22) "Prospective study" (also known as Follow-up or Cohort study) means an epidemiologic study in which two or more groups of people that are free of disease and that differ according to the extent of exposure to a potential cause of the disease are compared with respect to the incidence (occurrence of the disease) in each of the groups. This may include a comparison of treated and non-treated patients. The main feature of prospective study is observation of large numbers of people over a long period of time (commonly years) with comparison of incidence rates in groups that differ in exposure levels.

(23) "Randomized trial" means a clinical experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental diagnostic, preventive, or therapeutic procedure, maneuver, or intervention. The results are assessed by rigorous comparison of rates of disease, death, recovery, or other appropriate outcome in the study and control groups.

(24) "Reference standard" means the gold standard to which an index test is being compared

(25) "Risk of bias" means a term that refers to the advertent or inadvertent introduction of bias into trials because of methodological insufficiencies.

(26) "Selective outcome reporting" means the failure to report all of the outcomes that are assessed in a trial, including a post hoc change in the primary outcome.

(27) "Systematic review" means the application of strategies that limit bias in the assembly, critical appraisal, and synthesis of all relevant studies on a specific topic. Systematic reviews focus on peer-reviewed publications about a specific health problem and use rigorous, standardized methods for selecting and assessing articles. A systematic review differs from a meta-analysis in not including a quantitative summary of the results. However, a meta-analysis may be part of a systematic review.

(28) "Treatment benefits" means positive patient-relevant outcome associated with an intervention, quantifiable by epidemiological measures such as absolute risk reduction and number needed to treat.

(29) “Treatment harms” means an adverse patient-relevant outcome associated with an intervention, identifiable by epidemiological measures such as absolute increase risk of occurrence or number needed to harm if possible, but also identifiable by post-marketing surveillance.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.25.1. Process to Determine When Medical Care is Reasonable and Necessary

(a) Pursuant to Labor Code section 4600 the employer shall provide medical care that is reasonably required to cure or relieve the injured employee from the effects of his or her injury.

(b) The MTUS is the standard for the provision of medical care in accordance with Labor Code section 4600. However, in situations when the MTUS is inapplicable, medical care shall be in accordance with the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines and/or peer-reviewed published studies that are nationally recognized by the medical community.

(c) When the MTUS is inapplicable, a medical literature search shall be conducted by those providers making treatment decisions, including the requesting provider and medical reviewers, to find medical evidence that is directly applicable to the injured worker’s specific medical condition. Recommendations found in the medical treatment guideline and/or peer-reviewed published study that support and/or oppose the treatment or diagnostic service requested by the injured worker shall be cited.

(d) The cited recommendations shall be evaluated using EBM-based principles as set forth in sections 9792.25.2 and 9992.25.3 to determine which recommendation is supported with the best available

Comment [RW3]: This draft regulation has overlooked the most significant source of relevant evidence available: The response of the specific patient to a specific intervention under consideration.

There are many instances of individuals obtaining meaningful objective or functional benefit from modes of treatment that have not been found to be effective for a studied population. To deny these individuals effective care based on the results of a population study is a dubious proposition at best.

Likewise, there are many instances of individuals who appear to be excellent candidates for a specific intervention based on relevant scientific evidence; but for whom there exists a meaningful body of evidence of prior failed treatment of the type under consideration. To provide these individuals ineffective care is likewise a dubious proposition.

Clinical evidence of treatment efficacy arising from prior exposure of the specific patient to the specific modality under consideration deserves consideration at or near the very pinnacle of the EBM pyramid.

The proposed structure, coupled with the proposed deletion of the regulatory definition of functional improvement, effectively and inappropriately removes consideration of the specific patient from the EBM process.

medical evidence. Medical care that is reasonably necessary to cure or relieve the injured worker from the effects of his or her injury shall be in accordance with the recommendation supported with the best available medical evidence.

(e) Where there is a discrepancy between the recommendations of two different medical treatment guidelines or peer-reviewed published studies, the following framework to evaluate the strength of evidence used to support the differing recommendations shall apply:

(1) Medical Treatment Guidelines: Where there is a discrepancy between the recommendations of two medical treatment guidelines, the strength of evidence methodology set forth in section 9792.25.2 shall be used to determine the highest quality medical treatment guideline.

(2) Peer-reviewed Published Studies: Where there is a discrepancy between the recommendations of two peer-reviewed published studies, the strength of evidence methodology set forth in §9792.25.3 shall be used to determine the highest quality peer-reviewed published study.

(3) Medical Treatment Guidelines vs. Published Study: Medical treatment guidelines contain citations of studies used to support its recommendations. However, there are peer-reviewed studies that are scientifically based and published in journals that are nationally recognized by the medical community that have not been used to support a medical treatment guideline recommendation. Where there is a discrepancy between the recommendation in a medical treatment guideline and the recommendation of a published study that is not part of a medical treatment guideline, the strength of evidence methodology set forth in §9792.25.3 shall be used to determine the highest quality published study. The studies used to support the medical treatment guideline recommendation shall be evaluated against the peer-reviewed published study that has not been used to support a guideline recommendation.

(f) In the interest of efficiency and consistency, when conducting the medical literature search of the large body of available medical evidence, the following search sequence shall be followed:

Comment [RW4]: The operative question here is, "Who shall make this determination?"

