

**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 9792.26**

The Acting Administrative Director of the Division of Workers' Compensation, pursuant to the authority granted by Labor Code sections 59, 133, 4603.5, 5307.3 and 5307.27, has adopted and amended regulations contained in Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, sections 9792.20 through 9792.26, relating to the medical treatment utilization schedule (MTUS), as follows:

Amended Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Amended Section 9792.21	Medical Treatment Utilization Schedule
Amended Section 9792.22	General Approaches
Amended Section 9792.23	Clinical Topics
Adopted Section 9792.23.1	Neck and Upper Back Complaints
Adopted Section 9792.23.2	Shoulder Complaints
Adopted Section 9792.23.3	Elbow Complaints
Adopted Section 9792.23.4	Forearm, Wrist, and Hand Complaints
Adopted Section 9792.23.5	Low Back Complaints
Adopted Section 9792.23.6	Knee Complaints
Adopted Section 9792.23.7	Ankle and Foot Complaints
Adopted Section 9792.23.8	Stress Related Conditions
Adopted Section 9792.23.9	Eye
Adopted Section 9792.24	Special Topics
Adopted Section 9792.24.1	Acupuncture Medical Treatment Guidelines
Adopted Section 9792.24.2	Chronic Pain Medical Treatment Guidelines (DWC 2008)
Adopted Section 9792.24.3	Postsurgical Treatment Guidelines (DWC 2008)
Adopted Section 9792.25	Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence
Adopted Section 9792.26	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.**

## SUMMARY OF PROPOSED CHANGES

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

**Subdivision (c)** setting forth the definition for the term “chronic pain” was corrected for clerical error to delete the word “tissue” from the definition of “chronic pain.” The definition was corrected to reflect the definition as quoted from the textbook of *Bonica’s Management of Pain*, wherein the term is defined, in pertinent part, as “pain that extends beyond the expected period of healing.” (Turk, D. and Okifuji A. *Pain Terms and Taxonomies* in *Bonica’s Management of Pain*, 3rd edition. Philadelphia, PA, Lippincott Williams and Wilkins:17.)

**Subdivision (f)** setting forth the definition for the term “functional improvement” was modified to delete the word “quantifiable” and reinstate the original phrase “clinically significant” as contained in the original definition of the term “functional improvement” noticed during the 45-day comment period. Comments were submitted during the 45-day comment period objecting to the use of the word “quantifiable,” stating that functional improvement may not actually be quantifiable. After reviewing the comments, DWC agreed that the phrase “clinically significant” which was in the original definition of the text of the regulations was more appropriate and easier to be communicated by the treating physician in their reports. Therefore, the definition of functional improvement was reverted to the original definition as contained in the original text of the regulations.

### Modifications to Section 9792.23. Clinical Topics

**Subdivision 9792.23(b)** was modified to substitute the phrase “conditions or injuries” for the word “treatment.” The modification made the text of section 9792.23(b) consistent with the text of the statute (Lab. Code, §4604.5(e)), and with the text of other sections of the regulations (§9792.21(c), §9792.25(b), and §9792.25(c)(1)).

**Subdivision 9792.23(b)(1)** was modified to substitute the word “cure” for the phrase “surgical options for the complaint,” to substitute the word “for” for the word “in,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “with chronic pain.” The phrase “and supersede any applicable chronic pain guideline in accordance with section 9792.23(b)” was added at the end of the sentence. The purpose of the modifications were to clarify the applicability of the Chronic Pain Medical Treatment Guidelines when other “scientifically and evidence-based” guidelines are being used pursuant to section 9792.23(b) to provide treatment to the injured worker. DWC determined that the word “cure” was the appropriate word to substitute the phrase “surgical options for the complaint” because

when there is an “absence of any *cure* for the patient” and the patient “continues to have pain that persists beyond the anticipated healing,” that patient has a chronic condition and the chronic pain medical treatment guidelines apply. Moreover, it was further determined that the definition of the term “medical treatment” in the Labor Code encompasses the concept of “cure” when it states “care which is reasonably required to cure or relieve.” (See Lab. Code, 4600(a).) In this regard, the use of the definition of the term “chronic pain” (e.g., pain that persists beyond the anticipated time of healing) was determined to be clinically useful to the treating physician to redirect the treatment back from other guidelines pursuant to section 9792.23(b) into the MTUS, and specifically into the chronic pain medical treatment guidelines when the case becomes chronic. The language “and supersede any applicable chronic pain guideline in accordance with section 9792.23(b)” was added to clarify that the chronic pain medical treatment guidelines supersede other chronic pain treatment guidelines outside of the MTUS in accordance with section 9792.23(b). This avoids conflict between the MTUS and other guidelines as this subdivision makes it clear than when the injured worker is treating for chronic pain, the MTUS chronic pain medical treatment guidelines apply.

