

**STATE OF CALIFORNIA  
DEPARTMENT OF INDUSTRIAL RELATIONS  
DIVISION OF WORKERS' COMPENSATION**

**NOTICE OF MODIFICATION TO TEXT OF  
PROPOSED REGULATIONS**

**Subject Matter of Regulations – Medical Treatment Utilization Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS  
SECTIONS 9792.20 - 9792.23**

**NOTICE IS HEREBY GIVEN** that the Acting Administrative Director of the Division of Workers' Compensation, pursuant to the authority vested in her by Labor Code sections 59, 133, 4603.5, and 5307.3, proposes to modify the text of the following proposed regulations contained in Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations:

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

**PRESENTATION OF WRITTEN COMMENTS AND DEADLINE FOR  
SUBMISSION OF WRITTEN COMMENTS**

**PRESENTATION OF WRITTEN COMMENTS AND DEADLINE FOR SUBMISSION  
OF WRITTEN COMMENTS**

Members of the public are invited to present written comments regarding these proposed modifications. **Only comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.**

Written comments should be addressed to:

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

The Division's contact person must receive all written comments concerning the proposed modifications to the regulations no later than **5:00 p.m. on December 22<sup>nd</sup>**. Written comments may be submitted by facsimile transmission (FAX), addressed to the contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail), using the following e-mail address: [dwcrules@hq.dir.ca.gov](mailto:dwcrules@hq.dir.ca.gov).

**AVAILABILITY OF TEXT OF REGULATIONS AND RULEMAKING FILE**

Copies of the original text and modified text with modifications clearly indicated, and the entire rulemaking file, are currently available for public review during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers' Compensation. The Division is located at 1515 Clay Street, 17<sup>th</sup> Floor, Oakland, California.

Please contact the Division's regulations coordinator, Ms. Maureen Gray, at (510) 286-7100 to arrange to inspect the rulemaking file.

The specific modifications proposed include changes to the text of the proposed amendments Title 8, California Code of Regulations:

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

## DOCUMENTS SUPPORTING THE RULEMAKING FILE

- ACOEM Becomes Publisher of Its Practice Guidelines, ACOEM Press Release, August 25, 2006
- ACOEM's Methodology for Updates of ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, December 5, 2006
- ACOEM Practice Guidelines, 2<sup>nd</sup> Edition and Colorado Medical Treatment Guidelines Cross Reference Matrix
- *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG Insights, Winter 2005
- Colorado Medical Treatment Guidelines, Rule 17, 7 CCR 1101-3
- Comments from various interested parties concerning the regulations have been added to the rulemaking file.
- National Guideline Clearinghouse's (NGC) inclusion criteria at <http://www.guideline.gov/about/inclusion.aspx>
- *Safety of Neck Stents Debated*, October 25, 2006  
<http://www.nytimes.com/2006/10/25/business/25cnd-stent.html>
- *Study Questions Angioplasty Use In Some Patients*, November 15, 2006  
[www.nytimes.com/2006/11/15/health/15heart.html](http://www.nytimes.com/2006/11/15/health/15heart.html)
- United States National Library of Medicine, National Institutes of Health, Fact Sheet—What's the Difference Between MEDLINE® and PubMed®?  
[http://www.nlm.nih.gov/pubs/factsheets/dif\\_med\\_pub.html](http://www.nlm.nih.gov/pubs/factsheets/dif_med_pub.html)
- Updated and Revised CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, April 6, 2006

## FORMAT OF PROPOSED MODIFICATIONS

### Proposed Text Noticed for 45-Day Comment Period:

The new text is indicated by underlining, thus: underlined language.

## **Proposed Text Noticed for This 15-Day Comment Period on Modified Text:**

Deletions from the regulatory text, as proposed in May 2006, are indicated by underline/single strike-through, thus: ~~deleted language~~.

Additions to the regulatory text, as proposed in May 2006, are indicated by double underline, thus: added language.

### **SUMMARY OF PROPOSED CHANGES**

#### **Modifications to Section 9792.20 Medical Treatment Utilization Schedule—Definitions**

##### **Section 9792.20**

**Subdivision (a)** setting forth the definition for the term “acute” has been deleted. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic,” DWC agrees that the distinction between an acute stage and a chronic stage of a condition is a clinical one. Because the intent of the regulations is to state that the ACOEM Practice Guidelines apply to all conditions for the duration of the medical condition, the definitions of “acute” (Section 9792.20(a)) and “chronic” (Section 9792.20(d)) were removed from the regulations.

**Subdivision (b)** setting forth the definition for the term “American College of Occupational and Environmental Medicine (ACOEM)” has been re-lettered subdivision (a).

**Subdivision (c)** setting forth the definition for the term “ACOEM Practice Guidelines” has been re-lettered subdivision (b). Further the reference to the publisher (i.e., “published by OEM Press”) has been deleted. ACOEM has issued a news release informing the public that ACOEM is now the publisher of the ACOEM Practice Guidelines. The News Release entitled: *ACOEM Becomes Publisher of Its Practice Guidelines*, dated August 25, 2006, has been added to the formal rulemaking file as a document relied upon.

**Subdivision (d)** setting forth the definition for the term “chronic” has been deleted. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic.” DWC agrees that the distinction between an acute stage and a chronic stage of a condition is a clinical one. Because the intent of the regulations is to state that the ACOEM Practice Guidelines apply to all conditions for the duration of the medical condition, the definitions of “acute” (Section 9792.20(a)), and “chronic” (Section 9792.20(d)) were removed from the regulations.

**Subdivision (e)** setting forth the definition for the term “claims administrator” has been re-lettered subdivision (c).

**Subdivision (f)** setting forth the definition for the term “evidence-based” has been re-lettered subdivision (d).

A new definition has been added to the regulations in subdivision (e). Subdivision (e) sets forth the definition for the term “functional improvement” as follows:

“[E]ither 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.”

