

**State of California**  
**DEPARTMENT OF INDUSTRIAL RELATIONS**  
**Division of Workers' Compensation**

**FINAL STATEMENT OF REASONS**  
**AND UPDATED INFORMATIVE DIGEST**

**Subject Matter:**

Workers' Compensation – Medical Treatment Utilization Schedule

**Title 8, California Code of Regulations, sections 9792.20 through 9792.23**

The Administrative Director of the Division of Workers' Compensation, pursuant to the authority granted by Labor Code sections 59, 133, 4603.5, and 5307.3, has adopted Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, sections 9792.20 through 9792.23, as follows:

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 Strength of Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

**UPDATE OF INITIAL STATEMENT OF REASONS**

As authorized by Government Code §11346.9(d), the Administrative Director incorporates the Initial Statement of Reasons prepared in this matter. The purposes and rationales for the regulations as set forth in the Initial Statement of Reasons continue to apply unless noted in the Final Statement of Reasons.

**INFORMATIVE DIGEST**

There have been no changes to the statutes directly relating to this rulemaking.

The proposed regulation changes are summarized below.

**THE FOLLOWING SECTIONS WERE AMENDED FOLLOWING THE PUBLIC HEARING AND CIRCULATED FOR A 15-DAY COMMENT PERIOD (December 7, 2006 through December 22, 2006.)**

**SUMMARY OF PROPOSED CHANGES**

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

**Subdivision (a)** setting forth the definition for the term “acute” was deleted from the text of the proposed regulations. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic.” After review of the submitted comments,

DWC agreed that the distinction between an acute stage and a chronic stage of a condition is a clinical distinction. 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 definition of the term “acute” (Section 9792.20(a)) was removed from this subdivision.

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

**Subdivision (c)** setting forth the definition for the term “ACOEM Practice Guidelines” was re-lettered subdivision (b). Further, the reference to the publisher (i.e., “published by OEM Press”) was deleted based on ACOEM’s 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, was added to the formal rulemaking file as a document relied upon.

**Subdivision (d)** setting forth the definition for the term “chronic” was deleted from the text of the proposed regulations. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic.” DWC agreed with the comment that the distinction between an acute stage and a chronic stage of a condition is a clinical distinction. 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 definition of “chronic” (Section 9792.20(d)) was removed from this subdivision.

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

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

A new definition was added to the regulations at **subdivision (e)**. Subdivision (e) sets forth the definition for the term “functional improvement,” stating:

“[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.”

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

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

worker has regained specific physical functions necessary for reemployment. (See, ACOEM Practice Guidelines, at p. 77.)

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

Pain in today's work place presents a challenge to the occupational physician. Although mistreating or undertreating pain is of concern, an even greater risk for the physician is overtreating the chronic pain patient, especially with opioids and other medications. Overtreatment often results in irreparable harm to the patient's socioeconomic status, home life, personal relationships, and quality of life in general. However, because opioids are "easy" and represent a path of little resistance, they may prevent the patient, the physician, or both from vesting in a difficult and uncomfortable rehabilitation course. A physician's choice to palliate and not rehabilitate is a profound clinical, ethical, and medico-economic decision not 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, DWC found it necessary to clarify what ACOEM refers to as "demonstrated evidence of ongoing improvement." To this end, a definition of the term functional improvement was 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. This is further consistent with the Colorado Guidelines which provide that acupuncture treatment may be continued beyond 3 to 6 treatments if the patient shows improvement.

**Subdivision (g)** was amended to substitute the term "hierarchy of evidence" with the term "strength of evidence," and was re-lettered subdivision (l). The definition as contained in the original draft remained the same but the term was changed to "strength of evidence." This change resulted from comments submitted during the 45-day comment period, wherein 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 completed the updated methodology, and provided DWC with a justification for the change which was set forth in the notice of the 1<sup>st</sup> 15-day changes to the proposed text of the regulations (issued December 2006) as an explanation under the changes made in proposed Section 9792.22(c)(1), as set forth below. Because DWC adopted ACOEM's strength of evidence rating methodology into the MTUS, it was necessary to delete the term "hierarchy of evidence" and substitute it with the term "strength

of evidence.” This allowed 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” was re-lettered subdivision (f), and was corrected for clerical error. The subdivision 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” was re-lettered subdivision (g). The definition of “medical treatment guidelines” was amended to require that the medical treatment guideline being used be “the most current version” and “revised within the last five years.” This definition was amended for clarification purposes. During the 45-day comment period, commenters indicated that the definition should limit the effective date of the treatment guideline in order to insure currency of the guideline. DWC agreed this was important to prevent the use of outdated guidelines to guide the provision of medical treatment. DWC 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. DWC 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 was added to the rulemaking file under documents relied upon.

This subdivision was also amended to substitute the phrase “appropriate health care” with the phrase “medical treatment” for clarity purposes. This change resulted from comments during the 45-day comment period objecting 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. DWC agreed that the phrase “appropriate health care” should be replaced with the phrase “medical treatment” for clarity and consistency purposes because the proposed regulations as pointed out by the commenters already contained a definition of the term “medical treatment.”

This subdivision was further amended to include the requirement that the guidelines be developed “by a multidisciplinary process.” During the 45-day comment period, 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 reflected the findings of several studies showing that such panels are an important component of guideline quality. DWC agreed with the recommendation that multidisciplinary clinical panels be involved in the development of the guidelines. DWC, however, believed that this requirement related more appropriately to the definition of “medical treatment guidelines.” Thus, the definition of the term “medical treatment guidelines” was amended to include the requirement that the guidelines be developed by a multidisciplinary process. DWC referenced the justification for this requirement which is set forth in the ISOR at p. 20, and in the 2005 RAND Report at p. xviii.