Treating physicians and UR physicians are generally field practitioners rather than academics. Neither group has the skill set to apply the AGREE instrument properly. Additionally, treating physicians have an economic interest in exaggerating the quality of their favorite guideline, and UR physicians generally have an economic incentive to skip the process of guideline evaluation entirely.

In instances where the treating physician and UR physician disagree on which guideline is correct, the dispute will be settled by an IMR physician. That person is also not an academic, and has a strong economic interest in skipping the AGREE process entirely.

For these reasons, it is recommended that the AD consider having the Medical Evidence Evaluation Advisory Committee, or similar working group, conduct their own AGREE assessment of commonly used and/or state-developed guidelines; and to make those scores available in a public manner.

(1) Search the most current version of ACOEM and/or ODG and choose the recommendation that is supported by the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.3; if no relevant recommendations are found or if the current version is more than three years old then,

(2) Search the most current version of workers' compensation medical guidelines established by one or more US state governments or by the US federal government; if no relevant recommendations are found or if the current version is more than three years old then,

(3) Search other evidenced based medical treatment guidelines that are recognized by the national medical community and are scientifically based. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: www.guideline.gov/; if no relevant recommendations are found or if the current version is more than three years old then,

(4) Search for studies that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community. A search for peer-reviewed published studies may be conducted by accessing the U.S. National Library of Medicine's database of biomedical citations and abstracts that is searchable at the following website: www.ncbi.nlm.nih.gov/pubmed. Other searchable databases may also be used.

Comment [RW5]: Recommended that the use of peer-reviewed publications be restricted to randomized controlled clinical trials or better (systematic review of literature; meta-analysis).

Peer-reviewed publications also include hypotheses, in vitro studies, animal studies, case studies, case series, and non-randomized and/or non-controlled trials. All of these should be properly considered as not constituting scientific evidence of treatment safety or efficacy; and should not be used to support an assertion that any specific course of treatment is, or is not, medically necessary.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.25.2 Strength of Evidence - Method for Evaluating the quality of Medical Treatment Guidelines

(a) To evaluate the quality of a medical treatment guideline the modified Appraisal of Guideline for Research & Evaluation (AGREE) II medical guideline evaluation tool shall be applied.

(b) The modified AGREE II consists of 27 key items organized within 8 domains followed by 2 global rating items. Each domain captures a unique dimension of guideline quality.

(1) Each of the 27 key items shall be scored from 1 to 7, with 1 indicating strong disagreement with the statement expressed in the item and 7 indicating strong agreement with the statement expressed in the item. A score of 1 would be appropriate if there is no information or if the concept is very poorly reported, whereas a score of 7 would be warranted if the quality of the reporting is exceptional. Scores between 2 and 6 represent how close the reporting is to these two extremes.

(2) An overall score is then calculated for each of the eight domains. In order to do this, the total item scores for all of the items are summed. The scaled domain score is calculated in the following manner:

Scaled domain score =

Obtained score – minimum possible score

Maximum possible score – minimum possible score

The minimum possible score is 1 for each item and the maximum possible score is 7 for each item. If multiple reviewers are used, the minimum and maximum possible scores are the obtained score multiplied by the number of reviewers. The scaled domain score, when converted to a percentage by multiplying the final result by 100%, represents how close to perfect the score for that domain was.

(3) The guideline with the highest percentage score shall be used as the source to approve or deny a treatment or diagnostic service recommendation.

(A) Although the application of the AGREE II medical guideline evaluation tool leads to a percentage score, the figure may slightly vary between reviewers because individual judgments are still required.

Therefore, the percentage scores calculated by any reviewer shall remain confidential and will not be disclosed in the decision.

(c) The eight (8) domains and 27 key items of the modified AGREE II are as follows:

(1) Domain One - Scope and Purpose: is concerned with the overall aim of the guideline, the specific health questions, and the target population.

(A) Item 1. The overall objective(s) of the guideline is (are) specifically described.

(B) Item 2. The health question(s) covered by the guideline is (are) specifically described.

(C) Item 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

(2) Domain Two – Stakeholder Involvement: focuses on the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users.

(A) Item 4. The guideline development group includes individuals from all relevant professional groups.

(B) Item 5. The views and preferences of the target population (patients, public, etc.) have been sought.

(C) Item 6. The target users of the guideline are clearly defined.

(3) Domain Three – Rigor of Development: relates to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and to update them.

(A) Item 7. Systematic methods were used to search for evidence.

(B) Item 8. The criteria for selecting the evidence are clearly described.

(C) Item 9. The strengths and limitations of the body of evidence are clearly described.

(D) Item 10. The methods for formulating the recommendations are clearly described.

(E) Item 11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

(F) Item 12. There is an explicit link between the recommendations and the supporting evidence.

(G) Item 13. The guideline has been externally reviewed by experts prior to its publication.

(H) Item 14. A procedure for updating the guideline is provided.

(4) Domain Four – Clarity of Presentation: deals with the language, structure, and format of the guideline.

(A) Item 15. The recommendations are specific and unambiguous.

(B) Item 16. The different options for management of the condition or health issue are clearly presented.

(C) Item 17. Key recommendations are easily identifiable.

(5) Domain Five – Applicability: pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and resource implications of applying the guideline.

(A) Item 18. The guideline describes facilitators and barriers to its application.

(B) Item 19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

(C) Item 20. The potential resource implications of applying the recommendations have been considered.

(D) Item 21. The guideline presents monitoring and/or auditing criteria.

(6) Domain Six – Editorial Independence: is concerned with the formulation of recommendations not being unduly biased with competing interests.