This definition is adapted from the medical treatment philosophy that is incorporated in the ACOEM Practice Guidelines. For example, the ACOEM Practice Guidelines state at page 77 as follows:

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.)

Another example is contained at ACOEM Practice Guidelines, page 106, which states as follows:

Pain in today's work place presents a challenge to the occupational physician. Although mistreating or undertreating pain is of concern, and 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.)

The ACOEM's APG Insights, Winter 2005, at page 10, states "[t]he literature does not provide guidance regarding what number of treatments would ultimately be appropriate, but if patients have demonstrated evidence of ongoing improvement by the sixth treatment, completion of another six treatments would appear reasonable." Based on ACOEM's recent systematic review of acupuncture scientific evidence as reflected in the 2005 Winter APG Insights, and adapting it for the purposes of the medical treatment utilization schedule, it is necessary to clarify what ACOEM refers to as "demonstrated evidence of ongoing improvement." To this end, a definition of the term functional improvement has been added to the proposed regulations. The approach is to document improvement in activities of daily living and/or to document a reduction work restrictions, with the requirement that there would also be a documented reduction in the dependency on continued medical treatment. (See, Labor Code section 4660, see also, Guides to the Evaluation of Permanent Impairment, Fifth Edition, pp. 2, 8.). Moreover, the definition requires that the improvement be apparent enough that no special testing such as functional capacity evaluation should be required.

**Subdivision (g)** setting forth the definition for the term "hierarchy of evidence" has been amended as follows: The term has been re-named "strength of evidence" and has been re-lettered subdivision (l). The section now states: "Strength of Evidence" establishes the relative weight that shall be given to scientifically based evidence. Thus, although the definition remains the same, the name of the term has been changed to "strength of evidence." The change in the name of the term is because during the 45-day comment period, ACOEM notified DWC that it would adopt a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition. ACOEM has now completed the updated methodology, and has provided DWC a justification for the change which will be set forth below under Section 9792.22(c)(1). Because we have adopted ACOEM's strength of evidence rating methodology

into the MTUS, it is necessary to delete the term “hierarchy of evidence” and substitute it with the term “strength of evidence.” This allows the MTUS to remain consistent with ACOEM’s methodology to evaluate evidence-based medical treatment guidelines.

**Subdivision (h)** setting forth the definition for the term “medical treatment” has been re-lettered subdivision (f), and has been corrected for clerical error, and it now states that “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 9792.20-9792.23,” and not 9792.20-9722.23.

**Subdivision (i)** setting forth the definition for the term “Medical treatment guidelines” has been re-lettered subdivision (g). The definition of “medical treatment guidelines” has been amended to mean “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.” This definition has been amended for clarification purposes. Some commenters indicated that the definition should limit the effective date of the treatment guideline in order to insure currency. We agree this is important to prevent the use of outdated guidelines to guide the provision of medical treatment. We amended the definition of the term “medical treatment guidelines” to require that the guidelines be the most current version and also be revised within the last five years. We used the requirement of 5 years based on the National Guideline Clearinghouse (NGC)’s inclusion criteria at <http://www.guideline.gov/about/inclusion.aspx>. This document will be added to the rulemaking file under documents relied upon. Other commenters objected to the use of the phrase “appropriate health care” in the definition on the basis that the term “medical treatment” was more appropriate as the regulations already contained a proposed definition to that term. We agree that the phrase “appropriate health care” should be replaced with the phrase “medical treatment” for clarity purposes because the proposed regulations as pointed out by the commenters already contain a definition of the term medical treatment. Finally, some commenters suggested in connection with the definition of the term “nationally recognized,” that the phrase “multidisciplinary clinical panel” be added to the definition of that term as that phrase reflects the findings of several studies showing that such panels are an important component of guideline quality. We agree with the recommendation that multidisciplinary clinical panels should be involved in the development of the guidelines, however, DWC believes that this requirement relates more appropriately to the definition of “medical treatment guidelines.” Thus, the definition of the term “medical treatment guidelines” has been amended to include the requirement that the guidelines be developed by a multidisciplinary process. The justification for this requirement is set forth in the ISOR at p. 20, and in the 2005 RAND Report at p. xviii.

**Subdivision (j)** The term “medical treatment provider” as contained in subdivision (j) has been deleted. Some commenters suggested that the definition be deleted from the proposed regulations as unnecessary. We agree that the definition is not necessary because the term is only used once in the regulations at Section 9792.21(b), and the sentence in that section was changed as suggested by commenters without losing the contextual meaning in the section

**Subdivision (k)** Subdivision (k) setting forth the definition for the term “MEDLINE” has been re-lettered subdivision (h). The term has also been re-defined to state that “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. The website address remains the same as [www.pubmed.gov](http://www.pubmed.gov). The term has been amended to be consistent with the definition contained in the U.S. National Library of Medicines website. The definition may be found at: [http://www.nlm.nih.gov/pubs/factsheets/dif\\_med\\_pub.html](http://www.nlm.nih.gov/pubs/factsheets/dif_med_pub.html)

**Subdivision (l)** setting forth the definition for the term “nationally recognized” has been re-lettered subdivision (i). The definition has been amended to mean 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. During the 45-day period some commenters have raised questions as to whether their organization meets the definition of “nationally recognized” under the proposed definition requiring that the national organization be “based in two or more U.S. states.” In order to be more inclusive, the definition of the term “nationally recognized” will be amended to state “disseminated by a national organization with affiliates based in two or more states.” Moreover, some commenters argued that the adoption of a guideline by one or more U.S. state governments fails to satisfy the requirement that a guideline be “nationally” recognized and/or fails to require proper screening. This definition is also amended to require that the adopted guideline not only be adopted by one or more U.S. state governments, but also be in use by one or more U.S. state governments. This will satisfy the requirement that the guideline has gone through proper screening by the rulemaking process of the state using it, and that it be in actual use as opposed to just be adopted but not in use.

