



California Workers' Compensation Institute  
1111 Broadway Suite 2350, Oakland, CA 94607 • Tel: (510) 251-9470 • Fax: (510) 763-1592

July 1, 2014

VIA E-MAIL to [dwcrules@dir.ca.gov](mailto:dwcrules@dir.ca.gov)

Maureen Gray, Regulations Coordinator  
Department of Industrial Relations  
Division of Workers' Compensation, Legal Unit  
Post Office Box 420603  
San Francisco, CA 94142

**RE: Written Testimony – Medical Treatment Utilization Schedule (MTUS)**

Dear Ms. Gray:

This written testimony on proposed revisions to the Medical Treatment Utilization Schedule (MTUS) regulations is presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 71% of California's workers' compensation premium, and self-insured employers with \$46B of annual payroll (26% of the state's total annual self-insured payroll).

Insurer members of the Institute include ACE, AIG, Alaska National Insurance Company, AmTrust North America, Chubb Group, CNA, CompWest Insurance Company, Crum & Forster, Employers, Everest National Insurance Company, Fireman's Fund Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Group, Springfield Insurance Company, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members are Adventist Health, Agilent Technologies, Chevron Corporation, City and County of San Francisco, City of Santa Ana, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, County of San Bernardino Risk Management, County of Santa Clara Risk Management, Dignity Health, Foster Farms, Grimmway Enterprises Inc., Kaiser Permanente, Marriott International, Inc., Pacific Gas & Electric Company, Safeway, Inc., Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group, Southern California Edison, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the draft revised Medical Treatment Utilization (MTUS) regulations are indicated by underscore and ~~strikeout~~. Comments and discussion by the Institute are indented and identified by *italicized text*.

## Introduction

### The Statutory Mandate

The statutory scheme adopted by the Legislature in 2004 made fundamental changes to the provision of medical care to injured employees. Amendments to the Labor Code in sections 4600, 4604.5 and 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. (Emphasis added)

Section 5307.27, defines medical care as follows:

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)

Section 4604.5 specifies:

The recommended guidelines set forth in the schedule adopted pursuant to subdivision (a) shall reflect practices that are **evidence and scientifically based, nationally recognized, and peer reviewed**. (Emphasis added)

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 treatment provided in accordance with the medical treatment utilization schedule (MTUS). To the extent that the proposed revised MTUS regulation includes references to "best available research evidence with clinical expertise and patient values," they violate the statutory mandate established by the Legislature.

### Hierarchy of Scientific Medical Evidence

We are concerned that the proposed revisions to the Medical Utilization Treatment Schedule (MTUS) regulations do not establish, strengthen and facilitate the standard of medical care established by the Legislature with the adoption of evidence-based medicine. "Hierarchy of evidence" should be strengthened in order to more clearly establish the relative weight to be given to peer-reviewed and nationally recognized scientific medical evidence, and the strength of evidence should be noted with each recommendation in the MTUS.

### Value Assessment

The decision to approve a treatment or diagnostic test should not be based solely on whether there is evidence to support that request as cost effectiveness is also an important component of the analysis. Incorporation of cost effectiveness has been the standard practice for groups such as the US Preventative Services Task Force. Cost-effectiveness analysis includes not only the expected benefits and harms, but also the costs of alternative strategies.

The American College of Cardiology and the American Heart Association announced in March 2014 that they will begin to include value assessments when developing guidelines. A study published in JAMA Internal Medicine (2013: 173(12):1091-1097) showed that when formulating clinical guidance documents, 57% of physician societies explicitly integrated cost, 13% implicitly considered costs, and only 10% intentionally excluded costs.

Considering the cost of the therapy and approving a less expensive but equally effective treatment will help address and manage the rising costs of medical treatment. This has essentially been done with respect to brand versus generic drugs, and that concept should be expanded to all treatment requests. If a requesting provider believes a more expensive treatment will offer benefits not provided by a less expensive efficacious treatment, he or she can document why the more expensive treatment is needed at the time of request.

A treatment guideline that fails to include an assessment of cost vs benefit will unnecessarily increase expenses in the system.

### **Summary of Primary Recommendations**

- Make a literature search optional for treating physicians and utilization reviewers
- Retain the current methodology for criteria and the hierarchy of evidence
- Incorporate principles of value assessment and comparative effectiveness into the MTUS
- Note the strength of evidence for each recommendation in the MTUS
- If AGREE II protocols are adopted, limit required use to Independent Medical Review
- Require treating physicians who request goods and services not recommended in the MTUS to provide supporting evidence in the RFAs.