**Subdivision 9792.23(b)(2)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS or in accordance with section 9792.23(b)” at the end of sentence. This modification clarifies that following surgery, other applicable treatments in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The subdivision was further modified to add a sentence at the end of the subdivision which states, “The postsurgical treatment guidelines supersede any applicable postsurgical treatment guideline in accordance with section 9792.23(b).” This language was added to clarify that the postsurgical treatment guidelines supersede other postsurgical treatment guidelines outside of the MTUS in accordance with section 9792.23(b). The addition of the language avoids conflict between the MTUS and other guidelines as this subdivision makes it clear than when the injured worker is receiving postsurgical treatment, the MTUS postsurgical treatment guidelines apply.

### **Modifications to Section 9792.23.1. Neck and Upper Back Complaints**

**Subdivision 9792.23.1(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.1(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. This sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.1(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute

the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient’s choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

### **Modifications to Section 9792.23.2. Shoulder Complaints**

**Subdivision 9792.23.2(c)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.2(c) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient’s choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

### **Modifications to Section 9792.23.3. Elbow Disorders**

**The title of Section 9792.23.3** was corrected for clerical error to substitute the word “Complaints” with the word “Disorders.” This modification reflected the correct name of the revised ACOEM Chapter 12, which is entitled Elbow Disorders.

**Subdivision 9792.23.3(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.3(c)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to chronic pain” at the end of the sentence. The phrase was added to clarify the chronic pain medical treatment guidelines apply and supersede ACOEM’s Elbow Disorders Chapter’s text on chronic pain. This clarification avoids internal conflict in the application of the MTUS. Thus, subdivision 9792.23.3(c), as modified provides, “If recovery has not taken place with respect to pain by the end of the Elbow Algorithm 10-5, the chronic pain medical treatment guidelines in section 9792.24.2 shall apply and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to chronic pain.”

**Subdivision 9792.23.3(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.3(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient’s choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

#### **Modifications to Section 9792.23.4. Forearm, Wrist, and Hand Complaints**

**Subdivision 9792.23.4(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.4(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.4(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient’s choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

## **Modifications to Section 9792.23.5. Low Back Complaints**

**Subdivision 9792.23.5(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.5(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.5(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient’s choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

## **Modifications to Section 9792.23.6. Knee Complaints**

**Subdivision 9792.23.6(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.6(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.6(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same

language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient's choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

### **Modifications to Section 9792.23.7. Ankle and Foot Complaints**

**Subdivision 9792.23.7(b)** was modified to add the phrase “and supersede the text in the ACOEM chapter referenced in subdivision (a) above relating to acupuncture” at the end of the sentence. The reorganization of the MTUS, by separating the chapters into different sections and adopting them separately, affected the Acupuncture Medical Treatment Guidelines. Comments were submitted during the 45-day comment period requesting that language be inserted in the clinical topics sections of the regulations to clarify that the Acupuncture Medical Treatment Guidelines apply and supersede the text in the ACOEM chapters where acupuncture is addressed. DWC agreed that clarification was necessary and inserted the clarifying language as requested by the public in the text of the subdivision.

**Subdivision 9792.23.7(d)** was modified to add the phrase “together with any other applicable treatment guidelines found in the MTUS” at the end of the first sentence of the subdivision. The sentence was modified to clarify that following surgery, other applicable treatments, in addition to postsurgical physical medicine provided under the postsurgical treatment guidelines, will be addressed under the MTUS (e.g., postoperative pain medications). The second sentence of subdivision 9792.23.7(d) was modified to substitute the word “cure” for the phrase “surgical options for the complaint and,” to insert the word “for” after the word “cure,” and to substitute the phrase “who continues to have pain that persists beyond the anticipated time of healing” for the phrase “has chronic pain.” The modifications are consistent with modifications to the same language contained in subdivision 9792.23(b)(1) above, and to clarify that there are situations where surgery is considered, but the surgery may not be performed due to comorbidities/contraindications or by patient's choice. The modification clarifies that in those situations, the MTUS chronic pain medical treatment guidelines apply.

### **Modifications to Section 9792.24.1. Acupuncture Medical Treatment Guidelines**

**Subdivision 9792.24.1(b)(1)** was modified on a non-substantive basis to substitute the word “indicated” with the word “referenced” for clarity purposes. It was determined that the word “indications” carries a medical usage, which was not the intention in the context of the sentence. The meaning of the sentence was to reference one section of the MTUS with another. That is, to reference the acupuncture guidelines as applied to the specific clinical topic guidelines. Subdivision 9792.24.1(b)(1) was further modified on a non-substantive basis to delete the parenthetical information “(DWC 2008)” for clarity purposes. This modification will allow the date of effectiveness of the MTUS regulations to be the date of the chronic pain medical treatment guidelines.