A new definition has been added as subdivision (j). This subdivision now provides the a definition for the term “peer reviewed” which 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. This definition was requested by the public during the 45-day period comment because Labor Code Section 5307.27 requires the medical treatment utilization schedule to incorporate “evidence-based, peer-reviewed, nationally recognized standards of care.” We agree that a definition to this term is necessary to meet the requirements of the statute.

**Subdivision (m)** setting forth the definition for the term “scientifically based” has been re-lettered subdivision (k). The definition of the term “scientifically based” has been amended to mean 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. The definition has been amended for clarification purposes to tie the definition with other elements of the proposed regulations.

The new term “strength of evidence” has been added to the definitions in subdivision (l). This term substitutes the term “hierarchy of evidence” in the proposed regulations and is defined with the exact same definition of the term “hierarchy of evidence” as previously contained in subdivision (g), as explained above. Thus subdivision (l) now states that “strength of evidence” establishes the relative weight that shall be given to scientifically based evidence.

## **Modifications to Section 9792.21 Medical Treatment Utilization Schedule**

### **Section 9792.21(a)**

**Subdivision (a)** has been modified to state: The Administrative Director adopts the Medical Treatment Utilization Schedule consisting of Sections 9792.20 through Section 9792.23. The Administrative Director adopts and incorporates by reference the following medical treatment guidelines into the Medical Treatment Utilization Schedule:

**Subdivision (a)(1)** has been added to state: The American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines), Second Edition (2004). A copy may be obtained from OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 ([www.oempress.com](http://www.oempress.com)).

The change in this section was the result of comments from the public that the language of the regulations should be re-focused to reference the adoption of the MTUS, and the regulations should make it clear that the ACOEM Practice Guidelines, although the foundation of the MTUS, is just a component of the MTUS as the MTUS is expected to evolve based on revisions

of the ACOEM Practice Guidelines themselves (e.g., new editions), based on the results of work performed by the Medical Evidence Evaluation Advisory Committee (e.g., new guidelines added into the MTUS), and due to the inclusion of the Acupuncture Medical Treatment Guidelines. Thus Section 9792.21(a) has been amended to clarify the adoption of the MTUS, and a new subdivision (a)(1) has been added to the regulations to incorporate the ACOEM Practice Guidelines into the schedule. The phrase “published by OEM Press” has been deleted from the text of the regulations because ACOEM has issued a news release informing the public that ACOEM is now the publisher of the ACOEM Practice Guidelines. The News Release entitled: *ACOEM Becomes Publisher of Its Practice Guidelines*, dated August 25, 2006, has been added to the formal rulemaking file as a document relied upon.

### **Subdivision 9792.21(a)(2)**

A new subdivision 9792.21(a)(2) setting forth another component of the MTUS has been added to the text of the regulations. This subdivision sets forth the Acupuncture Medical Treatment Guidelines as follows:

#### **(2) Acupuncture Medical Treatment Guidelines**

The Acupuncture Medical Treatment Guidelines set forth in this subdivision shall supersede the text in the ACOEM Practice Guidelines, Second Edition, relating to acupuncture, except for shoulder complaints, and shall address acupuncture treatment where not discussed in the ACOEM Practice Guidelines.

#### **(A) Definitions:**

(i) “Acupuncture” is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. It is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

(ii) “Acupuncture with electrical stimulation” is the use of electrical current (micro- amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

(iii) “Chronic pain for purposes of acupuncture” means pain that persists for at least 30 days beyond the usual course of an acute disease or a reasonable time for an injury to heal or that is associated with a chronic pathological process that causes continuous pain (e.g., reflex sympathetic dystrophy). The very definition of chronic pain describes a delay or outright failure to relieve pain associated with some specific illness or accident.

(B) Indications for acupuncture or acupuncture with electrical stimulation include the following presenting complaints in reference to the following ACOEM Practice Guidelines Chapter Headings:

(i) Neck and Upper Back Complaints

(ii) Elbow Complaints

(iii) Forearm, Wrist, and Hand Complaints

(iv) Low Back Complaints

(v) Knee Complaints

(vi) Ankle and Foot Complaints

(vii) Pain, Suffering, and the Restoration of Function: Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy, chronic pain.

(C) Frequency and duration of acupuncture or acupuncture with electrical stimulation may be performed as follows:

(i) Time to produce functional improvement: 3 to 6 treatments.

(ii) Frequency: 1 to 3 times per week

(iii) Optimum duration: 1 to 2 months

(iv) Maximum duration: 14 treatments.

(D) Acupuncture treatments may be extended if functional improvement is documented as defined in Section 9792.20(e).

(E) It is beyond the scope of the Acupuncture Medical Treatment Guidelines to state the precautions, limitations, contraindications or adverse events resulting from acupuncture or acupuncture with electrical stimulations. These decisions are left up to the acupuncturist.

The Acupuncture Medical Treatment Guidelines have been added to the text of the proposed regulations for the following reasons:

The Initial Statement of Reasons (ISOR) sets forth the Division of Workers' Compensation's justification for not adopting an acupuncture medical treatment guideline in the proposed MTUS, as recommended by RAND and CHSWC. With respect to the Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition, December 2004, the ISOR specifically notes at page 35:

[An] ... example demonstrating guideline recommendation variation relates to the acupuncture treatment guidelines. Chapter Eleven of the ACOEM Practice Guidelines addressing forearm, wrist and hand complaints, such as carpal tunnel syndrome, de Quervain's tenosynovitis and trigger finger, states: "Most invasive techniques, such as needle acupuncture and injection procedures, have insufficient high quality evidence to support their use." (ACOEM Practice Guidelines, at 265) The *Acupuncture and Electroacupuncture: Evidence-Based Treatment Guidelines* written in 2004, however, state at page 63: "The use of acupuncture and eletroacupuncture is appropriate for, but

not limited to, the following types of forearm, hand, and wrist conditions: Forearm sprain/strain, deQuervains Syndrome, wrist/finger sprain/strain, arthritis, carpal tunnel syndrome, trigger finger, and tendonitis of forearm/wrist.” Thus, ACOEM instructs physicians that evidence does not support the use of acupuncture for these areas of the body, while the guideline written by acupuncturists supports its use.