**Subdivision (j)** setting forth the definition for the term “medical treatment provider” was deleted from the text of the proposed regulations. During the 45-day comment period, commenters suggested that the definition be deleted from the proposed regulations as unnecessary. After evaluating the comments, DWC agreed that the definition was not necessary because the term

was 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)** setting forth the definition for the term “MEDLINE” was re-lettered subdivision (h). The original definition contained in the proposed text of the regulations was deleted and substituted with the following definition: “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 as contained in the original definition remained the same as [www.pubmed.gov](http://www.pubmed.gov). The term was amended to make it consistent with the definition contained in the U.S. National Library of Medicines website. The website where the definition may be found was added to the rulemaking file as a document relied upon, and 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” was re-lettered subdivision (i). The subdivision was amended to insert the phrase “with affiliates” between the words “organization” and “based.” During the 45-day comment period commenters raised questions as to whether their organization met 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” was amended to state “disseminated by a national organization *with affiliates* based in two or more states.” This would qualify those organization with affiliates based in two or more states under this definition.

The subdivision was also amended to insert the phrase “for use” between the phrases “currently adopted” and “by one or more.” During the 45-day comment period commenters argued that the adoption of a guideline by one or more U.S. state governments failed to satisfy the requirement that a guideline be “nationally” recognized and/or failed to require proper screening. Based on these comments, the definition as contained in this subdivision was 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 change satisfied the requirement that the guideline go 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 term and definition was added as **subdivision (j)** to the text of the proposed regulations. This subdivision sets forth the 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 comment period because Labor Code Section 5307.27 requires the medical treatment utilization schedule to incorporate “evidence-based, *peer-reviewed*, nationally recognized standards of care.” DWC agreed that inclusion of the term and definition in the proposed regulations is necessary to meet the requirements of the statute.

**Subdivision (m)** setting forth the definition for the term “scientifically based” was re-lettered subdivision (k). The definition of the term “scientifically based” has been amended to insert the phrase “in MEDLINE” between the word “search” and the phrase “the identified literature.” The subdivision was further amended to substitute the word “graded” with the word “evaluated.” These two changes were made for clarification purposes to tie the definition with other elements of the proposed regulations.

A new term: “strength of evidence” was added to the proposed regulations at **subdivision (l)**. This term substituted the term “hierarchy of evidence” in the proposed regulations and is defined with the exact same definition of the term “hierarchy of evidence” which was 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)** was amended to reorganize this section by creating two separate paragraphs, i.e., subdivision (a) and subdivision (a)(1).

**Subdivision (a)** maintained the original proposed introductory language of the paragraph, i.e., “The Administrative Director adopts” and new language was inserted as follows: “the Medical Treatment Utilization Schedule consisting of Sections 9792.20 through Section 9792.23.” The next sentence was crafted of originally proposed language and new language as follows: “The Administrative Director adopts (new language) and incorporates by reference (originally proposed language) the following medical treatment guidelines into the Medical Treatment Utilization Schedule (new language):”

**Subdivision (a)(1)** was added to the proposed text of the regulations setting forth originally proposed language, which was moved down from subdivision (a), as follows: “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)).” Further, the reference to the publisher (i.e., “published by OEM Press”) was deleted from the proposed text of the subdivision.

In whole, and as amended, the two subdivisions state:

(a) 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:

(1) 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)).

During the 45-day comment period, comments were received from the public stating that the language of the regulations should be re-focused to reference the adoption of the MTUS, and the adoption of the ACOEM Practice Guidelines as one of the components of the MTUS. DWC agreed with these comments and amended subdivision (a) and created subdivision (a)(1) to clarify that the proposed regulations adopt the MTUS, and that the ACOEM Practice Guidelines, although the foundation of the MTUS, is just a component of the MTUS. It is expected that the

MTUS will evolve through further formal rulemaking 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. Therefore, Section 9792.21(a) was amended to clarify the adoption of the MTUS, and new subdivision (a)(1) was added to the regulations to incorporate the ACOEM Practice Guidelines into the schedule. The phrase “published by OEM Press” was deleted from the text of the proposed regulations because ACOEM had 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, was 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 was 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 were added to the text of the proposed regulations for the following reasons:

The Initial Statement of Reasons (ISOR) set 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 noted 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 p. 265.) The *Acupuncture and Electroacupuncture: Evidence-Based Treatment Guidelines* written in 2004, however, state at page 63: "The use of acupuncture and electroacupuncture 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.*"

In light of the numerous comments received on acupuncture during the 45-day comment period, DWC re-evaluated the 2005 RAND Study. 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.)

DWC noted that in reviewing the addressed topics, RAND did not evaluate acupuncture as a topic.

In its 2005 RAND Report, at page 86, RAND stated 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.)

DWC further noted that in its April 6, 2006 Updated and Revised CHSWC Recommendations to DWC on Workers' Compensation Medical Treatment Guidelines, CHSWC stated 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.

DWC further noted that CHSWC continued in its recommendations 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 indicated, in relevant part, that “stakeholder input indicates ACOEM is weak for ... acupuncture ...” CHSWC stated:

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 recommended 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.)

In reviewing the ACOEM Practices Guidelines and its discussion of acupuncture as a treatment modality, DWC noted that the Guidelines, at page 43, Chapter 3—Initial Approach to Treatment—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. Moreover, the ACOEM Practice Guidelines, at page 50 of Chapter 3, refer to “other methods and modalities,” but refers the reader to Chapters 8-16.

DWC staff reviewed these chapters in reference to acupuncture. It was determined that the ACOEM Practice Guidelines, 2<sup>nd</sup> 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.”