## **Modifications to Section 9792.24.2. Chronic Pain Medical Treatment Guidelines**

At the outset, it is noted that the Notice of Proposed Rulemaking issued June 2008, clearly noticed the regulated public that the Chronic Pain Medical Treatment Guidelines, consisting of part I. Introduction and Part 2. Pain Interventions and Treatments was proposed to be adopted and incorporated into the MTUS in Section 9792.24.2(a), as adapted from the Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain. The Chronic Pain Medical Treatment Guidelines—as proposed—was a separate, self-contained new document, consisting of 183 pages. The document contained its own original format, wherein certain titles and subtitles were single-underlined, certain references and citations were single-underlined, and page 5 contained an informational table. It would have been difficult for the regulated public to read and analyze the document had DWC single-underlined the entire document. Because the entire document was **all new** text/language, DWC noticed the document without the single-underlying. However, when further changes were made to the document, DWC noticed those changes accordingly and the public was properly informed of the format of the changes.

### **Modifications to Section 9792.24.2. Chronic Pain Medical Treatment Guidelines were as follows:**

**The title of the Section 9792.24.2** was modified to delete the parenthetical information “(DWC 2008)” for clarity purposes. This modification will allow the date of effectiveness of the MTUS regulations to be the date of the chronic pain medical treatment guidelines.

**Subdivision 9792.24.2(a)** was modified to delete the parenthetical information “(DWC 2008)” for clarity purposes. This modification will allow the date of effectiveness of the MTUS regulations to be the date of the chronic pain medical treatment guidelines. Subdivision 9792.24.2(a) was further modified to delete the phrase “and citations listed in the guidelines” in the last sentence of the subdivision. The phrase was deleted because the citations/references are now incorporated by reference in proposed subdivision 9792.24.2(e); and that subdivision informs the public where the citations/references may be obtained.

The Notice of Modification to Text of Proposed Rulemaking (1<sup>st</sup> 15-day Notice) informed the public that the Division of Workers' Compensation (DWC) proposed to adapt the most recent version of the Chronic Pain Medical Treatment Guidelines, **Part 1: Introduction and Part 2- Interventions and Treatments**. The public was further informed that the amendments to the guidelines were noticed in a document entitled **Appendix A1—Chronic Pain Medical Treatment Guidelines**. Appendix A1, which was served with the 1<sup>st</sup> 15-Day Notice, served as the notice of modification of the text of the DWC Chronic Pain Medical Treatment Guidelines as adapted from the Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain. The public was informed that the new version adapted was **dated October 23, 2008**. The public was also informed that the Work Loss Data Institute had given permission to the DWC to adapt the October 23, 2008 version of the chapter on pain at no cost. The public was reminded that pursuant to the 45-day notice of rulemaking, the chronic pain medical treatment guidelines proposed to replace the ACOEM's Practice Guidelines' Chapter 6—*Pain, Suffering, and the Restoration of Function* (Chapter 6) relating to chronic pain. The public was informed that DWC decided to explain the modifications to the Chronic Pain Medical

Treatment Guidelines in a separate document (i.e., Appendix A) because the document was going to be used in the future as an unincorporated reference document supporting the Chronic Pain Medical Treatment Guidelines. For example, Appendix A explains the specific changes made to the October 23, 2008 ODG chapter on pain version, and the reasons for those changes.

### **Modifications to the Chronic Pain Medical Treatment Guidelines as Contained in Appendix A1 Accompanying the Notice of Modification of the Text (1<sup>st</sup> 15-Day Notice)**

During the 45-Day Notice, the Notice of Proposed Rulemaking notified the public that the DWC proposed to adapt the ODG chapter on pain version dated October 31, 2007. Appendix A1 informed the public that that a new version being adapted is dated **October 23, 2008**. The newer version was proposed because DWC received many comments from the public requesting that the most recent version of ODG be adapted in order to allow the Medical Treatment Utilization Schedule (MTUS) to reflect the most recent advances in the science of medicine. (See further explanation at pages 8-9, Item No. 2, below.)

#### **Modifications to Part 1. Introduction Chronic Pain Medical Treatment Guidelines**

**1. The first paragraph, third sentence of the Introduction**, at page 1, was modified to delete the phrase ending at the sentence which states: “and the patient is reassessed over the next 3-4 weeks.” The fourth sentence was modified to delete the phrase “during this interval” immediately after the word “persists.” The fifth sentence was modified to delete the introductory phrase, “The chronic pain medical treatment guidelines apply to,” and to replace that phrase with the words, “If the.” The fifth sentence was further modified to make the word “patients” singular by striking out the “s” at the end of the word; the phrase in the same sentence which states, “who fail to recover and continue to have persistent complaints,” was stricken and replaced with the phrase “continues to have pain that persists beyond the anticipated time of healing.” The fifth sentence was also modified to delete the word “definitive” and to insert the phrase “plans for curative” in its place. The fifth sentence was completed by inserting the last phrase, “the chronic pain medical treatment guidelines apply.” The modifications in the first paragraph of the Introduction removed a defined time frame for reassessment of the patient after ruling out a potentially serious condition because the time frame may vary depending on the case. The modification resulted from public comments submitted stating that the interval or clinical circumstances for reassessment should be left to the judgment of the physician. The modifications in the paragraph further clarified when the chronic pain guidelines apply in relation to the clinical topics and other guidelines. The sentences were modified to state, “Upon ruling out a potentially serious condition, conservative management is provided. If the complaint persists, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for curative treatment, such as surgical options, the chronic pain medical treatment guidelines apply.”