### **Specific Recommendations**

#### **§ 9792.20. Medical Treatment Utilization Schedule -- Definitions**

##### **Recommendation**

(b) "ACOEM Practice Guidelines" means the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, ~~2<sup>nd</sup> Edition~~ (2004). ~~A copy~~ ACOEM Practice Guidelines 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).

##### **Discussion**

*DWC proposes to adopt a definition of ODG (Official Disability Guidelines) without specifying a particular dated version. It is also necessary to delete the reference to a particular version of the ACOEM Practice Guidelines in this definition so that treating physicians and reviewers can utilize the current version when searching or citing ACOEM Practice Guidelines. If a specific dated version is determined necessary, the Institute recommends revising the definitions for ACOEM and ODG guidelines to reflect the most recent versions. If the definition of ACOEM Practice Guidelines specifies an outdated version, there will be confusion and disputes over whether the guideline cited is valid.*

### **Recommendation**

(c) "Chronic pain" means any pain that persists beyond ~~the anticipated time of healing~~ three months.

### **Discussion**

*Most medical research (on which guidelines for chronic pain must be based) use a three-month duration to define chronic pain. The definition must match the medical evidence. Additionally, the use of a specified period of time will eliminate potential litigation over what constitutes "the anticipated time of healing."*

### **Recommendation**

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

### **Discussion**

*Clinical expertise and patient values are subjective and therefore inappropriate as standards to assess the appropriateness of medical care. It is therefore necessary to delete "clinical expertise and patient values" from the proposed definition of EBM. The MTUS has to be definitive in order to establish useful, clear, and scientific treatment guidelines as the statutes direct.*

*In addition, including the term "clinical expertise and patient values" contradicts the language now in section 9792.21(c) which accurately states: "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."*

*Alternatively, we suggest using instead the definition of Evidence-Based Medicine (EBM) that the Institute of Medicine (IOM) adopted in 2009: "EBM is the framework for methodologically analyzing best evidence so that the care provided to each patient delivers the most value. The benefits of EBM will be to reduce discrepancies in care of patients and improve value of the healthcare delivered. (IOM, Evidence-Based Medicine, 2009.)"*

### **Recommendation**

(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 9789.10-9789.19 ~~medical evaluation and treatment~~; and a reduction in the dependency on continued medical treatment.

### **Discussion**

*The evaluation and management (E/M) OMFS reference is useful because evaluation of functional improvement is a component of the evaluation and management service and should not be subject to duplicate payment. This was originally added to the MTUS*

*regulations as providers were beginning to bill for reporting functional improvement separately from the usual E & M codes. If this is removed, the issue may resurface; therefore this language should be retained. Restoring the reference will avert disputes that will otherwise unnecessarily occur.*

### **Recommendation**

(h) “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.

### **Discussion**

*It is not necessary to include a five-year limitation in the definition of medical treatment guidelines. The most current version of written recommendations should still be included in the definition of “medical treatment guidelines,” even if not revised within the last five years. For example, written MTUS, ACOEM and ODG recommendations that have not been revised within five years are still medical treatment guidelines. A guideline may be based on a definitive study for which there is no new evidence and therefore is not updated. That should not render the guideline invalid after 5 years. Pursuant to Labor Code section 77.5, which is referenced in Labor Code section 5307.27, only a periodic review is required. The DWC can therefore meet statutory review requirements to periodically update MTUS without imposing artificial deadlines. Retaining the five-year limitation in the regulations could lead to confusion, additional litigation and expense over whether or not MTUS remains valid since a self-imposed deadline has passed.*

### **Recommendation**

(i) ~~“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](http://www.pubmed.gov).~~

### **Discussion**

*MEDLINE should be deleted because it no longer appears in the proposed regulations.*

### **Recommendation**

(j) “Nationally recognized” means published in a peer-reviewed medical journal; ~~or and~~ either 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.

### **Discussion**

*“Nationally recognized” is also applicable and appropriate if the most current version has been adopted for use by the federal government or a state government in the United States.*

### **Recommendation**

(m) “Scientifically based” means based on objective, reproducible results in 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 to support a recommendation.

### **Discussion**

*For a study to be considered scientifically based, its results must be objective and replicable.*

## **§ 9792.21. Medical Treatment Utilization Schedule; ~~Medical Literature Search Sequence~~**

### **Recommendation**

Delete reference to Medical Literature Search Sequence from the title. The whole section addresses MTUS and this is unnecessary. Also the sequence of review is established by Labor Code §4610.5 and will control the sequence of review.