DWC staff further reviewed ACOEM’s article entitled *Acupuncture-Medical Literature Analysis and Recommendations*, published in the APG Insights, Winter 2005 (which was added to the documents relied upon in the formal rulemaking file). In this article, at p. 2, ACOEM performed an interim review of the scientific literature on acupuncture, and updated its position on the reasonableness of acupuncture treatment. ACOEM concluded 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. (Emphasis added.)*

The comments received during the 45-day comment period argued that the ACOEM Practice Guidelines do not address acupuncture properly, and requested that DWC adopt the *Acupuncture and Electroacupuncture Evidence-Based Treatment Guidelines, First Edition*, December, 2004. DWC agreed in part with the comments submitted. DWC determined that it was necessary to address the acupuncture modality in the medical treatment utilization schedule as DWC's first priority in supplementing the schedule. This decision was based on the fact that RAND did not evaluate acupuncture treatment, DWC's own review of the ACOEM Practice Guidelines as set forth above, and the determination that among all nonsurgical treatment options, acupuncture was not covered as well as the other modalities in the ACOEM Practice Guidelines. DWC further took into consideration ACOEM's own publication, the APG Insights as reviewed above, wherein ACOEM states that acupuncture should be regarded as an optional intervention. That is, DWC concluded that ACOEM's recommendation in the APG Insights was different from the recommendations contained in 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, DWC determined that it was necessary to address the acupuncture modality in the medical treatment utilization schedule as DWC's first priority in supplementing the schedule. For the aforementioned reasons, section 9792.21(a)(2) was added to the proposed regulations setting forth the Acupuncture Medical Treatment Guidelines.

The Acupuncture Medical Treatment Guidelines were written pursuant to RAND's and CHSWC's recommendations as described 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 was determined to be 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 DWC adopt a guideline such as the National Institutes of Health consensus statements, after review it was determined that these statements were non-specific and would not satisfy the statute's 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. DWC examined the acupuncture guideline from the State of Colorado, and upon review it was determined that these guidelines were more on point with the requirements of Labor Code section 5307.27. It was determined that the Colorado guideline had gone through multidisciplinary review and formal rulemaking prior to its adoption as a state regulation. (See, *State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines—Medical Treatment Guidelines Update Process*, wherein it is stated: "[n]ew guideline processes ... include ... a multidisciplinary Advisory Panel to provide clinical fee back to the Task Force and the Division. See also, State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines, General Information, <http://www.coworkforce.com/dwc/DivisionResources/mtgsummarybriefintro.pdf>.) This process is consistent with the process required by the proposed regulations. Moreover, it was further

determined that the Colorado Guidelines are evidence-based as required by the statute. (Lab. Code, § 5307.27.) (See, *The State of Colorado, Division of Workers' Compensation—Medical Treatment Guideline Update Process*, wherein it is stated: “[i]nitially, during ‘the internal review’ stage, current medical literature related to the guideline is systematically reviewed, critiqued, and graded by the Division and the multidisciplinary-task force.”) Thus, the Acupuncture Medical Treatment Guidelines as set forth in proposed Section 9792.21(a)(2) (e.g., definitions, frequency and duration of treatments) were crafted based on the Colorado Acupuncture Guidelines. (See, Colorado Medical Treatment Guidelines, Rule 17, 7 CCR 1101-3, [http://www.coworkforce.com/dwc/Medical\\_Treatment.asp](http://www.coworkforce.com/dwc/Medical_Treatment.asp).) Further, the Acupuncture Medical Treatment Guidelines were crafted taking into consideration ACOEM’s APG Insights, wherein ACOEM revised the medical literature and updated its position on the reasonableness of acupuncture treatment as an optional intervention.

As reflected in proposed **Subdivision 9792.21(a)(2)**, the regulations provide that the Acupuncture Medical Treatment Guidelines supersede the text in the ACOEM Practice Guidelines, Second Edition, relating to acupuncture, except for shoulder complaints, and address acupuncture treatment where not discussed in the ACOEM Practice Guidelines. DWC crafted the acupuncture guidelines based on the Colorado Guidelines. DWC, however, did not adopt their guidelines in their entirety to avoid internal conflict in the MTUS. As drafted, the regulations preserve the ACOEM Practice Guidelines as the foundation for the MTUS, and then add to the MTUS (and to ACOEM Practice Guidelines) any supplemental guidelines, including the Acupuncture Medical Treatment Guidelines. That is, the ACOEM Practice Guidelines are the framework for the MTUS appropriate for those conditions covered by the schedule. This approach avoids conflict and the negation of the presumption of correctness pursuant to Labor Code section 4604.5(a).

Proposed **Subdivision 9792.21(a)(2)(A)**, subparts (i), (ii), and (iii) set forth the definitions for the terms “acupuncture,” “acupuncture with electrical stimulation,” and “chronic pain for purposes of acupuncture.” Proposed **Subdivision 9792.21(a)(2)(C)** set forth the frequency and duration of acupuncture treatments.