**2. The second paragraph, fifth sentence, of the Introduction**, at page 1, was modified to delete the date “October 31, 2007” and to substitute it with the date “**October 23, 2008**.” The date reflected the new date of the new ODG version of the chronic pain chapter which was being proposed to be adapted in the DWC Chronic Pain Medical Treatment Guidelines. This new version was being adapted because many comments were submitted by the public

requesting that the most recent version of ODG be adapted in order to allow the “MTUS [to] reflect the most recent advances in the science of medicine.” (See, California Medical Association’s comment, August 11, 2008.) Appendix A1, accompanying the 1<sup>st</sup> 15-Day Notice, explained to the public the reasons for adapting the most recent version of the ODG chapter on pain as follows following the 45-day notice:

“DWC notes that Government Code section 11346.5(a)(3) requires the Notice of Proposed Rulemaking set forth an informative digest, containing in relevant part, a concise and clear summary of existing laws and regulations, if any, related directly to the proposed action and of the effect of the proposed action and a policy statement overview explaining the broad objectives of the regulation and, if appropriate, the specific objectives. Government Code Section 11346.8(c) prohibits any agency from adopting, amending, or repealing a regulation which has been changed from that which was originally made available to the public pursuant to Section 11346.5, unless the change is “(1) non-substantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action....”

“The Notice of Proposed Rulemaking issued in June 2008 put the public on adequate notice that the subject of Chronic Pain Medical Treatment Guidelines as adapted from Work Loss Data Institute’s Official Disability Guideline was addressed as part of the formal rulemaking. Specifically, the Notice states at page 11, in relevant part, as follows:

“ ‘15. Section 9792.24.2—Chronic Pain Medical Treatment Guidelines (DWC 2008)

“ ‘Section 9792.24.2(a) provides that the Chronic Pain Medical Treatment Guidelines (DWC 2008), consisting of two parts, are adopted and incorporated by reference into the MTUS. It indicates that Part 1 is entitled Introduction, and Part 2 is entitled Pain Interventions and Treatments. This section further provides that the guidelines replace Chapter 6 of the ACOEM Practice Guidelines, 2<sup>nd</sup> Edition (2004).” Moreover, Part I, of the Chronic Pain Medical Treatment Guidelines, entitled: Introduction, indicates that the guidelines is being adapted from the ODG guidelines as follows:

“ ‘The chronic pain medical treatment guidelines consist of two parts. Part 1 is the introduction. Part 2 consists of pain interventions and treatments. With a few exceptions, Parts 2 is primarily an adaptation of evidence-based treatment guidelines, from the Work Loss Data Institute’s Official Disability Guidelines (ODG) Treatment in Workers’ Comp – Chapter on Pain (Chronic). The version adapted is dated October 31, 2007, and it is being adapted with permission from the ODG publisher. Any section not adapted directly from ODG is labeled ‘[DWC]’.”

“DWC is precluded from automatically adopting future versions of documents incorporated by reference into a regulation in the absence of formal rulemaking.

However, DWC is able to adopt the most recent version of the ODG guidelines at this time because: (1) this rulemaking is still in progress and is not yet completed; (2) the regulated community has received adequate notice and has, in fact, requested the most recent version; (3) the update of the guidelines ‘is sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action.’ The ODG guidelines version being adapted is dated October 23, 2008, as requested by the public.

Pursuant to the explanation above, the sentence was modified to state, ‘The version adapted is dated October 23, 2008, and it is being adapted with permission from the ODG publisher.’”

**3. The definition of the term “Chronic pain,” under the subject *Definitions*,** at page 1, was corrected for clerical error to conform to the modifications to **Subdivision 9792.20(c)**, wherein the section was corrected for clerical error to delete the word “tissue” from the definition of “chronic pain.” The definition was corrected to reflect the definition as quoted from the textbook of *Bonica’s Management of Pain*, wherein the term is defined, in pertinent part, as “pain that extends beyond the expected period of healing.” (Turk, D. and Okifuji A. *Pain Terms and Taxonomies* in *Bonica’s Management of Pain*, 3rd edition. Philadelphia, PA, Lippincott Williams and Wilkins:17.)”