(A) Item 22. The views of the funding body have not influenced the content of the guideline.

(B) Item 23. Competing interests of guideline development group members have been recorded and addressed.

(7) Domain Seven – Conflict of Interest: is concerned with a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

(A) Item 24. All conflicts of interest of each guideline development group member were reported and discussed by the prospective development group prior to the onset of his or her work.

(B) Item 25. Each panel member explained how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendation.

(C) Item 26. The chairperson of the guideline development group had no conflict of interest.

(8) Domain Eight – Currency of Guideline: is concerned with how recently the

guideline was developed or the timeliness of the guideline updates.

(A) Item 27. The guideline is being updated in a timely fashion (typically at least every 3 years and, if the guideline is more than 5 years old, it should be considered to be out of date).

(d) After each of the 27 items are reviewed and scored, an assessment of the entire guideline shall be made as follows:

(1) The first step is an overall assessment of the quality of the guideline and represents a subjective assessment, again scored from 1 (lowest quality) to 7 (highest quality).

(2) The second step in the assessment is the recommendation regarding using the guideline and will result in one of three possibilities:

(A) Recommending the guideline for use as it is;

(B) Recommending the guideline for use with modifications; or

(C) Not recommending the guideline for use.

(g) If a guideline is recommended as “Yes” or “Yes with modifications”, then it may be considered a source to approve or deny medical treatment recommendations on a given medical condition.

(h) If a guideline is recommended as a “no” it should not be used as the source to approve or deny a medical treatment recommendation. However, the individual recommendations in this guideline may still be used as the source to approve or deny a medical treatment recommendation. The original studies supporting the individual recommendation must be evaluated using the process described in section 9792.25.3.

Comment [RW6]: This form of global recommendation is one that will have to be provided by some group or individual who is independent from the specific course of treatment being considered. Perhaps the Medical Evidence Evaluation Advisory Committee?

(i) The Modified AGREE II Worksheet for the Evaluation of Medical Guidelines is set forth in Appendix A and may be used when applying the Modified AGREE II medical evaluation tool.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

Appendix A to Section 9792.25.2.

THE MODIFIED AGREE II WORKSHEET FOR THE EVALUATION OF MEDICAL GUIDELINES

Domain 1. Scope and purpose

Item 1. The overall objective(s) of the guideline is (are) specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 2. The health question(s) covered by the guideline is (are) specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 2. Stakeholder involvement

Item 4. The guideline development group includes individuals from all relevant professional groups

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 5. The views and preferences of the target population (patients, public, etc.) have been sought

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 6. The target users of the guideline are clearly defined

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 3. Rigor of development

Item 7. Systematic methods were used to search for evidence

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 8. The criteria for selecting the evidence are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 9. The strengths and limitations of the body of evidence are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 10. The methods for formulating the recommendations are clearly described

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 11. The health benefits, side effects, and risks have been considered in formulating the recommendations

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 12. There is an explicit link between the recommendations and the supporting evidence

1	2	3	4	5	6	7
<u>Strongly disagree</u>						<u>Strongly agree</u>

Comments:

Item 13. The guideline has been externally reviewed by experts prior to its publication

1	2	3	4	5	6	7
<u>Strongly disagree</u>						<u>Strongly agree</u>

Comments:

Item 14. A procedure for updating the guideline is provided

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Domain 4. Clarity of presentation

Item 15. The recommendations are specific and unambiguous

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Item 16. The different options for management of the condition or health issue are clearly presented

<u>1</u> Strongly disagree	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> Strongly agree
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Comments:

Item 17. Key recommendations are easily identifiable

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 5. Applicability

Item 18. The guideline describes facilitators and barriers to its application

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 19. The guideline provides advice and/or tools on how the recommendations can be put into practice

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 20. The potential resource implications of applying the recommendations have been considered

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 21. The guideline presents monitoring and/or auditing criteria

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 6. Editorial independence

Item 22. The views of the funding body have not influenced the content of the guideline

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 23. Competing interests of guideline development group members have been recorded and addressed

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 7. Conflict of interest

Item 24. All conflicts of interest of each guideline development group member were reported and discussed by the prospective development group prior to the onset of his or her work

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 25. Each panel member explained how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendation

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Item 26. The chairperson of the guideline development group had no conflicts of interest

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Domain 8. Currency of guideline

Item 27. The guideline is being updated in a timely fashion (typically at least every 3 years and, if the guideline is more than 5 years old, it should be considered to be out of date)

<u>1</u> <u>Strongly disagree</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u> <u>Strongly agree</u>
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Comments:

Overall guideline assessment

1. Rate the overall quality of this guideline

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>
<u>Lowest possible quality</u>						<u>Highest possible quality</u>

Comments:

2. I would recommend this guideline for use

- Yes
- Yes, with modifications
- No

Comments:

§ 9792.25.3 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support Studies Published in the Medical and Scientific Literature

(a) To evaluate the quality of evidence used to support a study published in the medical or scientific literature, the DWC/MTUS Hierarchy of Evidence for Different Clinical Question as set forth in section 9792.25(b) shall be applied as follows:

(1) Determine if the study is directly applicable to the specific medical condition or diagnostic test requested by the injured worker. Direct applicability refers to the extent to which the individual patients, workers, or subjects, interventions, and outcome measures are similar to the injured worker and his or her specific medical condition or diagnostic service request. A study published in the medical or scientific literature that is not directly applicable to the specific medical condition or diagnostic test requested by the injured worker if it evaluates a different population, setting, or intervention should not be used as the source to approve or deny a medical treatment recommendation unless a directly applicable study is not available. If directly applicable studies are not available, the population most similar to the injured worker should be used and the reasoning documented.