The Initial Statement of Reasons concluded at page 36:

Because of inconsistencies between the above-referenced guidelines and the ACOEM Practice Guidelines in terms of recommendations and the system of scientific review used in the development of these guidelines, the Administrative Director determined that adopting multiple contradictory guidelines at this time as recommended by CHSWC would result in disputes and negate the presumption of correctness. (Labor Code section 4604.5(a).) These guidelines will be examined in the future by the medical evidence evaluation advisory committee, and after proper evaluation, recommendations will be provided to the Administrative Director.

Labor Code section 4600(a) provides that “[m]edical, surgical, chiropractic, *acupuncture*, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer....”.

Labor Code section 4600(b) provides that “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 Occupational Medicine Practice Guidelines.*

Labor Code section 5307.27 provides that “... the administrative director ... shall adopt ... a medical treatment utilization schedule, that shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care ..., 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.*”

DWC has re-evaluated the 2005 RAND Study in light of the multiple comments received on acupuncture during the 45-day comment period. In its evaluation of the medical treatment guidelines study, RAND’s approach was to identify guidelines addressing work-related injuries, screen those guidelines using multiple criteria, and evaluate the guidelines that met their criteria. (RAND Report, at p. 21.) RAND applied the selection criteria in three phases. (RAND Report at pp. 25-26.) To apply the third phase of the selection criteria, RAND:

“determined whether the guidelines addressed most of [its] cost-driver topics: MRI of the spine, spinal injections, spinal surgery, physical therapy, chiropractic manipulation, surgery for carpal tunnel and related conditions, shoulder surgery, and knee surgery.” (2005 RAND Report, at p. 26.)

In reviewing the addressed topics, it is noted that RAND did not evaluate acupuncture as a topic.

Moreover, in its 2005 RAND Report, at page 85, RAND stated: “[o]ur findings questioned the validity of the ACOEM Guideline for the physical modalities and the residual content, but our evaluation methods appeared to have important limitations for these areas; therefore, we are not confident that the ACOEM Guideline is valid for nonsurgical topics.” RAND goes on to state that they “recommend that to identify high-quality guidelines for the nonsurgical topics, the State

proceed with the intermediate-term solutions described ....” In its intermediate-term recommendations, RAND states, in relevant part, at page 86, that “[i]f the State wishes to develop a patchwork of existing guidelines addressing work related injuries, [their] research suggests the following priority topic areas: physical therapy of the spine and extremities, chiropractic manipulation of the spine and extremities, spinal and paraspinal injection procedures, magnetic resonance imaging (MRI) of the spine, chronic pain, occupational therapy, devices and new technologies, and *acupuncture*.” (Emphasis added.)

In its April 6, 2006 Updated and Revised CHSWC Recommendations to DWC on Workers’ Compensation Medical Treatment Guidelines, CHSWC states at p. 2:

CHSWC recommends the ACOEM guidelines as the primary basis for the medical treatment utilization schedule because their flexibility allows medical decisions to take into consideration the full range of valid considerations and thus to provide optimal care for individual patients.

CHSWC, however, continues at page 2: “Numerous gaps and weaknesses in the ACOEM or any other existing set of guidelines will have to be filled by reliance on other guidelines.” CHSWC indicates, in relevant part, that “stakeholder input indicates ACOEM is weak for ... acupuncture ....” CHSWC then states:

Recognizing that general guidelines are subject to abuse by both excessive treatment and unwarranted denials, CHSWC recommends that specific guidelines be established for these therapies. *The quality of the guidelines developed by specialty organizations in these fields has not been independently evaluated, so CHSWC cannot recommend those guidelines.* Instead, CHSWC recommends using National Institutes of Health consensus statements and other states’ established guidelines, such as Colorado, to compose guidelines containing:

- A list of conditions for which each modality may be appropriate,
- A documentation process to justify the initiation of a treatment plan,
- A documentation process to justify continuation of a treatment plan by demonstrating functional improvement at specified intervals, and
- A maximum number of visits and duration of course of treatment.

In sum, CHSWC recommends that:

[T]he AD consider adopting interim guidelines for specified therapies, including ... acupuncture ... consisting of a prior authorization process in which the indications for treatment and the expected progress shall be documented, and documentation of actual functional progress shall be required at specified intervals as a condition of continued authorization for the specified modalities (At page 1.)

Chapter 3—Initial Approach to Treatment of the ACOEM Practice Guidelines, at page 43, sets forth the recommended initial approach to treatment of industrial injuries. In addressing nonsurgical management of industrial injuries, ACOEM presents options on pages 46-50, which include discussions on physical methods. These physical methods include chiropractic and physical therapy but do not include acupuncture. Page 50 of Chapter 3 does refer to “other methods and modalities,” but refers the reader to Chapters 8-16.