**4. The first paragraph, fourth sentence under the subject *Overview*,** at page 1, was modified to substitute the word “managing” for the word “preventing.” The modification resulted from a public comment indicating that early recognition of chronicity is important to provide effective care. DWC agreed that the use of the concept “prevention” was not correct because we cannot be certain in any given case that a worse outcome would have occurred absent the intervention. DWC decided that the concept of “management” was a better concept because early recognition of chronicity does change the management approach in treating the chronic condition. The sentence was modified to state, “Therefore, effective early care is paramount in managing chronic pain.”

**5. The third paragraph, second sentence under the subject *Overview*,** at page 2, was modified for clerical error to add a comma to the parenthetical example, thus “(e.g., injury).” The sentence was modified to state, “Traditionally, the biomedical model explains pain through etiologic factors (e.g., injury) or disease whose pathophysiology results in pain.”

**6. The fifth paragraph, under the subject *Pain Mechanisms*,** at page 3, was modified to insert the phrase “symptoms such as” before the word “lancinating,” and to add two examples of symptoms: “electric shock-like,” and “numbing.” The modifications were suggested by the regulated public as contained in the lexicon of neuropathic pain symptoms. The sentence was modified to state, “Neuropathic pain is characterized by symptoms such as lancinating, electric shock-like, paroxysmal, tingling, numbing, and burning sensations that are distinct from nociceptive pain.”

**7. The sixth paragraph, third sentence under the subject *Pain Mechanisms*,** at page 3, was modified to insert the phrase “but are not limited to” within a parenthetical comma after the introductory phrase, “These conditions include.” The phrase was inserted in agreement with public comments that there are additional conditions which are not included in the list

provided in the referenced article of Mackey and Maeda 2004. The revised sentence acknowledged that there may be other chronic pain conditions that have a large centralized component, such as diabetic neuropathy. The sentence was modified to state, “These conditions include, but are not limited to, chronic low back pain (CLBP), fibromyalgia, irritable bowel syndrome, and Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD). (Mackey and Maeda 2004)”

**8. The first paragraph, under the subject *Models***, at page 3, was modified to add the phrase, “to understand pain and serve to establish parameters for reasonable outcomes and acceptable standards of care” after the word “framework” in the first sentence. The paragraph was further modified to insert the phrase, “These are helpful” before the phrase, “for physicians” in the second sentence. The second sentence was further modified by substituting the word “facilities” with the word “providers” and by deleting the end of the sentence which stated, “for understanding pain.” The following sentence which stated, “Models help to establish parameters for reasonable outcomes and acceptable standards of care” was deleted. The last sentence of the paragraph was modified by deleting the last phrase of the sentence, “insights and limitations” and inserting the phrase, “strengths and weakness” in its place. The paragraph was rewritten to clarify what models are and how they are used. The modified paragraph states, “Models are the conceptual framework to understand pain and serve to establish parameters for reasonable outcomes and acceptable standards of care. These are helpful for physicians, patients, families, healthcare providers, carriers, and compensation systems. Several different models of pain have developed over time, each with strengths and weaknesses.”

**9. The first paragraph, second sentence, under the subject *Acute vs. Chronic Pain Model***, at page 3, was modified to insert the word “protective” before the word “warning.” During the 1<sup>st</sup> 15-day notice, a public comment was submitted suggesting the word “protective” be used in this paragraph, and the DWC agreed that the word “protective” is a useful concept due to the meaning of the word (i.e., protective nature). DWC, however, decided to place the word “protective” before the word “warning” for contextual purposes throughout the text of the “*Acute vs. Chronic Pain Model*” section of the Introduction. The modified second sentence of the paragraph states, “Fundamentally, it serves as a protective warning of actual or impending tissue damage.”

**10. The second paragraph, first sentence, under the subject *Acute vs. Chronic Pain Model***, at page 3, was modified to delete the word “or,” to insert the phrase “and may”, and to delete the “s” at the end of the word “respond.” After reviewing public comments submitted during the 1<sup>st</sup> 15-day notice, DWC agreed that most acute pain is self-limited. DWC also agreed with comments that most acute pain responds to short term administration of analgesics and conservative therapies. Since both concepts are true, DWC determined that one does not exclude the other, and therefore the use of the word “or” in the sentence was used incorrectly. DWC determined that there may be instances, however, where acute pain is self-limited, but may not respond to short term administration of analgesics and conservative therapies. DWC decided that the use of the phrase “and may” was a more accurate description. The modified sentence states, “Most acute pain is self-limited and may respond to short term administration of analgesics and conservative therapies.”