The definitions as drafted in the proposed Acupuncture Medical Treatment Guidelines were obtained from the Colorado Medical Treatment Guidelines. It was necessary to define these terms as these terms are used in the acupuncture medical treatment guidelines, and they need to be clear and easily understandable to the regulated public. The first two definitions (for the terms “acupuncture” and “acupuncture with electrical stimulation”) are set forth generally in all of their guidelines which provide for acupuncture treatment, and the third definition (for the term “chronic pain for purposes of acupuncture”) is set forth in the Chronic Pain Disorder Guideline. (See, 7 CCR 1101-3-Rule 17 Medical Treatment Guidelines, [http://www.coworkforce.com/dwc/Medical\\_Treatment.asp](http://www.coworkforce.com/dwc/Medical_Treatment.asp); Chronic Pain Disorder Guideline, <http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%209%20Chronic%20Pain%20Disord.pdf>, exhibit page 5.) The frequency and duration of acupuncture treatments were further crafted based on the Colorado Medical Treatment Guidelines. The Colorado specific guidelines and exhibit page number where the acupuncture guidelines, if addressed, may be found at the following links:

**Low Back Pain,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%201%20%20Low%20Back%20Pain.pdf>, at exhibit page 17

**Carpal Tunnel Syndrome,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%202%20CTS.pdf>, at exhibit page 18

**Thoracic Outlet Syndrome,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%203%20Carpal%20Tunnel.pdf>, (no mention of acupuncture)

**Shoulder Injury,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%204%20Shoulder%20Injury.pdf>, (no mention of acupuncture)

**Cumulative Trauma Disorder,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%205%20Cumulative%20Trauma%20Disorder.pdf>, at exhibit page 18

**Lower Extremity,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%206%20Lower%20Extremity%20Injury.pdf>, at exhibit page 31

**Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%207%20Comp%20Reg%20Pain%20Syn.pdf>; at exhibit page 20

**Cervical Spine Injury,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%208%20Cervical%20Spine%20Injury.pdf>, at exhibit page 19

**Chronic Pain Disorder,**

<http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%209%20Chronic%20Pain%20Disord.pdf>, at exhibit page 25

Proposed **Subdivision 9792.21(a)(2)(B)** specifies 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 as being superseded because the Colorado Guidelines did not specifically identify acupuncture as a treatment for shoulder conditions. However, the ACOEM Practice Guidelines discuss acupuncture in this chapter. The Advisory Committee will provide recommendations to the Medical Director concerning further development of the Acupuncture Medical Treatment Guidelines, if necessary.

Proposed **Subdivision 9792.21(a)(2)(D)** provides that “[a]cupuncture treatments may be extended if objective functional improvement is documented.” This requirement was 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 Practice Guidelines, at p. 106.) In order to objectify functional improvement, the AMA Guides (see, Lab. Code, § 4660(b)(1), 8 CCR 9805) 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.

Proposed **Subdivision 9792.21(a)(2)(E)** emphasizes the professional discretion of the acupuncturist, and limits the scope of the acupuncture guidelines as set forth in the proposed regulations. The subdivision is intended to note the professional discretion that the acupuncturist must apply in considering potential complications prior to administering acupuncture.

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

**Subdivision (b)** was modified to substitute the phrase “ACOEM Practice Guidelines” with the phrase “Medical Treatment Utilization Schedule.” The change in this subdivision is consistent with the changes as explained in subdivisions 9792.21(a) and (a)(1) above. The purpose of the change was to re-organize the proposed regulations to reference the adoption of the MTUS, and to further reference the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS.

Subdivision (b) was further amended to delete the phrase “medical treatment provider” from this subdivision, and to add the phrase “in the provision of medical treatment.” During the 45-day comment period commenters suggested that the phrase “medical treatment provider” be deleted from the proposed subdivision as unnecessary. After evaluating the comments, DWC agreed that the proposed redrafting of the sentence was appropriate, and the beginning of the first sentence in subdivision 9792.21(b) was 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)** was modified to substitute the phrase “ACOEM Practice Guidelines” with the phrase “Medical Treatment Utilization Schedule.” This change is consistent with the changes as explained in subdivisions (a), (a)(1), and (b). The purpose of the change is to re-organize the proposed regulations to reference the adoption of the MTUS, and to reference the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS.

Subdivision (c) was further modified to insert the phrase “peer-reviewed” in the second sentence of the subdivision describing the 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. This requirement was added to the subdivision pursuant to the statutes and the public comments submitted. As explained above, a definition to the term “peer-reviewed” was added to the proposed regulations at Section 9792.20(j).

Subdivision (c) was amended to replace the word “generally” with the word “nationally” and to delete the word “national,” 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 ...” During the 45-day comment period, comments were received 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. (See, also Response No. 5 “Generally recognized by the national medical community” language and definition of term “nationally recognized,” which is part of the 45-day comment period chart.)

Subdivision (c) was further amended to insert the phrase “and pursuant to the Utilization Review Standards found in Section 9792.6 through Section 9792.10” at the end of the last sentence of the subdivision. This change was made to clarify that the proposed 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 (8 CCR Section 9792.6 through Section 9792.10). Proposed Section 9792.21(c) anticipates situations where the MTUS will not address certain conditions or injuries. In those situations, the claims administrator is responsible to provide treatment pursuant to other treatment guidelines that meet the requirements of that section. If examined guidelines do not support the treatment request, the claims administrator may request “appropriate information which is necessary to render a decision” following the UR process and appropriate timeline. (See, 8 CCR Section 9792.9.) This may include requesting from the requesting physician “specific references to and excerpts from other nationally recognized, scientifically and evidence-based medical treatment guidelines” or other MEDLINE references that support the medical treatment request. The claims administrator does not need to conduct a MEDLINE search to “prove a negative” i.e., that the request for treatment is not supported by the medical literature. Comments were submitted during the various comments periods requesting that language such as “one or more” or “a set of” be placed immediately before the phrase “other scientifically and evidence-based, peer-reviewed, medical treatment guidelines” in this subdivision. DWC disagreed with these suggestions because the various suggestions restricted and/or expanded the meaning of the statute. Labor Code section 4604.5(e) requires that the authorized treatment not addressed by the MTUS be “in accordance with other ... guidelines....” DWC does not have authority to expand or restrict the meaning of the statute by regulations. Its authority is limited to implement, interpret and make specific the requirements of the statute.