A review of these chapters reflects that the ACOEM Practice Guidelines, Second Edition, references acupuncture treatment as follows: Acupuncture treatment is addressed in the

guidelines at pages 174, 204, 235, 300, 339. In Chapter 10. Elbow Complaints, page 235, the guidelines indicate: “The efficacy of needle acupuncture is not yet clearly supported by quality medical evidence.” In Chapter 13. Knee Complaints, page 339, the guidelines indicate: “Some studies have shown that transcutaneous electrical neurostimulation (TENS) and acupuncture may be beneficial in patients with chronic knee pain, but there is insufficient evidence of benefit in acute knee problems.” In Chapter 12. Low Back Complaints, page 300, the guidelines state: “Acupuncture has not been found effective in the management of pain based on several high-quality studies, but there is anecdotal evidence of its success.” In Chapter 8. Neck and Upper Back Complaints, page 174, the guidelines state: “Invasive techniques (e.g., needle acupuncture and injection procedures such as injection of trigger points, facet joints, or corticosteroids, lidocaine, or opioids in the epidural space) have no proven benefits in treating acute neck and upper back symptoms.” In Chapter 9. Shoulder Complaints, page 204, the guidelines state: “Some small studies have supported using acupuncture, but referral is dependent on the availability of experienced providers with consistently good outcomes.”

In its article entitled *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG Insights, Winter 2005 (which has been added to the documents relied upon in the formal rulemaking file), at p. 2, ACOEM performs an interim review of the scientific literature on acupuncture, and updates its position on the reasonableness of acupuncture treatment. ACOEM concludes in that article that:

*It would consequently seem most reasonable for acupuncture to be classified, as stated in the initial second edition of the guidelines, as an optional intervention; with indications for its use, and discontinuation, as stated in this article.*

The comments received argue that the ACOEM Practice Guidelines do not address acupuncture properly, and request that we adopt the Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition, December, 2004. We agree in part. We have determined that it is necessary to address the acupuncture modality in our medical treatment utilization schedule as our first priority in supplementing the schedule. This is based on the fact that RAND did not evaluate acupuncture treatment, our own review of the ACOEM Practice Guidelines as set forth above, and the determination that among all nonsurgical treatment options, acupuncture is not covered as well as the other modalities in the ACOEM Practice Guidelines. Indeed ACOEM’s own publication, the APG Insights as reflected above, states that Acupuncture should be regarded as an optional intervention. The recommendation in the APG Insights is different from the ACOEM Practice Guidelines, Second Edition.

In recognizing that Labor Code section 4600 provides that the injured worker is entitled to acupuncture as reasonably required medical treatment to cure or relief the effects of the industrial injury, and because Labor Code section 5307.27 requires that the medical treatment utilization schedule *address, at a minimum*, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases, it is necessary to address the acupuncture modality in our medical treatment utilization schedule as our first priority in supplementing the schedule. Accordingly, Section 9792.21(a)(2) has been added to the proposed regulations setting forth the Acupuncture Medical Treatment Guidelines.

The Acupuncture Medical Treatment Guidelines have been written pursuant to RAND’s and CHSWC’s recommendations as set forth above. Both RAND and CHSWC suggested adoption of ACOEM supplemented with specific guidelines addressing gaps. As indicated above, it was determined that the acupuncture guideline was a priority because acupuncture is the treatment that is not covered as well in the ACOEM Practice Guidelines yet access to acupuncture is required by Labor Code section 4600. Although CHSWC recommended that we adopt a guideline such as the National Institutes of Health consensus statements, it was determined that these statements were non-specific and would not satisfy the requirements that the guideline

“shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.” (Lab. Code, § 5307.27.) CHSWC also recommended that a guideline such as the guideline on acupuncture from the State of Colorado be examined. Upon review of Colorado’s guidelines on acupuncture it was determined that these guidelines were more on point with the requirements of Labor Code section 5307.27. The Colorado guideline has gone through multidisciplinary review and formal rulemaking prior to its adoption as a state regulation. This process is also consistent with that proposed by these regulations. Thus, the Acupuncture Medical Treatment Guideline has been crafted based on the Colorado Acupuncture Guidelines, and taking into consideration ACOEM’s APG Insights, wherein ACOEM has revised the medical literature and has updated its position on the reasonableness of acupuncture treatment as an optional intervention.

As reflected in the Acupuncture Medical Treatment Guidelines, we have crafted the guidelines based on the Colorado Guidelines but have not adopted their guidelines in their entirety to avoid conflict. ACOEM remains the foundation for the MTUS, and any supplemental guidelines including the Acupuncture Medical Treatment Guidelines, must be fitted to ACOEM as it provides the framework for the MTUS appropriate for those conditions covered by ACOEM. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). The language contained in the proposed regulations at Section 9792.21(a)(2)(D) stating that “[a]cupuncture treatments may be extended if objective functional improvement is documented,” has been crafted to be more consistent with the philosophy of functional restoration as a goal of medical treatment in the ACOEM Practice Guidelines. The ACOEM Practice Guidelines provide that the “[p]atient and clinician should remain focused on the ultimate goal of rehabilitation leading to optimal functional recovery, decreased healthcare utilization, and maximal self-actualization. (ACOEM, at p. 106.) In order to objectify functional improvement, the AMA Guides can offer a systematic approach to track improvement. For example, the ACOEM Practice Guidelines, state at page 89, that “[t]he first step in managing delayed recovery is to document the patient’s current state of functional ability (including activities of daily living) and the recovery trajectory to date as a timeline.” Assessing activities of daily living is a component of the AMA Guides in addition to other objective methods. Moreover, we are not including the Colorado acupuncture guideline’s section on “other acupuncture modalities” as these adjunctive acupuncture modalities discussed in the section are not specific to acupuncture.

As reflected in Section 9792.21(a)(2), we specify in the regulations that the Acupuncture Medical Treatment Guidelines supersede the ACOEM Practice Guidelines chapters of Neck and Upper Back Complaints, Elbow Complaints, Forearm, Wrist, and Hand Complaints, Low Back Complaints, Knee Complaints, Ankle and Foot Complaints, and Pain, Suffering, and the Restoration of Function. The Colorado Medical Guidelines were used to the extent that it supplemented ACOEM in the area of acupuncture. The Chapter Shoulder Complaints was not included because the Colorado Guidelines did not specifically identify acupuncture as a treatment for shoulder conditions. However, the ACOEM Practice Guidelines does discuss acupuncture in this chapter. The Advisory Committee will provide recommendations to the Medical Director concerning further development of consistent Acupuncture Medical Treatment Guidelines, if necessary.