(2) Determine the design used to support the original study. Study designs are categorized as follows:

(A) Systematic Review of:

1. Randomized Control Trial

2. Prospective or Cohort Studies

(B) Randomized Control Trial

(C) Observational studies:

1. Prospective study or Cohort Study

2. Cross-sectional study

3. Case-control study

5. Case-series

6. Uncontrolled or observational study

7. Case report

D. Published expert opinion

(3) Determine the study quality used to support the original study. Factors to consider include, but are not limited to, the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective outcome reporting, early stopping, and intention to treat. A study that is determined to be of poor quality due to the presence of these factors shall not be used as justification for a medical treatment decision.

(4) Answer the four clinical questions in the Hierarchy of Evidence for Different Clinical Questions as set forth in Section 9792.25.4 and apply the corresponding hierarchy of evidence. The four clinical questions are as follows:

Comment [RW7]: It is recommended that study designs in C and D be excluded from consideration as evidence in deciding questions of medical necessity.

(A) If the original study answers the question how useful is Treatment X in treating patients with Disease Y; then the hierarchy of evidence set forth under Treatment Benefits shall apply.

(B) If the original study answers the question how useful is Test X in diagnosing patients with Disease Y; then the hierarchy of evidence set forth under Diagnostic Test shall apply.

(C) If the original study answers the question what will happen to a patient with Disease Y if nothing is done; then the hierarchy of evidence set forth under Prognosis shall apply.

(D) If the original study answers the question what are the harms of intervention (treatment or diagnostic test) X in patients with Disease Y; then the hierarchy of evidence set forth under Treatment Harms shall apply.

(5) The levels of evidence are listed from highest to lowest, as defined by the principles of Evidence Based Medicine, in each Clinical Question category. Levels of evidence shall be applied in the order listed. Recommendation for or against medical treatment based on a lower level of evidence shall be permitted only if every higher ranked level of evidence is inapplicable to the employee's medical condition. The level of evidence for each published study (e.g. 1a, 1b, 2, etc.) shall be documented and included with the citation.

Comment [RW8]: Excellent concept, but impractical in context. Who makes this determination?

Just as with the AGREE instrument, treating physicians, UR physicians and IMR physicians will be ill-equipped to categorize publications with regard to evidence quality. WCAB judges will be completely lost in this process.

While the concept is sound, without a simplified implementation scheme and an independent "rater of evidence", this will create more problems than it will solve.

(A) When relying on lower levels of evidence, documentation shall be provided that higher levels of evidence are absent.

(b) DWC/MTUS Hierarchy of Evidence for Different Clinical Questions shall apply:

DWC/MTUS Hierarchy of Evidence for Different Clinical Questions

<u>Evidence Level</u>	<u>Treatment Benefits</u> How useful is Treatment X in treating patients with Disease Y?	<u>Diagnostic Test</u> How useful is Test X in diagnosing patients with Disease Y?	<u>Prognosis</u> What will happen to a patient with Disease Y if nothing is done?	<u>Treatment Harms</u> What are the harms of intervention (treatment or diagnostic test) X in patients with Disease Y?
<u>1a</u>	<u>Systematic review of low risk of bias randomized trials</u>	<u>Systematic review of high-quality prospective studies (homogeneous sample of patients, consecutively enrolled, all undergoing the index test and reference standard) or systematic review of low risk of bias randomized control trial with low risk bias</u>	<u>Systematic review of inception cohort studies or of control arms of low risk of bias randomized trials</u>	<u>Systematic review of randomized trials with low risk of bias</u>
<u>1b</u>	<u>Randomized trial with low risk of bias</u>	<u>High-quality prospective study or cohort study or randomized control trial with low risk of bias</u>	<u>Inception cohort study or control arm from one randomized trial with low risk of bias</u>	<u>Randomized trials with low risk of bias</u>
<u>1c</u>	<u>One or more randomized trials with identified risks of bias (or systematic review of such trials)</u>	<u>Biased cross-sectional study</u>	<u>Cohort study or control arm of randomized trial with identified risks of bias</u>	<u>Prospective study</u>
<u>2</u>	<u>Non-randomized cohort studies that include controls</u>	<u>Case-control study enrolling a broad spectrum of patients and controls with</u>	<u>Case-series or case control studies</u>	<u>Randomized trial(s) with identified risk of bias</u>

		<u>conditions that may be confused with the disease being considered</u>		
<u>3</u>	<u>Case-control studies or historically controlled studies</u>	<u>Case-control study using severe cases and healthy controls</u>		<u>Non-randomized controlled cohort/follow-up study (post-marketing surveillance)</u>
<u>4</u>	<u>Uncontrolled studies (case studies or case reports)</u>		<u>Uncontrolled studies (observational studies, case studies, or case reports)</u>	<u>Consistent case reports (for example, individual case safety reports from US Food and Drug Administration, which are available at the following website: www.fda.gov/ForIndustry/DataStandards/IndividualCaseSafetyReports/default.htm)</u>
<u>5</u>	<u>Published expert opinion</u>	<u>Published expert opinion</u>	<u>Published expert opinion</u>	<u>Toxicological or mechanistic data that demonstrate or support biologic plausibility</u>

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

§ 9792.26. Medical Evidence Evaluation Advisory Committee

(a)(1) The Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Medical Director on matters concerning the MTUS. The recommendations are advisory only and shall not constitute scientifically based evidence.