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

The phrase “hierarchy of scientific based evidence” set forth in the title of the section was 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 is 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. The term “Strength of Evidence” is a better term to describe the ACOEM evidence based review process as opposed to “hierarchy of scientific based evidence” based on ACOEM’s description and justification for its updated methodology as set forth in its Amendments to ACOEM’s Methodology Advances for Occupational Practice Guidelines, 2<sup>nd</sup> Edition, March 13, 2007, added to the rulemaking file. Moreover, this term is a universal term which is also used by AHRQ (Agency for Health Care Research and Quality) (see, AHRQ Report No. 47 Systems to Rate the Strength of Scientific Evidence, <http://www.ahrq.gov/clinic/epcsums/strengthsum.htm>).

**Subdivision (a)** was amended to substitute the phrase “ACOEM Practice Guidelines” and the word “guidelines” with the phrase “Medical Treatment Utilization Schedule.” The change in this section is consistent with the changes as explained in Section 9792.21, subdivisions (a), (a)(1), (b), and (c). The purpose of the change is to re-organize the regulations to reference the adoption of the MTUS, and to reference the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS.

Subdivision (a) was amended to delete the terms “acute” and “chronic” from the first sentence of this subdivision, and to insert the phrase “the duration of the” in the same sentence. Comments were submitted during the 45-day comment period objecting to the definitions of the terms “acute” and “chronic” on the basis that the distinction between an acute and chronic state was a clinical determination. DWC agreed with the comment. Because the intent of the proposed 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” were 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.” Further, the word “conditions” was changed to singular (condition) for consistency purposes.

**Subdivision (b)** was modified to substitute the phrase “ACOEM Practice Guidelines” with the phrase “Medical Treatment Utilization Schedule.” 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 purpose of the change is to re-organize the regulations to reference the adoption of the MTUS, and further reference the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, as a component of the MTUS.

Subdivision (b) was amended to replace the word “generally” with the word “nationally” and to delete the word “national.” This change parallels the change made in subdivision 9792.21(c), and was made for the same reasons set forth above.

**Subdivision (c)(1)** was modified to insert the word “either” before the words “subdivisions (a) or (b). This change was pursuant to a public comment that the word “either” would clarify the requirements of the subdivision. DWC agreed with the suggestion.

Subdivision (c)(1) was further modified to substitute the word “hierarchy” with the phrase “ACOEM’s strength of evidence rating methodology.” Further the subdivision was modified by inserting clarifying language stating that 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. Further, the phrase “shall apply to determine the effectiveness of” and the words “different” and “and” were 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.”

The changes set forth below in subdivisions (c)(1) and (c)(2) resulted from ACOEM’s adoption of a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition. ACOEM provided DWC its new methodology and a justification for the adoption of the new methodology during the 45-day comment period, which has been added to the rulemaking file. (ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM’s Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*.) See further explanation below.

Pursuant to proposed **Subdivision (c)(1)**, the “Strength of Evidence” will be used to evaluate scientific evidence for specific treatment recommendations in the course of treatment of an injured worker when such requested treatment: (1) falls outside the MTUS or outside “other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community;” (2) is at variance with the MTUS and “other scientifically and evidence-based medical treatment guidelines that are nationally recognized by the medical community (e.g., new studies not included in guidelines);” and (3) is recommended by a “scientifically and evidence-based medical treatment guideline that is nationally recognized by the medical community” but is at variance with another guideline which meets the very same requirements (e.g., one guideline recommends requested treatment while the other guideline does not recommend the requested treatment).

Subdivision (c)(1) was amended by deleting subparts (A), (B) and (C) from the text of the original proposed regulations. New subpart (A) was 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.

<b>Criteria</b>	<b>Rating Explanation</b>
<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 patient.</p> <p>Rating is “0.5” if it mentions blinding, but the methods are</p>

	<p>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>

<p><b>Dropout Rate:</b> Measures the drop-out rate.</p>	<p>Rating is “0” if there is no mention of drop-outs or it cannot be inferred from the data presented.</p> <p>Rating is “0.5” if the drop-out issue is briefly addressed and the description suggests that there were few drop-outs, but a complete assessment is not possible.</p> <p>Rating is “1.0” if there are specific data and the drop-out rate is under 20%.</p>
<p><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>

New subpart (B) was 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)** was amended to be consistent with the above changes, and the phrase “hierarchy of evidence” was substituted by the phrase “strength of evidence.”

As stated above, the changes set forth above in subdivisions (c)(1) and (c)(2) resulted from ACOEM’s adoption of a new methodology to evaluate the scientific evidence for its updates of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition. In its justification, ACOEM stated, in pertinent part:

***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 updated its methodology, and in light of the fact that DWC proposes to adopt the ACOEM Practice Guidelines into the MTUS, subdivision (c)(1) was amended to reflect ACOEM’s updated methodology. As explained throughout the documents supporting this proposed regulations, ACOEM remains the foundation for the MTUS. 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

that 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).

During the 45-day comment period, comments were received that the level “D” as contained in the ACOEM’s original hierarchy of evidence in the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, at page 501, should be included in the DWC’s original proposed hierarchy. DWC had omitted level “D” as insufficient evidence. In the amended methodology, ACOEM has changed level “D” to level “I” and defines it, stating: “Evidence is insufficient or irreconcilable.” This new terminology clarifies that this level of evidence is insufficient. For this reason, DWC included level “I” in subdivision (c)(1). 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 included level “I” in subdivision (c)(1). (See, Table B, Subdivision 9792.22(c)(1)(B).)