The Acupuncture Medical Treatment Guidelines contain three definitions. One definition is for the term “acupuncture,” and the second definition is for the term “acupuncture with electrical stimulation.” These definitions were obtained from the Colorado Medical Treatment Guidelines (7 CCR 1101-3-Rule 17 Medical Treatment Guidelines). Moreover, the Acupuncture Medical Treatment Guidelines contain a third definition for the term “chronic pain for purposes of acupuncture.” This definition was obtained from Exhibit 9 to the Colorado Medical Treatment Guidelines (7 CCR 1101-3-Rule 17 Medical Treatment Guidelines).

### **Subdivision 9792.21(b)**

**Subdivision (b)** has been modified to state: The Medical Treatment Utilization Schedule 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 change in this section is consistent with the changes as explained in subdivisions (a) and (a)(1). The goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS. Thus, the language “ACOEM Practice Guidelines” was substituted with the language “Medical Treatment Utilization Schedule.” Further the phrase “medical treatment provider” has been deleted. Some commenters suggested that the phrase was unnecessary, and suggested that the beginning of the first sentence in 9792.21(b) be changed to state “[t]he Medical Treatment Utilization Schedule is intended to assist in the provision of medical treatment ....”

### **Subdivision 9792.21(c)**

**Subdivision (c)** has been modified to state: Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the Medical Treatment Utilization Schedule. 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 9792.22, and pursuant to the Utilization Review Standards found in Section 9792.6 through Section 9792.10.

The change in this section is consistent with the changes as explained in subdivisions (a), (a)(1), and (b). The goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS. Thus, the language “ACOEM Practice Guidelines” was substituted with the language “Medical Treatment Utilization Schedule.” This subdivision now provides a definition for the term “peer reviewed” which 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. This definition was requested by the public during the 45-day period comment, and it was added to the proposed regulations for clarification purposes. The phrase “peer-reviewed” has been inserted in the second sentence of subdivision (c) in the description of medical guidelines which may be used to provide medical treatment if the medical treatment is not addressed by the MTUS. The requirement that the guidelines be “peer-reviewed” was requested by the public for clarification purposes and because both Labor Code sections 4604.5(b) and 5307.27 contain this requirement. The requirement was added to the pursuant to the statutes, and a definition was added to the regulations which 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. The requirement of peer review and the definition were requested by the public during the 45-day period comment, and it was added to the proposed regulations for clarification purposes. Further, the word “generally” has been replaced with the word “nationally” and the word “national” has been deleted in the second sentence of the subdivision, so that beginning of the sentence reads as follows: “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 ....” This change results from comments from the public requesting that the word “generally” be removed from this sentence as non-specific. After reviewing applicable Labor Code sections (Lab. Code §§ 77.5, 5307.27 and 4604.5(b)), it was determined that these sections consistently refer to “nationally recognized” by the medical community when referring to medical treatment guidelines, and that

section 4604.5(e) is the only section that uses the term “generally recognized by the national medical community.” The Administrative Director determined that both terms have essentially the same meaning, and in order to implement, interpret, and make specific Labor Code section 4604.5(e), it was necessary to harmonize this section (Lab. Code, §4604.5(e)) with the remaining statutes (Lab. Code, §§ 77.5, 5307.27, and 4604.5(b).) The Administrative Director further determined that it was appropriate to use the term “nationally recognized” throughout the regulations as this term is used consistently in Labor Code sections 77.5, 5307.27 and 4604.5(b), and it is already defined in the proposed regulations. Thus, the language “generally recognized by the national medical community” contained in Sections 9792.21(c) and 9792.22(b) was substituted with the language “nationally recognized.” Further, the phrase “pursuant to the Utilization Review Standards found in Section 9792.6 through Section 9792.10” has been inserted in this section to clarify that these regulations do not change the current Utilization Review practice, and decisions to approve, modify or deny treatment are controlled by the Utilization Review Standards regulations (Section 9792.6 through Section 9792.10).

### **Modifications to Section 9792.22 Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence**

The phrase “hierarchy of scientific based evidence” has been substituted with the phrase “strength of evidence.” Thus, the section is entitled: Presumption of Correctness, Burden of Proof and Strength of Evidence.

This change, which will be explained in full detail in the explanation for the changes of Section 9792.22(c), is the result of ACOEM adopting a new methodology to evaluate scientific evidence for its updates of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition. ACOEM’s justification for the change and DWC’s explanation for the modifications are set forth below.

#### **Section 9792.22(a)**

**Subdivision (a)** has been modified to state: The Medical Treatment Utilization Schedule is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the Medical Treatment Utilization Schedule 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.

The change in this section is consistent with the changes as explained in Section 9792.21, subdivisions (a), (a)(1), (b), and (c). The goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS. The terms “ACOEM Practice Guidelines,” and “guidelines” have been substituted with the phrase “Medical Treatment Utilization Schedule.” Further, the terms “acute” and “chronic” have been deleted from the first sentence of this subdivision, and the phrase “the duration of the” has been inserted. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic.” DWC agrees that the distinction between an acute stage and a chronic stage of a condition is a clinical one. Because the intent of the regulations is to state that the ACOEM Practice Guidelines apply to all conditions for the duration of the medical condition, the terms “acute” and “chronic” have been deleted from the first sentence of this subdivision. Thus the sentence now reads: “The Medical Treatment Utilization Schedule is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in the Medical Treatment Utilization Schedule for the duration of the medical condition.”

## **Section 9792.22(b)**

**Subdivision (b)** has been modified to state: For all conditions or injuries not addressed by the Medical Treatment Utilization Schedule, 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.