(A) If the Medical Director position becomes vacant, the Administrative Director shall appoint a competent person to temporarily assume the authority and duties of the Medical Director as set forth in this section, until such time that the Medical Director position is filled.

(2) The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of ~~17~~ 19 members of the medical community holding the following licenses: Medical Doctor (M.D.) board certified by an American Board of Medical Specialties (ABMS) approved specialty board; Doctor of Osteopathy (D.O.) board certified by an ABMS or American Osteopathic Association (AOA) approved specialty board; M.D. board certified by a Medical Board of California (MBC) approved specialty board; Doctor of Chiropractic (D.C.); Physical Therapy (P.T.); Occupational Therapy (O.T.); Acupuncture (L.Ac.); Psychology (PhD.); ~~or~~ Doctor of Podiatric Medicine (DPM); Pharmacologist (PharmD); Nurse Practitioner (NP) or Registered Nurse (RN) or equivalent, and representing the following specialty fields:

(A) One member shall be from the orthopedic field;

(B) One member shall be from the chiropractic field;

(C) One member shall be from the occupational medicine field;

(D) One member shall be from the acupuncture medicine field;

(E) One member shall be from the physical therapy field;

(F) One member shall be from the psychology field;

(G) One member shall be from the pain specialty field;

(H) One member shall be from the occupational therapy field;

(I) One member shall be from the psychiatry field;

(J) One member shall be from the neurosurgery field;

(K) One member shall be from the family physician field;

(L) One member shall be from the neurology field;

(M) One member shall be from the internal medicine field;

(N) One member shall be from the physical medicine and rehabilitation field;

(O) One member shall be from the podiatrist field;

(P) One member shall be from the pharmacology field;

(Q) One member shall be from the nursing field;

(PR) Two additional members shall be appointed at the discretion of the Medical Director or his or her designee.

(3) In addition to the ~~seventeen~~ nineteen members of the medical evidence evaluation advisory committee appointed under subdivision (a)(2) above, the Medical Director, or his or her designee, may appoint an additional three members to the medical evidence evaluation advisory committee as subject matter experts for any given topic.

(b) The Medical Director, or his or her designee, shall serve as the chairperson of the medical evidence evaluation advisory committee.

(c) To evaluate evidence when making recommendations to revise, update or supplement the MTUS, the members of the medical evidence evaluation advisory committee shall:

(1) ~~Apply the strength of evidence methodology as set forth in requirements of subdivision (b) of section 9792.25 section 9792.25.2 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence based, and nationally recognized by the medical community to evaluate the quality of medical treatment guidelines.~~

(2A) ~~Apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of section 9792.25 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of section 9792.25;~~ Recommendations in guidelines that have a low AGREE II overall score may still be used provided that the evidence used to support the recommendations are the best available medical evidence. To determine the best available medical evidence, the strength of evidence methodology set forth in section 9792.25.3 shall apply.

Comment [RW9]: What constitutes a "low" score"? Who will be doing the scoring?

(2) Apply the strength of evidence methodology as set forth in section 9792.25.3 to determine the highest quality peer-reviewed published study.

Comment [RW10]: Not sure what the Committee is being charged with here.

Will the Committee serve as an ad hoc advisory group to determine which side of a dispute has the strongest peer-reviewed evidence?
Will they be making a recommendation regarding the strongest peer-reviewed evidence for use of service X in the treatment/evaluation of condition Y?
Something altogether different?

~~(3) Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of section 9792.25.~~

(d) The members of the medical evidence evaluation advisory committee, except for the three subject matter experts, shall serve a term of two year period, but shall remain in that position until a successor is selected. The subject matter experts shall serve as members of the medical evidence evaluation advisory committee until the evaluation of the subject matter guideline is completed. The members of the committee shall meet as necessary, but no less than ~~four (4)~~ three (3) times a year.

(e) The Administrative Director, in consultation with the Medical Director, may revise, update, and supplement the MTUS as necessary.

Authority: Sections 133, 4603.5, 5307.3, and 5307.27, Labor Code.

Reference: Sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

Hans Evers, M.D.

August 25, 2013

Why is there a reference to clinical expertise and patient or community values in the new definition of "Evidence Based Medicine"? Blood-letting was practiced for centuries because of clinical expertise of medical authorities and bloodletting was in great demand because of patient and community values. Regarding current patient and community values treating physicians could -per proposed regs- request TX with magnets or homeopathic TX and requesting physicians could cite "scientific" and peer-reviewed articles in support of this treatment. How shall a UR organization respond to such a request after MEDLINE is abolished as a reference and after scientific is defined in a circular way: ""Scientifically based" means based on scientific literature,....." If California's DWC does not like Evidence Based Medicine than DWC should

say so. And why making the term "scientific" meaningless instead of honestly saying "not scientific"?

Why getting rid of the definition of "functional improvement"? What is the new definition of "functional improvement"?

Also troublesome are the sections which address the issue of "when MTUS is inapplicable". After watering down the term "Evidence Based Medicine" and making the term "scientific" meaningless the proposed new regs require a multi-step and cumbersome evaluation of the merits of new supporting scientific evidence submitted by the requesting physician if this scientific evidence is not considered in ACOEM or OGD etc.. ("The studies used to support the medical treatment guideline recommendation shall be evaluated against the peer-reviewed published study that has not been used to support a guideline recommendation.") That would be a very time-consuming and subjective process and effectively shut down the UR process.