**11. The second paragraph, second sentence, under the subject *Acute vs. Chronic Pain Model***, at page 3, was modified to substitute the word “poor” with the phrase “less than adequate.” The language “less than adequate” was substituted because DWC agreed with a public comment that the phrase “less than adequate” better expressed the concept as it is understood that there are tradeoffs that need to be considered in the control of pain. The tradeoffs represent a balance of the benefits or potential benefits of the intervention vs. the side effects, risks, or complications. DWC determined that using the phrase “less than adequate” better reflected the challenges of controlling pain. In that regard, DWC noted that poor pain control represented a more extreme clinical situation, and it was important to target adequate pain control as the desired goal. The sentence was further modified to delete the phrase “leading to a neuropathic pain state.” The phrase was deleted as superfluous because it carried the same meaning as the phrase “lead to peripheral and central sensitization” which was already used in the sentence. The modified second sentence states, “However, continued activation of nociceptors with less than adequate pain control can lead to peripheral and central sensitization, a risk factor for persistent pain with prolonged disability, delayed return to baseline function, and delayed return to work.”

**12. The third paragraph, second sentence, under the subject *Acute vs. Chronic Pain Model***, at page 4, was modified to insert the word “protective” before the word “warning.” As previously indicated, a public comment was submitted suggesting the word “protective” be used in this paragraph, and the DWC agreed that the word “protective” was a useful concept due to the meaning of the word (i.e., protective nature). DWC, however, decided to place the word “protective” before the word “warning” for contextual purposes throughout the text of the *Acute vs. Chronic Pain Model* section of the Introduction. The modified second sentence states, “Whereas acute pain serves as a protective warning signal, chronic pain has no known survival benefit.”

**13. The third paragraph, third sentence, under the subject *Acute vs. Chronic Pain Model***, at page 4, was deleted. The sentence was deleted as superfluous.

**14. The third paragraph, last sentence, under the subject *Acute vs. Chronic Pain Model***, at page 4, was modified to insert the word “may” before the word “involve” and to strike the “s” at the end of the word “involves,” and to add the word “and/” before the words “or anxiety.” The word “may” was inserted based on a public comment stating that persistent, inadequately treated acute pain does not always result in changes in the nervous system giving rise to neuropathic pain, hence the word “may involve” is more accurate than the word “involves.” DWC agreed with the comment, and modified the sentence accordingly. Moreover, the word “and/” was inserted prior to the word “or” following a public comment requesting that the sentence be clarified to denote the concept that chronic pain may be associated with depression and/or anxiety independently or concurrently because these complications may occur together. The modified sentence states, “To complicate matters, unremitting pain may be associated with depression and/or anxiety.” The modified sentence states, “Evidence suggests that generation and subsequent maintenance of chronic pain, as opposed to acute pain, may involve changes in central pain processing mediated through mechanisms of neural plasticity and ultimately leading to hyper-excitability of central structures in the spinal cord and brain.”

**15. The fourth paragraph, under the subject *Acute vs. Chronic Pain Model***, at page 4, was modified by inserting a second sentence which states, “The Division of Workers’ Compensation definition of chronic pain, ‘any pain that persists beyond the anticipated time of healing,’ is derived from Bonica’s Management of Pain (Turk and Okifuji, 2001).” The new sentence clarified that the source of the definition of the term “chronic pain” was Bonica’s Management of Pain. (Turk and Okifuji, 2001)

**16. The first paragraph, last sentence, under the subject *Illness Behavior Model***, at page 4, was modified to include the phrase “but are not limited to” within a parenthetical comma before the phrase “a tendency toward anxiety.” The sentence was modified after public comments requesting clarification that the list of illness behaviors in the sentence are not meant to be all-inclusive but are meant to be illustrative. The modified sentence states, “These might include, but are not limited to, a tendency toward anxiety, depression, somatization, fear avoidance, emotional lability, catastrophizing, job dissatisfaction and embellishment.”

**17. The last paragraph, under the subject *Biomedical vs. Biopsychosocial Model***, at page 5, was modified to delete the first two sentences of the last paragraph but to include the same substantive information in one sentence which was written in a more comprehensive manner. The paragraph was re-written for clarification purposes. The complete modified last paragraph states, “Linton identified strong evidence that psychosocial variables are strongly linked to the transition from acute to chronic pain disability and that psychosocial variables generally have more impact than biomedical or biomechanical factors on back pain disability. (Linton 2000) Thus, when clinical progress is insufficient, the clinician should always be prepared to address confounding psychosocial variables, in a coordinated, multidisciplinary manner.”

**18. The first paragraph, first sentence, under the subject *Medical vs. Self-Management Model***, at page 5, was modified to place the word “cured” in quotation marks. The placement in quotation marks resulted from a public comment indicating that the quotations add emphasis to the word “cured” as a clinical issue that arises as often expressed by the patient. DWC agreed with the comment because the quotation marks help understand the use of the term “cured” and reflect that the term is a common expression from patients with pain, e.g., “I want to be cured of pain.” The modified sentence states, “Understandably, patients want their chronic pain “cured” or eliminated.”

**19. The first paragraph, last sentence, under the subject *Medical vs. Self-Management Model***, at page 5, was modified for clerical error to add an “s” to the word “failure” thus, “failures.” The modified sentence states, “This unrealistic curative view, often unwittingly fostered by healthcare providers or others, predictably leads to repeated failures, delayed recovery, and unnecessary disability and costs.”