The change in this section is consistent with the changes as explained in Section 9792.21, subdivisions (a), (a)(1), (b), and (c), and Section 9792.22(a). The goal is to re-organize the regulations to reference the adoption of the MTUS, and the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS. The term “ACOEM Practice Guidelines” has been substituted with the phrase “Medical Treatment Utilization Schedule.” Further, the word “generally” has been replaced with the word “nationally” and the word “national” has been deleted in the second sentence of the subdivision, so that the sentence reads as follows: For all conditions or injuries not addressed by the Medical Treatment Utilization Schedule, 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. After reviewing applicable Labor Code sections (Lab. Code §§ 77.5, 5307.27 and 4604.5(b)), it was determined that these sections consistently refer to “nationally recognized” by the medical community when referring to medical treatment guidelines, and that section 4604.5(e) is the only section that uses the term “generally recognized by the national medical community.” The Administrative Director determined that both terms have essentially the same meaning, and in order to implement, interpret, and make specific Labor Code section 4604.5(e), it was necessary to harmonize this section (Lab. Code, §4604.5(e)) with the remaining statutes (Lab. Code, §§ 77.5, 5307.27, and 4604.5(b).) The Administrative Director further determined that it was appropriate to use the term “nationally recognized” throughout the regulations as this term is used consistently in Labor Code sections 77.5, 5307.27 and 4604.5(b), and it is already defined in the proposed regulations. Thus, the language “generally recognized by the national medical community” contained in Sections 9792.21(c) above, and 9792.22(b) was substituted with the language “nationally recognized.”

## **Section 9792.22(c)**

**Subdivision (c)(1)** has been modified to state: 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) or (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:

The word “either” has been inserted in the subdivision before the words “subdivisions (a) or (b). This change was pursuant to a public comment to clarify the requirements of the subdivision. Further the word “hierarchy” has been substituted by the phrase “ACOEM’s strength of evidence rating methodology,” and the sentence is clarified that this 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. Further, the phrase “shall apply to determine the effectiveness of” and the words “different” and “and” have been deleted and the sentence clarified to state that “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.”

Because a new methodology to rate the strength of the evidence has been adopted the hierarchy proposed in the July 2006 draft has been deleted, thus subdivisions (A), (B), and (C), setting forth the hierarchy have been deleted from the text of the regulations. A new subdivision (A) has been inserted setting forth Table A—Criteria Used to Rate Randomized Controlled Trials as follows:

**Subdivision (c)(1)(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><b>Randomization:</b> 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>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><b>Treatment Allocation Concealed:</b> 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 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><b>Baseline Comparability:</b> 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><b>Patient Blinded</b></p>	<p>Rating is “0” if there is no mention of blinding of the</p>

	<p>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>
<b>Provider Blinded</b>	<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>
<b>Assessor Blinded</b>	<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>
<b>Co-interventions Avoided:</b> The degree to which the study design avoided multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication).	<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-interventions were avoided.</p>
<b>Compliance Acceptable:</b> Measures the degree of non-compliance.	<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>
<b>Dropout Rate:</b> Measures the drop-out rate.	<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</p>

	<p>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><b>Timing of Assessments:</b> Timing rates the timeframe for the assessments between the study groups.</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 apart).</p> <p>Rating is “1.0” if the timing of the assessments between the groups is identical.</p>
<p><b>Analyzed by Intention to Treat:</b> 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><b>Lack of Bias:</b> 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>

Further a new subdivision (B) has been inserted setting forth Table B— Strength of Evidence Ratings as follows:

**Subdivision (c)(1)(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.

<b>A</b>	<b>Strong evidence-base:</b> One or more well-conducted systematic reviews or meta-analyses, or two or more high-quality studies.
<b>B</b>	<b>Moderate evidence-base:</b> 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.
<b>C</b>	<b>Limited evidence-base:</b> At least one study of intermediate quality.
<b>I</b>	<b>Insufficient Evidence:</b> Evidence is insufficient or irreconcilable.

**Subdivision (c)(2)** has been amended to be consistent with the above changes, and the phrase “hierarchy of evidence” has been substituted by the phrase “strength of evidence.” Thus section 9792.22(c)(2) has been modified to state: “Evidence shall be given the highest weight in the order of the strength of evidence. The reasons for the changes in the text of the proposed regulations are set forth below:”

During the 45-day comment period, ACOEM notified DWC that it would adopt a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition. ACOEM has now completed the updated methodology, and has provided DWC the following justification:

***Methodology Advances for Occupational Medicine Practice Guidelines, 2<sup>nd</sup> Edition***

The methodology that the American College of Occupational and Environmental Medicine (ACOEM) has adopted for updates to its Occupational Medicine Practice Guidelines, 2<sup>nd</sup> Edition, is designed to produce the most rigorous, reproducible, and transparent occupational health guidelines available. There are several advances with this methodology, including improvements in: 1) criteria to grade articles; 2) strength of evidence ratings; and 3) evidence-based recommendation categories. Each of these advances is briefly described below as are the reasons for these improvements.

To rate the articles, ACOEM used an adapted 11 variable (or attribute) system (see Table 1), established explicit criteria for each of the 11 variables and then scored each attribute using a scale of 0, 0.5 or 1.0. This approach results in a numerical rating of each individual article, ranging 0 to 11.0. Those numerical article ratings are then mapped to the study quality range ratings of: low quality (3.5 or less); intermediate quality (4-7.5); and high quality (8-11).

These study quality ratings are then used to determine the Strength of Evidence Ratings for the evidence base for a particular topic (see Table 2). There are 3 levels of such evidence: Strong (A), Moderate (B), and Limited (C) Evidence Bases. There is a fourth category of “I” Insufficient Evidence. All are clearly defined and are linked to ratings of the articles.