My overall impression is: the proposed regs are a potential big win for health care providers who are seeking to treat patients with other than scientific and evidence based medicine and who are afraid of their medical treatment being evaluated in terms of objective functional improvement.

Richard S. Lieberman, M.D. President
California Society of Industrial Medicine & Surgery

August 23, 2013

The Mental Health Treatment Subcommittee of the California Society of Industrial Medicine and Surgery (CSIMS) is writing to alert the Division to what is a growing number of injured workers with legitimate needs for psychiatric treatment within existing case law (*Granado v WCAB* and *Braewood v WCAB*) and consistent with SB863 but are not able to receive such treatment. This letter is one of urgency for your consideration.

Especially since July 1, 2013, we and many of our peers throughout the state have observed that patients with accepted injuries and verified mental conditions have encountered a pattern of denial of care for psychiatric services. Responses received from claims adjusters, utilization reviewers and subsequently, independent medical reviewers, contain almost no cases of authorized treatment despite ample documentation of need for treatment in Requests for Authorization (RF A), even when the RF A includes citations of evidence based guidelines appropriate for treatment of the condition. We have attached two examples for your reference.

[Copies available upon request.] Literally hundreds more could be supplied. As you will read, both treating physicians submitted a request for quite modest durations of treatment.

The first is a denial from [NAME REDACTED] working on behalf of [NAME REDACTED], dated 7/29/13. In it, the reviewer (not a psychiatrist or psychologist) cites then Medical Treatment Utilization Schedule (MTUS) guidelines for chronic pain, ignoring the diagnosis of Major Depression. He then cites the Work Loss Data Institute's *Official Disability Guidelines* (ODO) to recommend cognitive behavioral therapy for depression but, ironically, finds language within those same ODG guidelines with which to question the need for even a clinical office visit.

The second is a response from [NAME REDACTED] on behalf of [NAME REDACTED] for its insured, [NAME REDACTED], and dated 6/21/13. In this response, the reviewer limits his consideration to the MTUS guidelines for chronic pain. While he notes that such guidelines do recommend treatment, he cites a lack of an established "causal relationship of the psychological complaints to the industrial injury" and denies care. This physician inappropriately made his own AOE/COE determination and used it as the primary reason to deny treatment.

Of course, neither reviewer has ever examined the injured worker. It is also important to note that this pattern of denial of care occurs even when the physician is a member of the appropriate MPN and has an appropriate referral.

We believe that the main contributor to this pattern is the lack of clear guidelines for psychiatric treatment upon which Utilization Review (UR) and Independent Medical Review (IMR) can rely in order to authorize treatment. The Medical Treatment Utilization Schedule (MTUS) is cited repeatedly in denials even though it contains no guidelines addressing psychiatric treatment. In error, reviewers often rely upon the MTUS guidelines for treatment of chronic pain instead. This may be expeditious for UR, but it is not medically appropriate and ultimately may be very dangerous for the injured worker.

The Medical Board of California (MBC) was asked recently by a member of the legislature to investigate a similar incident committed by a state licensee. We understand that investigation may be ongoing, but these situations should not get that far.

We would like to add that we consider both the [NAME REDACTED] and [NAME REDACTED] denials auditable violations subject to penalties pursuant to 8CCR, § 9792.12 in that they do not correctly cite an applicable guideline upon which to base a denial of care. We also cannot avoid reiterating the egregious nature of the [NAME REDACTED] reviewer's unilateral decision regarding AOE/COE. We do not read that he has any such authority. Since he is a California licensee, based on a negative outcome for the injured worker, his actions expose him to a possible investigation and action by the MBC. While the IMR process is available to resolve these UR denials, we believe the goal is to avoid this costly and, especially for mental health patients, very time consuming process.

The California Code of Regulations, Title 8, § 9792.8(a) (2) states that when conditions or injuries are not addressed by the.... MTUS, "authorized treatment shall be in accordance with other evidence based medical treatment guidelines ... " Similarly, Labor Code§ 4610.S(c) (2) (A) provides that medical necessity decision in the course of the Independent Medical Review (IMR) process, shall be based upon the contents of the MTUS. If the MTUS does not contain an applicable guideline for the condition, then the reviewer shall rely on the following standards in this order: (B) peer reviewed scientific and medical evidence regarding the effectiveness of the disputed service, (C) nationally recognized professional standards, (D) expert opinion and finally, (E) generally accepted standards of medical practice. This regulation instructs that in IMR these criteria are to be "applied in the order listed allowing reliance on a lower ranked standard only if every higher ranked standard is inapplicable to the employee's medical condition.... "

Application of the MTUS Chronic Pain Guidelines to psychiatric conditions such as Major Depression and Post Traumatic Stress Disorder (PTSD) is a clear violation of the Labor Code and Regulations as cited above. Yet, this pattern of utilization review practice has been demonstrated repeatedly by reviewers.

With respect to psychiatric conditions, UR and IMR reviewers have no clear guideline as to what standards of medical necessity apply since the MTUS is mute on this vital issue. This circumstance leads to confusion and does not allow for a rational, consistent pattern of authorizing necessary care.