ACOEM’s criteria used to rate randomized controlled trials (Table A) and the strength of evidence ratings (Table B) were included in proposed Section 9792.22. An additional table (Table 3) set forth in ACOEM’s justification (see also, ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM’s Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*) 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)** was modified to substitute the term “Administrative Director” 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)** was modified to increase the number of members of the medical evidence evaluation advisory committee from 10 members to 17 members. This subdivision was also amended to require that the members of advisory committee have licenses in their areas of specialties as follows: “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.” These changes resulted from public comments suggesting that advisory committee be augmented in recognition of the role and contribution of other specialties in the treatment of workplace injuries. DWC agreed with the public comments and increased the number of disciplines included in the advisory committee to better address “the ... treatment procedures and modalities commonly performed in workers’ compensation cases” as required by the statute (Lab. Code, § 5307.27).

Subdivision (a)(2) was further amended to reflect the increase of the committee members. Subdivision (a)(2)(E) was modified to delete the words “or occupational;” subdivision (a)(2)(F) was modified to delete the words “or psychiatry;” subdivision (a)(2)(H) was 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) was

added to require that one member shall be from the neurosurgery field; subdivision (a)(2)(K) was added to require that one member shall be from the family physician field; subdivision (a)(2)(L) was added to require that one member shall be from the neurology field; subdivision (a)(2)(M) was added to require that one member shall be from the internal medicine field; subdivision (a)(2)(N) was added to require that one member shall be from the physical medicine and rehabilitation field; and subdivision (a)(2)(O) was added to require that one member shall be from the podiatrist field; and 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.

**Subdivision (a)(3)** was modified to delete the number “ten” and substitute with the number “seventeen.”

**Subdivision (d)** was modified to substitute the number “one” with the number “two,” thus increasing the term of service of the committee members from one year to two years. Subdivision (d) was further modified to add the new language that “[t]he members of the committee shall meet as necessary, but no less than four (4) times a year.” The subdivision was further amended to add an “s” to the word “member” to correct a typographical error. The changes in Subdivision (d) resulted from accepted comments from the public requesting that the term of service of the committee members be increased from one year to two years, and requesting that a minimum time of meetings of the committee members be specified in the proposed regulations.

**Subdivision (f)** was amended to delete the phrase “medical evidence evaluation advisory committee” and to substitute it with the phrase “Medical Director.” The subdivision was amended to clarify that it is the Medical Director who will be advising the Administrative Director about revisions, updates and supplementation of the medical treatment utilization schedule as necessary, not the advisory committee.

**THE FOLLOWING SECTIONS WERE AMENDED FOLLOWING THE FIRST 15 DAY COMMENT PERIOD AND CIRCULATED FOR A SECOND 15-DAY COMMENT PERIOD (March 29, 2007 through April 16, 2007.)**

**1. Modifications to Section 9792.20 Medical Treatment Utilization Schedule—Definitions**

**Subdivision (b)** setting forth the definition for the term “ACOEM Practice Guidelines” was amended to delete the phrase “ OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 ([www.oempress.com](http://www.oempress.com))” and to substitute it with the phrase “the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 ([www.acoem.org](http://www.acoem.org)).” This change sets forth the correct source and address where a copy of the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2<sup>nd</sup> Edition (2004) may be obtained.

**Subdivision (e)** was amended to add a comma following the phrase “physical exam.” The comma following the phrase “physical exam” in the definition of the term “functional improvement” clarifies that not only the reduction in work restrictions, but also the clinically significant improvement in activities of daily living, are measured during the history and

physical exam and must be documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS).

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

**Subdivision 9792.21(a)(1)** incorporating the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition, into the schedule and setting forth the source and address where a copy of the guidelines may be obtained was amended to delete the phrase “ OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 ([www.oempress.com](http://www.oempress.com))” and to substitute it with the phrase “the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 ([www.acoem.org](http://www.acoem.org)).” This change sets forth the correct source and address where a copy of the American College of Occupational and Environmental Medicine’s Occupational Medicine Practice Guidelines, 2<sup>nd</sup> Edition (2004) may be obtained.

**Subdivision 9792.21(a)(2)(C)(iv)**, allowing for 14 treatments maximum, was deleted from the proposed regulations. This section was deleted from the text of the regulations for clarification purposes. Section 9792.21(a)(2)(C)(iii) allowed for 3 to 6 acupuncture treatments, and Section 9792.21(a)(2)(C)(iv) allowed for 14 treatments, all subject to functional improvement pursuant to Section 9792.21(a)(2)(D). It was determined that Section 9792.21(a)(2)(C)(iv) allowing for 14 treatments maximum, was confusing because the treatment may be continued upon a showing of functional improvement after the initial series of treatments under Section 9792.21(a)(2)(C)(iii). It was further determined that Section 9792.21(a)(2)(C)(iv) might be interpreted to constitute a cap on treatment, which was not the intention of the proposed regulations. The requirement that acupuncture achieve functional improvement serves to appropriately justify continued acupuncture treatment as this would lead to “a clinically significant improvement in activities of daily living or a reduction in work restrictions ..., and a reduction in the dependency on continued medical treatment.”

### **Modifications to Section 9792.22 Presumption of Correctness, Burden of Proof and Strength of Evidence**

**Subdivision (c)(1)(A)** setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended. Table A, under the “Randomization” criteria was amended to include an asterisk after the word “successfully” and to include below at the end of the sentence an explanation of the context in which the term “successful” is used. The explanation added stated: “Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful”.