The Strength of Evidence Ratings is then utilized to develop the Evidence-Based Recommendations (see Table 3). ACOEM has developed 9 recommendation categories that parallel the strength of evidence categories. There are also 3

categories for “insufficient evidence”, including 1 category for recommendations that would include very low-cost, low-risk interventions (such as the use of acetaminophen) that are unlikely to be subject to randomized controlled trials (RCTs).

There are several reasons for these changes. The underlying reason for all of the changes is a desire to improve clarity, transparency, reproducibility, and communication. The criteria to rate articles are purposefully more detailed than in other previously available guidelines. By providing these explicit ratings and ultimately mapping them to “strength of the evidence”, the entire system and process becomes more reproducible. It also becomes possible for others to critique the process, analyses, recommendations, and thereby resulting in continual quality improvement.

The Strength of Evidence Ratings changes include the elimination of the “D” rating. This recognizes that the former “D” level evidence included either a lack of evidence or a consensus of experts and is not evidence based. Thus, it was replaced with “I” (Insufficient), rather than implying it was the next lower level below “C.” The recommendations are developed from those improvements in the strength of evidence by making them parallel. For example, there are 2 levels of “A” recommendations, one in favor and one against. At each step in this process, there are explicit criteria with definitions to make a process that is as reproducible as possible.

Because ACOEM has updated its methodology, and in light of the fact that we have adopted ACOEM into the MTUS, we have amended Section 9792.22(c)(1) to reflect ACOEM’s updated methodology. ACOEM remains the foundation for the MTUS, and the adoption of the updated methodology allows the MTUS to remain consistent with ACOEM’s current methodology to evaluate evidence-based medical treatment guidelines. Just as new evidence emerges that will change treatment recommendations over time, the instrument used to evaluate the evidence will also evolve over time. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a). For the same reasons, the term “hierarchy of evidence” as previously defined in section 9792.20(g) has been moved to section 9792.20(1), and re-named “strength of evidence.” The definition as noticed remains the same.

Comments were received that the level “D” should be included in DWC’s hierarchy. DWC agrees with ACOEM’s change from level “D” to level “I” as this new terminology clarifies that this level of evidence is insufficient. For this reason, DWC will now include level “I” in its hierarchy.

Given that ACOEM has established a new strength of evidence rating system, with grading criteria for levels A, B, C, and I, the term “hierarchy of evidence” in the original proposed regulation will now be replaced by the term “strength of evidence” into the MTUS.

“Strength of Evidence” is a better term to describe the ACOEM evidence based review process and it will be used to evaluate scientific evidence for specific treatment recommendations in the course of treatment of an injured worker when such requested treatments fall outside the presumption afforded by the MTUS.

The criteria used to rate randomized controlled trials and the strength of evidence ratings is included in proposed Section 9792.22. The additional section (Table 3) from ACOEM’s justification as reflected on the document relied upon provided to DWC by ACOEM was not included in the proposed regulations because that table is for creation of treatment guidelines which falls outside of the scope of this regulation.

## Modifications to Section 9792.23 Medical Evidence Evaluation Advisory Committee

### Section 9792.23

**Subdivision (a)(1)** has been modified to read: The Medical Director shall create a medical evidence evaluation advisory committee to provide recommendations to the Medical Director on matters concerning the medical treatment utilization schedule. The recommendations are advisory only and shall not constitute scientifically based evidence.

The term “Administrative Director” has been substituted with the term “Medical Director.” The modification makes it clear that the medical evidence evaluation advisory committee (advisory committee) will be advising the Medical Director, not the Administrative Director.

**Subdivision (a)(2)** has been modified to state: 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 members of the medical community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), Psychology (PhD.), or Doctor of Podiatric Medicine (DPM) licenses, and representing the following specialty fields:

This subdivision has been amended to reflect that the members of the advisory committee will be composed of 17 members, and to require that they have licenses in their areas of specialties. Many commenters have suggested that advisory committee be augmented in recognition of the role and contribution of other specialties in the treatment of workplace injuries. The number disciplines included in the advisory committee has been expanded to better address “the ... treatment procedures and modalities commonly performed in workers’ compensation cases” as required by the statute (Lab. Code, § 5307.27). The modifications in subdivisions (a)(2)(A)-(O) are as follows:

Subdivision (a)(2)(E) has been modified to delete the words “or occupational;” subdivision (a)(2)(F) has been modified to delete the words “or psychiatry;” subdivision (a)(2)(H) has been added to require that one member shall be from the occupational therapy field; subdivision (a)(2)(I) has been added to require that one member shall be from the psychiatry field; subdivision (a)(2)(J) has been added to require that one member shall be from the neurosurgery field; subdivision (a)(2)(K) has been added to require that one member shall be from the family physician field; subdivision (a)(2)(L) has been added to require that one member shall be from the neurology field; subdivision (a)(2)(M) has been added to require that one member shall be from the internal medicine field; subdivision (a)(2)(N) has been added to require that one member shall be from the physical medicine and rehabilitation field; and subdivision (a)(2)(O) has been added to require that one member shall be from the podiatrist field;

Subdivision (a)(2)(P) was modified to reduce the number of members appointed at the discretion of the Medical Director from three to two as suggested by the public. Thus the section now states: (P) Two additional members shall be appointed at the discretion of the Medical Director or his or her designee.

**Subdivision (a)(3)** has been modified to reflect the increase in the members of the advisory committee from ten to seventeen. Thus, the subdivision now states: In addition to the seventeen 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.

**Subdivision (d)** has been modified to read: 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) times a year.

There are two pertinent changes in this subdivision. The first change the term of service was increased from one year to two years, and to specify a minimum time of meetings. These two changes were suggested by the public.

**Subdivision (f)** was amended to clarify that the Medical Director will be advising the Administrative Director about revisions, updates and supplementation of the medical treatment utilization schedule as necessary, not the advisory committee. Thus, the subdivision now states: The Administrative Director, in consultation with the Medical Director, may revise, update, and supplement the medical treatment utilization schedule as necessary.