(a) The Administrative Director adopts the Medical Treatment Utilization Schedule (MTUS) consisting of section 9792.202 through section 9792.264.3.

### **Discussion**

*While the Medical Treatment Utilization Schedule regulations encompass sections 9792.20 through 9792.26, the Medical Treatment Utilization Schedule itself includes only sections 9792.22 through 9792.24.3. The remainder of the sections includes information that pertains to the Schedule, but is not part the schedule, including procedures to follow when the MTUS does not apply. If the sections that identify circumstances when the MTUS **does not** apply are within the MTUS as currently proposed, the MTUS **does** apply and we find ourselves with Alice in Wonderland. Such confusion can be avoided by adopting only sections 9792.22 through 9792.24.3 as the MTUS.*

### **Recommendation**

(b) Medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury is treatment based on the MTUS. The MTUS provides a framework for the most effective treatment of work-related illness or injury to achieve functional improvement, return-to-work, and to minimize disability-~~prevention~~.

### **Discussion**

*The recommended additional language sets out clearly the heart of the statutory requirements for the MTUS in Labor Code sections 4600, 4604.5, and 5307.27. See introduction.*

*We suggest using “minimize disability” as this term is broader and more accurate in this context than “disability prevention.”*

### **Recommendation**

(c) Evidence-Based Medicine (EBM) is a systematic approach to making clinical decisions ~~which allows the integration of~~ based on the best available research evidence ~~with clinical expertise and patient 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 for 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 EBM.~~

## Discussion

*EBM is based on the best available medical evidence. See comments on section 9792.20(e). This section also introduces a duplicate definition. To avoid confusion and disputes over which definition controls, a single definition of Evidence-Based Medicine should be included in the regulation and thereafter Evidence-Based Medicine should be used as a term that simply refers back to the definition. We recommend deleting the last portion of this section because it is not necessary and may be misconstrued, thereby setting up a potential conflict with the code. The Institute suggests the Administrative Director consider moving the contents of (c) (as modified) into the definition of Evidence-Based Medicine (EBM) in Section 9792.20(e), and simply stating here in (c) "Medical Necessity decisions shall be based on Evidence-Based Medicine."*

## Recommendation

(d) The MTUS is based on ~~the principals of~~ EBM. The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services for the duration of the medical condition. The MTUS shall constitute the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions.

## Discussion

*The MTUS is based on EBM, not only on its principles; therefore we suggest deleting "the principals of" for a more accurate, clearer statement.*

## Recommendation

(e) ~~The MTUS does not address every medical condition or diagnostic test and the MTUS's presumption of correctness may be successfully rebutted.~~

~~(f) The MTUS's presumption of correctness~~ is one affecting the burden of proof. It may be rebutted if medical evidence is cited in a request for authorization that contains a recommendation applicable to the specific injury medical condition and to the treatment or diagnostic test requested by the injured worker treating physician, and the recommendation is supported with a higher level of evidence than the medical evidence used to support the MTUS's recommendation. the medical evidence establishes by a preponderance of the evidence that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury.

## Discussion

*We suggest clarifying here the nature of the presumption.*

*Additionally, the request for authorization form (Section 9785.5) instructs the treating physician to include all information needed to substantiate the request and states:*

*"For requested treatment that is:*



*(a) inconsistent with the Medical Treatment Utilization Schedule (MTUS) found at California Code of Regulations, title 8, section 9792.20, et seq.;*

*or*

*(b) for a condition or injury not addressed by the MTUS, you may include scientifically based evidence published in peer-reviewed, nationally recognized journals that recommend the specific medical treatment or diagnostic services to justify your request.”*

*Instructing treating physicians to include citations to relevant supporting medical evidence when requesting authorization for services that are inconsistent with the MTUS will be helpful, will avoid unnecessary delays, and will conform to Section 9785.5.*

*The treatment is being requested by the treating physician rather than by the injured worker.*

*The presumption and burden of proof as stated conflicts with Labor Code 4604.5 and 4610.5. Labor Code 4610.5 states that the MTUS is the highest standard and lower standards can only be considered if “every higher ranked standard is inapplicable to the employee’s medical condition.” Labor Code 4604.5 states that the “presumption may be rebutted 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 this or her injury.” The original regulation language from 9792.25 correctly stated this and therefore should be retained for the purpose of rebutting the MTUS.*