**20. The first paragraph, last sentence, under the subject *Subacute Delayed Recovery***, at page 6, was modified by adding the phrase, “If necessary” at the beginning of the last sentence and to change the letter “p” from upper case to lower case in the word patients at the beginning of the sentence. The modification clarified the treating physician has the option to refer the patient to a multi-disciplinary program or to specialists if necessary. The

modified sentence states, “If necessary, patients should be directed toward resources capable of addressing medical and psychosocial barriers to recovery.”

**21. The first paragraph, first sentence, under the subject *History and Physical Examination*,** at page 6, was modified by inserting the following phrase at the end of the first sentence, “and includes a review of medical records.” The sentence was modified to signify that it is important for the treating physician to not only obtain a thorough history directly from the patient, but to include a medical history from other sources. DWC noted that often the patient may not have a medical understanding of his or her problem or may not recall critical parts of his or her medical history. The modified sentence states, “Thorough history taking is always important in clinical assessment and treatment planning for the patient with chronic pain, and includes a review of medical records.”

**22. The first paragraph, under the subject *History and Physical Examination*,** at page 6, was amended by inserting a new modified third sentence, and adding a fourth sentence. These sentences were crafted from the deleted third paragraph under the same subject for clarity purposes. After public comments, it was determined that the third paragraph under the same subject was out of sequence. The third paragraph was crafted into two sentences and these sentences were inserted to follow the first two sentences of the first paragraph under the same subject. The paragraph was organized to discuss obtaining a history from the patient that includes record review to identify previously unknown or undocumented medical and/or psychosocial issues. Then to denote that based on the history, a physical examination is performed to establish and confirm the diagnosis and to observe and understand pain behavior. The paragraph was further organized to signify that thereafter, a doctor-patient relationship is established. The modified sentences state, “A thorough physical examination is also important to establish/confirm diagnoses and to observe/understand pain behavior. The history and physical examination also serves to establish reassurance and patient confidence.”

**23. The fifth paragraph, under the subject *Functional Restoration Approach to Chronic Pain Management*,** at page 8, was modified by inserting three new sentences in the middle of the paragraph. The three new sentences clarified the language of the paragraph and addressed public comments expressing concern that complexities of the patient’s conditions and circumstances that warrant additional treatment should be taken into consideration in providing medical treatment if the treatment is evidence-based. DWC noted that the complexities of the patient’s conditions are addressed in various sections of the MTUS such as the Chronic Pain Medical Treatment Guidelines and the Postsurgical Medical Treatment Guidelines. However, DWC determined that that it was also important to insert clarifying language in this paragraph to address the complexities of the patient’s conditions in the Introduction. Moreover, comments were submitted by the public requesting that that the Chronic Pain Medical Treatment Guidelines include language regarding dosing information, and that the guidelines contain clarifying language in the Introduction to advise physicians that (1) they should know the prescribing information for drugs, and (2) if they are prescribing a medication for an indication not in the approved FDA labeling, they have the responsibility to be well informed about the medication and the use. This information was further included in the paragraph for the benefit of the public. The fifth paragraph was modified to insert three new sentences in the middle of the paragraph. The new fourth, fifth, and sixth sentences state: “The physician should tailor medications and dosages to the

individual taking into consideration patient-specific variables such as comorbidities, other medications, and allergies. The physician should be knowledgeable regarding prescribing information and adjust the dosing to the individual patient. If the physician prescribes a medication for an indication not in the approved FDA labeling, he or she has the responsibility to be well informed about the medication and that its use is scientific and evidence-based.” Further, the eighth sentence was modified to delete the phrase “or neuropathic” at end of the sentence because the inclusion of the phrase was a clerical error. The modified eighth sentence states, “There are no drugs that have been proven to reverse, cure, or “heal” chronic pain.”

**24. The seventh paragraph, under the subject *Functional Restoration Approach to Chronic Pain Management*, at page 8, was modified by inserting a new second sentence, stating: “Selection of treatment must be tailored for the individual case.” This new sentence was added because it is important to take into consideration the patient’s condition(s) and circumstances in order to properly select treatment customized to the individual needs of the patient with chronic pain.**

**25. The first and second paragraphs, under the subject *Pain Outcomes and Endpoints*, at page 8, were modified. The first paragraph was modified by deleting the last sentence, which stated: “Moreover, ‘[t]he desired end point in pain management is return to function rather than complete or immediate cessation of pain.’ (ACOEM Practice Guidelines, 2nd Edition, p. 116.)” The second paragraph, was modified at the beginning of the first sentence for clerical error to change the word “Physicians” to its singular form, thus “The physician.” The modified sentence states, “The physician treating in the workers’ compensation system must be aware that just because an injured worker has reached a permanent and stationary status or maximal medical improvement does not mean that they are no longer entitled to future medical care.”**