In this regard, DWC noted that successful randomization is a statistical concept. It entails, as stated in *Evidence-based Medicine: How to Practice and Teach EBM* (2005), at p. 118,

“Randomization balances the treatment groups for prognostic factors, even if we don’t yet know enough about the target disorder to know what they all are. If these factors exaggerated the apparent effects of an otherwise ineffectual treatment, the effects of their imbalance could lead to the false-positive conclusion that the treatment was useful when in fact it wasn’t. In contrast, if they nullified or counteracted the effects of a really efficacious treatment, this could lead to a false-negative conclusion that a useful

treatment was useless or even harmful. We should insist on random allocation to treatment because it comes closer than any other research design to creating groups of patients at the start of the trial who are identical in their risk of the event we are trying to prevent. We determine if the investigators used some method analogous to tossing a coin to assign patients to treatment groups.”

During the 1<sup>st</sup> 15-day comment period, a comment was received from the public stating that an explanation of the context in which the term successful is used was necessary to clarify Section 9792.22(c)(1)(A). After discussions with ACOEM, ACOEM agreed that it was necessary for clarification purposes to add an explanation of the context in which the term successful is used in Table A. ACOEM agreed that it is correct that simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. In order to assess the success of randomization, the additional factor is that the groups must be comparable, otherwise the randomization was unsuccessful. Unsuccessful randomization can also be addressed by statistically controlling for variables known to be associated with the outcome measure under investigation in any analysis. Accordingly, pursuant to a document submitted by ACOEM entitled *Amendments to ACOEM’s Methodology Advances for Occupational Practice Guidelines, 2<sup>nd</sup> Edition*, dated March 13, 2007, which was added to the rulemaking file, Subdivision (c)(1)(A) setting forth Table A – Criteria Used to Rate Randomized Controlled Trials was amended as reflected above.

**Subdivision (c)(1)(A)** setting forth Table A – Criteria Used to Rate Randomized Controlled Trials was amended at Table A, under the Co-Interventions Criteria. The phrase “Controlled for” was inserted before the word “Co-Interventions” and the word “Avoided” was deleted at the subtitle of the section. In the text immediately after the subtitle in the section, the word “avoided” was deleted and the phrase “controlled for” was inserted. Further the language contained in the parentheses was amended to insert the following phrase: “or mention of not using other treatments during the study.” As changed the sentence now states: “**Controlled for Co-interventions:** The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during the study).”

During the 1<sup>st</sup> 15-day comment period, a comment was received from the public requesting that this criterion (Co-interventions Avoided) be changed to reflect how any co-interventions were controlled rather than how they were avoided. The commenter stated that while co-interventions can mask significant effects or make non-significant effects appear significant, they can be controlled much more practically than they can be avoided. In reviewing the comment, DWC noted that co-interventions are problematic, especially in musculoskeletal studies where they are common. Yet, the strength of the ACOEM methodology is that it recognizes the problem and does not exclude articles with such co-interventions, but rather incorporates this issue into the article rating. DWC noted that it is not possible to control for co-interventions in all circumstances, and in many studies they are tracked poorly such that an independent analysis of this problem is not possible. However, because there may be flaws, ACOEM agreed that it is better to include a rating criterion that accounts for co-intervention, rather than excluding studies that did not control for them. ACOEM has amended this portion of Table A to reflect that the criterion should reflect how co-interventions were controlled for rather than avoided. (See, *Amendments to ACOEM’s Methodology Advances for Occupational Practice Guidelines, 2<sup>nd</sup> Edition*, March 13, 2007, which has been added to the rulemaking file.)

## **Modifications to Section 9792.23 Medical Evidence Evaluation Advisory Committee**

### **Section 9792.23**

**Subdivision (a)(2)** was amended to include members of the specialty boards who are approved by the Medical Board of California (MBC) in the Medical Evidence Evaluation Advisory Committee. Thus, the following language was inserted in the text of the subdivision: “Medical Doctors (M.D.), who are board certified by a Medical Board of California (MBC) approved specialty board.” This section was amended based on a public comment stating that Section 9792.23(a)(2) limits M.D. members of that committee to those who are board certified by an American Board of Medical Specialties (ABMS). The commenter indicated that the Medical Board of California (MBC) established a process to review and approve certification training programs that can demonstrate “equivalence” to ABMS certification programs, and that to date, the MBC has approved four specialty certification programs as equivalent to ABMS. These boards include: American Board of Facial Plastic and Reconstructive Surgery; American Board of Pain Medicine; American Board of Sleep Medicine; and The American Board of Spine Surgery. Based on this comment it was agreed that the Medical Board of California (MBC) has approved a number of specialty boards which are not part of the American Board of Medical Specialties (ABMS). Based on these comments, the section was amended to include members of the specialty boards who are approved by the Medical Board of California (MBC).

**Subdivision (c)** was amended to include new introductory language stating: “To evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule,” and to delete the higher case letter “T” and substitute it with the lower case letter “t.” Subdivision (c) was further amended to delete the end of sentence, which stated: “use the hierarchy of evidence set forth in subdivision (c)(1) of section 9792.22 to evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule.”

Subdivision (c) was amended to add the following language as contained in paragraphs (1), (2) and (3). “(1) Apply the requirements of subdivision (b) of Section 9792.22 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community;” “(2) Apply the ACOEM’s strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of Section 9792.21 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21;” and “(3) Apply in reviewing the scientific evidence, the ACOEM’s strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of Section 9792.21.”

The changes in subdivision (c) resulted from comments from the public wherein it became apparent that the proposed regulations were not clear as to the process to be used by the medical evidence evaluation advisory committee in making recommendations to the Medical Director to revise, update or supplement the medical treatment utilization schedule. The regulations now clarify that the committee first will apply the requirements of subdivision (b) of Section 9792.22

in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community, and then apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of Section 9792.21 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21. The committee is also responsible to apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed. Thus, as written this subdivision now clearly sets forth the process to be used by the medical evidence evaluation advisory committee in making recommendations to the Medical Director to revise, update or supplement the medical treatment utilization schedule.