### **Recommendation**

*(f) ~~When The MTUS does not address every injury. For injuries not covered by the MTUS, is silent on a particular medical condition or diagnostic test or when the MTUS is successfully rebutted, authorized~~ medical care shall be in accordance with ~~the best available medical evidence found in other~~ scientifically and evidenced-based, nationally recognized medical treatment guidelines ~~or peer-reviewed published studies that are nationally recognized by the medical community.~~*

*(g) When the MTUS is ~~silent on a particular medical condition or diagnostic test or when~~ successfully rebutted, medical care shall be in accordance with the best available medical evidence ~~found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.~~*

### **Discussion**

*The Institute recommends separating (f) into two sections because the requirement for an injury that is not addressed in the MTUS differs from that of an injury that is addressed in the MTUS, but where the MTUS recommendation is successfully rebutted.*

*The MTUS is presumptively correct unless the injury is not covered by the MTUS. Labor Code section 4604.5(d) specifies that authorized medical care for injuries not covered by the MTUS must be in accordance with other evidence-based medical treatment guidelines that are nationally recognized and scientifically based.*

*If, on the other hand, the MTUS is being rebutted, authorized treatment is the treatment supported by the best available medical evidence.*



## Recommendation

~~(gh) In situations described in subdivision (f), a~~ A medical literature search ~~shall~~ may be conducted by the treating physician or medical reviewer ~~s-making treatment decisions and should be conducted by the requesting provider~~, to find the recommendation supported with the highest level of evidence applicable to the injured worker's specific medical condition.

## Discussion

*The Institute strongly recommends replacing "shall" with "may" so it is clear that a literature search is optional. There is no statutory basis or necessity for requiring the treating physician or utilization reviewer to conduct a literature search, although either may choose to do so. If an injury or condition is not covered by the MTUS, Labor Code section 4604.5 requires authorized treatment to be in accordance with other scientifically-based, nationally recognized guidelines. When an injury is addressed in the MTUS but the MTUS recommendation is successfully rebutted, authorized treatment must be treatment supported by the best available medical evidence. The treating physician and/or the utilization reviewer may wish to perform a literature search, but none is required. If an IMR is requested, the independent medical reviewer can compare the strength of evidence that supports the service recommended in the MTUS or other guideline (if applicable) and the evidence cited to support the requested service, and can perform a complete literature search where appropriate.*

*In addition, requiring a medical literature search ignores the very tight statutory and regulatory time constraints on utilization review. If the requirement remains, it will become another fertile field for disputes and allegations of procedural defects fueling the jurisdictional battle between the WCAB and UR/IMR. Applicant's attorneys will argue over whether or not the literature search was required, whether it was complete and properly performed, and whether it was done in a timely manner. Under Dubon, any of these issues will shift the case from a prompt evaluation of the best medical care to litigation at the Board as to whether the UR decision contains "material procedural defects that undermine the integrity of the UR decision." This will simply become a new way to divert decisions by medical professionals, flood the Board with questionable disputes, and increase the cost of utilization reviews.*

## Recommendation

(h) Conducting a comprehensive medical literature search is resource-intensive. A treating physician or reviewer ~~Providers making treatment decisions~~ may conduct a comprehensive medical literature search, but for purposes of this section and in the interest of efficiency and consistency, the medical literature search sequence set forth in subdivision (i) shall be sufficient.

## Discussion

*This guidance on the level and type of literature search is helpful and appreciated. The minor language modification is suggested for simplicity and clarity.*

## Recommendation

(i) When conducting a medical literature search of the large body of available medical evidence, the following search sequence, may at a minimum, ~~shall~~ be followed:

(1) Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. ~~If the current version is more than five years old, or if~~ no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(2) Search the most current version of other evidence-based medical treatment guidelines that are nationally recognized ~~and by the national medical community and are~~ scientifically based to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. Medical treatment guidelines can be found in the National Guideline Clearinghouse that is accessible at the following website address: [www.guideline.gov/](http://www.guideline.gov/). ~~If the current version is more than five years old, or if~~ no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence, then

(3) Search for current studies, ~~five years old or less~~ that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. 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](http://www.ncbi.nlm.nih.gov/pubmed). Other searchable databases may also be used.