This lack of guidance is magnified when a course of past treatment or the treatment plan for a newer injury may require pharmacological intervention. On this specific issue, we cannot emphasize enough the destructive force of a knee-jerk comparison of a psychiatric disorder with what otherwise might be cast as a pain management problem. Yet, as we previously mention and as the attached examples point out, a lack of appropriate treatment guidelines provides UR with no place to turn. It is apparent that as a result, rather than seek clinically applicable treatment guidelines, denials are becoming the norm.

Numerous injured workers have legitimate need for psychiatric treatment, and many of these individuals are depressed, experience suicidal ideation, and are, as a result, in poor compliance with other medical/surgical treatment regimens for industrial injuries. Deteriorating overall health and a lack of recovery from all injuries are almost always consequences of this pattern. Far past the point of failing to cure or relieve, this lack of a clear, appropriate MTUS guideline for psychiatric treatment is now, unfortunately, actively causing harm to this population.

Your attention to this issue is needed urgently. We hope you agree.

While clearly a secondary concern to the health of our patients, the added costs to employers of IMR and to our own and our staff time in follow up, plus the "hidden" costs of the unnecessary

deterioration in the patient's health and ability to return to a productive lifestyle, all combine to create yet another source of urgency for a solution to this undeniable and growing problem. It is made clear to us daily, and we hope after reading this letter to you as well, that an evidence-based guideline specifically addressing psychiatric treatment must be established within the MTUS as soon as possible.

Unfortunately, one possible alternative, the ODO guidelines, do not meet the criteria outlined in CCR8, §9792.8(a) (2) (B), (C), (D), and (E), as mentioned earlier and create artificial limitations on treatment that are not supported by evidence based, peer reviewed studies. As an example, the requirement that there be "objective evidence of functional improvement after 6 sessions of psychotherapy" to justify additional psychotherapy is akin to recommending that a respirator be withdrawn if the patient fails to breathe on their own after 6 days, or that an antibiotic not be continued or changed if the infection doesn't get better after 6 days, or that treatment for high blood pressure or diabetes or chronic obstructive pulmonary disease should cease if the patient doesn't "objectively" improve in 6 weeks, or recommending that an antibiotic be discontinued if the infection doesn't remit after an incomplete 6 day course of the best choice medication. Further, nothing in the ODO guidelines defines the process required to measure "objective improvement," thus creating another arbitrary obstacle to necessary care. We know you appreciate that psychiatric conditions are complicated, painful, disabling, and potentially lethal, similar to other medical conditions. They should not be subject to discriminatory, capricious exclusions. The arbitrary limitations on treatment frequency imposed by ODO are not found in Medicare outpatient treatment guidelines, nor are they found in those of commercial carriers such as Anthem/ Blue Cross. Further, these limitations are contrary to the parity requirements for mental health treatment under California law, as well as the federal Affordable Care Act.

Psychiatric and psychological treatment, more than any other medical specialty, requires the establishment of a relationship between doctor and patient that is not disrupted prematurely by delays and interruptions from UR and IMR. If Medicare and Anthem see fit to provide reasonable continuity of care without impingement on the doctor patient therapy relationship, why should injured workers not be afforded similar care? In cases where liability for conditions such as major Depression and Post Traumatic Stress Disorder has been accepted we believe that no less than 25 sessions of psychotherapy and 6 medication visits should be authorized, consistent with American Psychiatric Association guidelines. This initial regimen should be followed by UR reviews according to American Psychiatric Association treatment standards.

Most psychiatrically injured workers suffer from either a Major Depressive Disorder due to the emotional impact of disabling physical injuries or PTSD when the injury has been violent or life threatening. Often both occur together and in such instances are very difficult to treat. Fortunately, well established evidence based guidelines exist for both conditions: the APA guidelines for Major Depression and the Department of Defense/Veteran's Administration (DOD/VA) guidelines for PTSD.

The American Psychiatric Association Treatment Guidelines for depression and numerous other disorders is a product of the preeminent body in this field of specialty. The APA guidelines clearly meet all the necessary standards found in Labor Code § 4610.5 (c) and 8CCR § 9792.8. The APA Guidelines rely on peer reviewed scientific and medical evidence regarding effectiveness of treatment, nationally recognized standards, expert opinions, and generally accepted professional standards of practice. These guidelines provide clear parameters of frequency and duration of cognitive behavioral therapies, pharmacologic, and other treatment modalities appropriate to patients in need of psychiatric treatment.

The APA guidelines can be accessed at: <http://psychiatryonline.org/guidelines.aspx>.

Similarly, the standards described in the DOD/VA guidelines are by far the most recognized standards for treatment of PTSD in its various forms. These guidelines are also evidence based, relying on numerous scientific studies spanning decades of treatment and research, with the highest rate of clinical success.

The *DODN A* guidelines can be accessed at:
http://www.healthquality.va.gov/ptsd/cpg_PTSD-FULL-201011612.pdf.

We submit both sets of guidelines for your consideration and that of the Medical Evidence Evaluation Advisory Committee (MEEAC) at the very first opportunity.

It is very important to note that neither we nor any of the members of the CS IMS subcommittee convened to develop this recommendation have any financial ties to the American Psychiatric Association. On their merit, these guidelines are well defined and have been used in practice for many years. We believe they afford both employers and providers access to a reasonable, structured system for establishing the need for and extent of treatment of psychiatric injuries as well as evidence-based criteria against which to consistently evaluate requests for authorization. We cannot urge you enough to please prioritize the addition of specific psychiatric/psychological treatment guidelines to California's Medical Treatment Utilization Schedule as soon as possible.