**Amended Economic and Fiscal Impact Statement Added to the Rulemaking File**

An Amended Economic and Fiscal Impact Statement (Form 399) has been added to the rulemaking file reflecting the changes to the cost impact analysis resulting from the proposed modifications to the text of the regulations relating to the Acupuncture Medical Treatment Guidelines, Proposed Section 9792.21(a)(2).

**UPDATE OF MATERIAL RELIED UPON / DOCUMENTS ADDED TO RULEMAKING FILE**

In addition to the documents identified in the Initial Statement of Reasons, the following documents were relied upon by the Division and were made available to the public as required by Government Code Section 11347.1.

**Title of Document Added to Rulemaking File      Dates of Availability for Public Comment**

Comments received by the Division of Workers' Compensation concerning the Division's proposed changes.	July 7, 2006 through August 23, 2006 December 7, 2006 through December 22, 2006 March 29, 2007 through April 16, 2007
Pre-Notice comments from DWC Forum Pre-Notice comments Pre-Notice comments from DWC Public Forum	November 24, 2004 through December 6, 2004 December 7, 2004 through June 22, 2005 June 23, 2005 through July 8, 2005

Documents added to the formal rule making file and Noticed in the 1<sup>st</sup> 15-Day Notice:

- *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

- ACOEM Practice Guidelines, APG Insights, Winter 2005, *Acupuncture-Medical Literature Analysis and Recommendations*
- Colorado Medical Treatment Guidelines, Rule 17, 7 CCR 1101-3  
[http://www.coworkforce.com/dwc/Medical\\_Treatment.asp](http://www.coworkforce.com/dwc/Medical_Treatment.asp)
- Comments from various interested parties concerning the regulations have been added to the rulemaking file.
- National Guideline Clearinghouse's (NGC) inclusion criteria  
<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

Documents added to the formal rulemaking file and Noticed in the 2<sup>nd</sup> 15-Day Notice

- ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*
- Amended Economic and Fiscal Impact Statement (Form 399)
- *Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines*, 2<sup>nd</sup> Edition, March 13, 2007
- *Cochrane Handbook for Systematic Reviews of Interventions 4.2.6*, September 2006, The Cochrane Collaboration,  
<http://www.cochrane.org/resources/handbook/Handbook4.2.6Sep2006.pdf>
- Comments from various interested parties concerning the regulations added to the rulemaking file
- *Evidence-based Medicine: How to Practice and Teach EBM* (2005), Third Edition, Straus, Richardson, Glasziou, Haynes, pp. 117-119, 281
- *Evidence Based Medicine: What it is and What it isn't*,  
<http://www.bmj.com/cgi/content/full/312/7023/71>

- *Evidence Report/Technology Assessment: Number 47, Systems to Rate the Strength of Scientific Evidence*, Agency for Healthcare Research and Quality (AHRQ), Summary, <http://www.ahrq.gov/clinic/epcsums/strengthsum.htm>
- Medical Board of California (MBC) website link (<http://www.medbd.ca.gov/alphalist.htm>)
- MEDLINE, Information on MEDLINE from the Wikipedia Encyclopedia, as of the date of the March 2007 2<sup>nd</sup> 15-Day Notice <http://en.wikipedia.org/wiki/Medline>
- SIGN 50: A Guideline Developers' Handbook Methodology Checklist 2: *Randomised Controlled Trials* <http://www.sign.ac.uk/guidelines/fulltext/50/checklist2.html>
- State of Colorado, Division of Workers' Compensation, Executive Summary of the Medical Treatment Guideline Care Review and Cost Studies <http://www.coworkforce.com/dwc/PUBS/execsummary.pdf>
- State of Colorado, Division of Workers' Compensation, Low Back Pain, Medical Treatment Guidelines <http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%201%20%20Low%20Back%20Pain.pdf>
- State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines
  - Medical Treatment Guidelines Update Process
  - Evidence-Based Parameters
  - Consensus Parameters
- State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines, General Information <http://www.coworkforce.com/dwc/DivisionResources/mtgsummarybriefintro.pdf>
- 2005 *California Workers' Compensation Losses and Expenses*, Workers' Compensation Insurance Rating Bureau (WCIRB), June 23, 2006, page 9

Document added to the rulemaking file after the 2<sup>nd</sup> 15-Day Notice period ended.

- *Guides to the Evaluation of Permanent Impairment*, Fifth Edition, pages 2 and 8

## **LOCAL MANDATES DETERMINATION**

- Local Mandate: None. The proposed regulations will not impose any new mandated programs or increased service levels on any local agency or school district. The proposed amendments do not apply to any local agency or school district.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None. The proposed amendments do not apply to any local agency or school district.
- Other nondiscretionary costs/savings imposed upon local agencies: None.

## **CONSIDERATION OF ALTERNATIVES**

The Division considered all comments submitted during the public comment periods, and made modifications based on those comments to the regulations as initially proposed. The Administrative Director has now determined that no alternatives proposed by the regulated public or otherwise considered by the Division of Workers' Compensation would be more effective in carrying out the purpose for which these regulations were proposed, nor would they be as effective as and less burdensome to affected private persons and businesses than the regulations that were adopted.

## **SUMMARY OF COMMENTS RECEIVED AND RESPONSES THERETO CONCERNING THE REGULATIONS ADOPTED**

The comments of each organization or individual are addressed in the following charts.

The public comment period was as follows:

### **Initial 45-day comment period on proposed regulations:**

July 7, 2006 through August 23, 2006.

### **First 15-day comment period on modifications to proposed text:**

December 7, 2006 through December 22, 2006.

### **Second 15-day comment period on modifications to proposed text:**

March 29, 2007 through April 16, 2007.