## Discussion

*The Institute strongly recommends clarifying that a literature search by a reviewer or treating physician is optional, not required. As discussed in comments section (gh), there is no statutory basis or necessity for requiring the treating physician or utilization reviewer to conduct a literature search, although either may choose to do so.*

*If an injury or condition is not covered by the MTUS, Labor Code section 4604.5 requires authorized treatment in accordance with other scientifically based nationally recognized guidelines. When an injury is addressed in the MTUS, but the MTUS recommendation is successfully rebutted, authorized treatment is treatment supported by the best available medical evidence. The treating physician and/or the utilization reviewer may wish to perform a literature search, but should not be required to do so. If an IMR is requested, the independent medical reviewer can compare the strength of the evidence supporting the competing guidelines/studies, and can perform a complete literature search if appropriate.*

*The term "recognized by the national medical community" is not defined. The Institute recommends instead using the term "nationally recognized" which is defined in Section 9792.20(j).*

*It is not necessary to limit studies that are five years old or less. Labor Code section 77.5, which is referenced in Labor Code section 5307.27, only requires periodic updates without establishing a time frame that would call into question the validity of the MTUS*

*after a period of time passed. Also, an older study is still a valid study and may have definitively determined the issue, making it the best or the only available medical evidence.*

### **Recommendation**

(j) ~~After conducting~~ If a medical literature search *has been conducted*, Utilization Review decisions and Independent Medical Review decisions shall contain the citation of the medical treatment guideline or peer-reviewed published study with the recommendation supported with the highest level of evidence, and t. ~~Treating physicians may shall~~ cite the medical treatment guideline or peer-reviewed published study that contains the recommendation supported with the highest level of evidence in the ~~chart notes or~~ Request for Authorization, ~~particularly if barriers to getting authorization are anticipated.~~

(1) The citation shall include, at a minimum, information that clearly identifies the source of the recommendation.

### **Discussion**

*The suggested changes support an optional literature search. When a literature search is performed, it is reasonable for the treating physician to cite the guideline or study that supports the requested treatment in the Request for Authorization, and for the reviewer to cite the guideline or study supporting the review decision. Additionally, striking the last part of the sentence removes unnecessary language that encourages the perception that the medical necessity process creates barriers and creates an adversarial system.*

### **Recommendation**

(k) Finally, if there is a discrepancy between the recommendations cited, and an Independent Medical review has been properly requested, the Independent Medical Reviewer shall evaluate the underlying medical evidence supporting the differing recommendations ~~shall be evaluated~~ according to the strength of evidence methodology set forth in section 9792.25.1 to determine which recommendation is supported with the highest level of 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 MTUS, or if applicable, the recommendation supported with the best available medical evidence.

### **Discussion**

*If IMR is requested, the independent medical reviewer can compare the strength of the medical evidence supporting the competing guidelines/studies, and can perform a complete literature search if appropriate. Without this modification, the section as written sets up a battle of experts and litigation for any medical necessity determination which would increase administrative and legal expense for all parties.*

## **§ 9792.25. Strength of Evidence - Definitions**

### **Recommendation**

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

~~(1)~~ “Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, published September 2013” means a tool designed primarily to help guideline

developers and users assess the methodological rigor and transparency in which a guideline is developed. The AGREE II Instrument can be found in the following website: [www.agreetrust.org](http://www.agreetrust.org)

### **Discussion**

*The Institute recommends retaining the current methodology for evaluating criteria and determining strength of evidence. Using AGREE II protocols will not limit MTUS recommendations to those supported by peer-reviewed, and nationally recognized scientific medical evidence as Sections 4604.5 and 5307.27 require. Extensive training is necessary for all those who will use the protocols. Applying the protocols is much more time consuming than the existing standards.*

*If the Administrative Director decides to adopt the AGREE II Instrument and methodology, it is necessary to identify the specific version adopted in this regulation.*

*The appraisal guidelines were developed to assist MEEAC perform their duties, not for casual users. This should be made clear so that lay people do not attempt to use these to individually assess MTUS guidelines that are adopted.*

### **Recommendation**

Delete (a)(2) through (a)(29).