Robert R. Kutzner, M.D.

August 21, 2013

Once more the MTUS Medical Evidence Evaluation Advisory Committee § 9792.26 has done a great job. As it should be; the Committee has bolstered the heroic spirit behind their work and clarified its clinical intent. Ooh-Rah!

As for constructive criticism; Mine is as follows with discussion IN CAPs within the MTUS Proposed Changes below.

1) Remove "and patient or community values" in Definitions, 9792.20 e, or include the definition of what is meant by "patient and community values".

2) Put back into the MTUS Definitions, 9792.20 f, your definition of "Functional Improvement".

My closing thought is that your "Proposed Changes" to the MTUS, posted here, is all about Part I. **WHERE IS THE BEEF?** What changes are in the Clinical Part II of the MTUS?

***** PROPOSED CHANGES TO THE MTUS *****

9792.20. Medical Treatment Utilization Schedule—Definitions

(e) ~~“Evidence based Evidence Based Medicine” means based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE. means a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values.~~ I THINK THAT MOST UNDERSTAND THE SPIRIT BEHIND "EVIDENCE BASED MEDICINE" AND THE INTENT TO MAKE REASON, LOGIC, AND SCIENCE ITS FOUNDATION. THIS IS A TAXPAYER FUNDED GOVERNMENT AGENCY EFFORT, BASED ON EVIDENCE NOT POLITICS, TO IMPROVE WC PATIENT CARE, INCREASE FUNCTIONALITY, AND DECREASE HEALTH CARE COST - TRULY ADMIRABLE. MY CONCERN IS THAT THESE PROPOSED CHANGES INCLUDE PATIENT OR COMMUNITY VALUES. PATIENTS ALREADY HAVE THE CONSTITUTIONAL RIGHT TO REFUSE HEALTH CARE AND WHAT DOES THE COMMUNITY HAVE TO DO WITH IT? THROUGH THE MTUS, THE DIV OF WC, IS MAKING HERCULEAN EFFORTS TO OFFER THE BEST "EVIDENCE BASED MEDICINE" GUIDELINES IT CAN. THIS SHOULD NOT BE DEPENDENT ON PERSONAL OPINION NOR COMMUNITY POLITICAL AGENDAS. **OBVIOUSLY THIS NEEDS TO BE STRICKEN.** I DON'T WANT THE CARE I GIVE TO BE DEPENDANT ON NON-MEDICAL PEOPLE. I ALREADY HAVE THAT PROBLEM WITH PATIENTS AND INSURANCE ADJUSTERS. THINK OF THE RAMIFICATIONS: A PATIENT SAYS, "I DON'T WANT, THIS OR THAT, ALL'S I'M HERE FOR IS OXYCONTIN. HOW ABOUT: "I DON'T NEED A PSYCH EVALUATION. I TOLD YOU I HAD ANXIETY SO GIVE ME MY VALIUM." THE REST OF THE MTUS PROPOSED CHANGES DON'T SUPPORT THE NOTION OF PATIENT OR COMMUNITY VALUES HAVING A BEARING ON "EVIDENCE BASED MEDICINE". ALTHOUGH LAW, THE MTUS DOES NOT IMPOSE CARE ON PATIENTS, IT GIVES GUIDELINES WHICH CAN BE FOUND IN ANY PAIN MANAGEMENT TEXT BOOK. WHAT'S THE ALTERNATIVE?

ARE WE SUGGESTING THAT MEDICAL CARE SHOULD BE SUBJECT TO OPINION OR POLITICS? YIKES, DON'T WE ALREADY HAVE TOO MUCH OF THAT. IF IT IS DECIDED TO KEEP THIS PHRASE, THEN AT LEAST INCLUDE THE DEFINITION, OR WHAT YOU MEAN BY, "PATIENT AND COMMUNITY VALUES" IN THIS "DEFINITION" SECTION OF THE MTUS?

~~(f) "Functional improvement"~~ THIS WHOLE SECTION HAS BEEN REMOVED. WHY? ARE WE NO LONGER MEASURING PATIENT IMPROVEMENT WITH FUNCTIONALITY? PROBABLY NEED TO RE-THINK THIS.

§ 9792.21. Medical Treatment Utilization Schedule

(a) The Administrative Director adopts the Medical Treatment Utilization Schedule (MTUS) consisting of section 9792.20 through section 9792.26.

~~(b) The MTUS is intended to assist in the provision of medical treatment by offering an analytical framework for the evaluation and treatment of injured workers and to help those who make decisions regarding the medical treatment of injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers, in accordance with section 4600 of the Labor Code. The MTUS provides a framework for the most effective treatment of injured and ill workers and is based on the principles of Evidence Based Medicine (EBM). EBM is a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient or community values. EBM is a method of improving the quality of care by encouraging practices that work, and discouraging those that are ineffective or harmful. EBM asserts that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for making clinical decisions. Instead, EBM requires the evaluation of medical evidence by applying an explicit systematic methodology to determine the strength of evidence used to support the recommendations of a medical condition. The best available evidence is then used to guide clinical decision making. In order to effectively promote health and well-being, health care professionals shall base clinical decisions on evidenced based medicine. I AGREE AND THINK THIS IS VERY REASONABLE. BUT ISN'T THIS IN CONTRADICTION TO THE DEFINITION PRESENTED, AND ARGUED AGAINST, IN SECTION 9792.20 e ABOVE?~~