### **Discussion**

*The Administrative Director intends to adopt the AGREE II protocols, and provides the AGREE II web site address. If the Administrative Director adopts the AGREE II methodology, including details such as definitions (2) through (29) in this section does not appear necessary since the AGREE II Instrument and AGREE II Training Tools and related resources are available on that web site. Including these details also adds complexity that is not necessary and which will lead to additional disputes and confusion.*

### **Note:**

*AGREE II protocols are complex and time-consuming. Correctly applying the AGREE II tool will require thorough training. If the Administrative Director adopts the AGREE II tool, the Institute strongly recommends that the Administrative Director not require their use by treating physicians and utilization reviewers, and require that:*

- 1) IMR reviewers and MEEAC members are thoroughly trained on applying the AGREE II tool before the effective date of these regulations.*
- 2) The MTUS include the strength of evidence for each recommendation.*

## **§ 9792.25.1 Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support a Recommendation; MTUS Hierarchy of Evidence for Different Clinical Questions**

### **Recommendation**

*Delete this proposed section.*

## Discussion

*The Institute recommends retaining the current methodology for evaluating criteria and determining strength of evidence. See comment on section 9792.25(a).*

## § 9792.26. Medical Evidence Evaluation Advisory Committee

### Recommendation

(d) The advisory MEEAC recommendations shall be supported by the best available ~~medical—scientific~~ evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.

### Discussion

*According to the Initial Statement of Reasons, the Division proposes to remove from the current regulations the Strength of Evidence methodology adopted from ACOEM because that methodology is designed to identify the strength of scientific evidence, which ACOEM believes is limited to randomized controlled trials.*

*The Initial Statement of Reasons states: “DWC takes the position that the MTUS shall be supported by the current best available evidence in making clinical decisions.” The DWC wishes to include other evidence including published expert opinion and case reports. Published expert opinion and case reports, however are not scientific evidence and Labor Code sections 4604.5 and 5307.27 require the Administrative Director to adopt a Medical Treatment Utilization Schedule (MTUS) that is evidence and scientifically based, nationally recognized, and peer-reviewed. MTUS recommendations must therefore be based on the best scientific evidence that has been peer-reviewed and is nationally recognized. To comply with the statutory requirements, the Institute urges the DWC to modify its position to require that recommendations in the MTUS shall be supported by the best available **scientific** evidence.*

### Recommendation

(e) To assess the quality and methodological rigors used to develop a medical treatment guideline, members of MEEAC shall use ~~a modified version of~~ the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument, published September 2013. The AGREE II Instrument consisting of 23 key items organized within six domains followed by two global rating items and can be found in the following website: [www.agreetrust.org](http://www.agreetrust.org)

### Discussion

*To comply with statutory requirements, as discussed in (d) above, the Institute believes it better for the MEEAC to utilize the current methodology including the criteria and strength of evidence in recommendations to develop or update the MTUS. AGREE II is much more complex than the current methodology, and requires extensive training and is very time-consuming to properly apply.*

*If the Administrative Director decides to retain the requirement for MEEAC to use AGREE II, it is not necessary to modify the AGREE II Instrument.*

*As previously mentioned, the specific AGREE II version adopted in this regulation must be identified in these regulations.*

**Recommendation**

(e)(B) 1. Key Item in this domain - The guideline is being updated in a timely fashion (typically at least every three years and, if the guideline *is has not been reviewed and updated if necessary in* more than five years ~~old~~, it ~~should~~ may be considered to be out of date).

**Discussion**

*While the guideline (MTUS) should be updated timely, it should not be rejected if it is not. Individual recommendations can be challenged with stronger evidence if any.*

**Recommendation**

(f) Recommendations in guidelines that have a low AGREE II overall score may still be considered, provided that the evidence supporting the recommendations is the best available peer-reviewed, and nationally recognized scientific medical evidence.

**Discussion**

*Guidelines and medical evidence must still comply with the Labor Code section 4604.5 and 5307.27 requirements.*

**Recommendation**

(g) To determine the best available medical evidence, members of MEEAC shall rank the medical evidence used to support recommendations found in either guidelines or peer-reviewed published studies by applying the strength of evidence methodology set forth in section 9792.25.2 and shall choose the recommendations supported by the best available peer-reviewed, and nationally recognized scientific medical evidence.

**Discussion**

*Guidelines and medical evidence must still comply with the Labor Code section 4604.5 and 5307.27 requirements.*



Thank you for considering these recommendations and comments. Please contact me if additional clarification would be helpful.

Sincerely,

Brenda Ramirez  
Claims & Medical Director

BR/pm

cc: Christine Baker, DIR Director  
Destie Overpeck, DWC Acting Administrative Director  
Dr. Das, DWC Executive Medical Director  
John Cortes, DWC Attorney  
CWCI Claims Committee  
CWCI Medical Care Committee  
CWCI Regular Members  
CWCI Associate Members  
CWCI Legal Committee