The second paragraph was further modified by inserting the following new language crafted from the California Medical Board to define the treatment plan for chronic pain and the need for periodic review: “The physician should periodically review the course of treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of pain management depends on the physician’s evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. When prescribing controlled substances for pain, satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. ([http://www.medbd.ca.gov/pain\\_guidelines.html](http://www.medbd.ca.gov/pain_guidelines.html).)” The revised language was inserted based on public comments which persuaded DWC, stating that there are situations where further functional improvement is no longer possible for the patient. DWC also agreed with public comments that during the natural history of chronic pain it is anticipated that the patient may experience fluctuations or episodes of breakthrough pain during their clinical course. The deletion of the last sentence in the first paragraph and the further clarification in the language of the paragraph was necessary to address the purpose of the treatment plan for a chronic condition to maintain the patient’s level of function.

Further, a third clarifying paragraph emphasizing the importance of the goal of maintaining the patient's level of function was added stating, "Additionally, fluctuations are likely to occur in the natural history of patients with chronic pain. Exacerbations and 'breakthrough' pain may occur during the chronic clinical course and adjustments to the treatment will be necessary."

**26. The first paragraph, first sentence under the *Conclusion*,** at page 9, was modified for clerical error to delete the word "neuropathic" and substitute it with the word "chronic." The modified sentence states, "We now have an appreciation that chronic pain is associated with structural and functional changes of the peripheral and central nervous system." The first paragraph was further modified at item no. (3), fourth sentence, to delete the phrase "intractable chronic pain" immediately before the word "patient" and to insert the phrase "with intractable chronic pain" immediately after word "patient." The modified sentence states, "While biologic mechanisms play a role in the perception of pain, it is also important to recognize that psychological and environmental factors are important. Recognition of these factors will allow the physician to better (1) treat the recently injured patient, (2) identify the "at risk" patient, and (3) refer the patient with intractable chronic pain to the appropriate resources." The modifications were made for clarification purposes.

## **Modifications to Part 2. Intervention and Treatments Chronic Pain Medical Treatment Guidelines**

### **A. Modifications Made by Work Loss Data Institute ODG Version Dated October 23, 2008 as Adapted Into the DWC Chronic Pain Medical Treatment Guidelines**

Appendix A1—**Chronic Pain Medical Treatment Guidelines** served as the Supplement of Notice of Modification of the Text (1<sup>st</sup> 15-day Notice) of the DWC Chronic Pain Medical Treatment Guidelines. In Appendix A1, the regulated public was notified that because the modifications to the ODG October 23, 2008 version (from the October 31, 2007 version) by the Work Loss Data Institute, and adapted by DWC, were not those of DWC and because they were numerous, they would not be summarized in Appendix A1. The public was further notified that a copy of **Part 2-Interventions and Treatments** correspondingly would not be served with this Notice of Modification to Text of Proposed Rulemaking and Appendix A1. In order to make the public aware of the modifications to the guidelines made by the Work Loss Data, however, the public was informed that the entire Chronic Pain Medical Treatment Guidelines (**Part 1-Introduction and Part 2-Pain Interventions and Treatments**) would be made available on the DWC's website at <http://www.dwc.ca.gov>. The public was further informed that if any member of the public was interested in obtaining a hard copy of **Part 2-Pain Interventions and Treatments**, they could contact DWC's Rulemaking coordinator at the contacting information provided in the accompanying Notice and arrangements would be made to make a copy available to the requesting party.

The public was further informed that the specific modifications to **Part 2-Interventions and Treatments**, as revised in the ODG October 23, 2008 version by the Work Loss Data Institute and adapted by DWC, would be noticed to the public in the following format: The deletions in the text **Part 2-Interventions and Treatments** would be reflected by double strike-through, thus: ~~deleted language~~. Additions to **Part 2-Interventions and Treatments** would be reflected by a double underline, thus: added language.

Moreover, the public was informed that the entire Chronic Pain Medical Treatment Guidelines (**Part 1-Introduction and Part 2-Pain Interventions and Treatments**) was also part of the rulemaking file which was currently available for public review during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers' Compensation. The public was provided with the address of the Division: 1515 Clay Street, 17<sup>th</sup> Floor, Oakland, California.

**A. General Modifications Made by DWC to the ODG Version Dated October 23, 2008 as Adapted Into the DWC Chronic Pain Medical Treatment Guidelines.**

Because DWC did not adopt the entire October 23, 2008 version of ODG's chronic pain chapter, *but adapted that version* to meet the requirements of the MTUS, DWC edited the selected ODG version. The modifications made by DWC to the October 23, 2008 version of ODG's chronic pain chapter were noticed to the public in Appendix A1 to the 1<sup>st</sup> 15-day Notice. These modifications were noticed to the public as follows:

**1. Modifications to the Entire Guidelines**

**DWC edited the entire text of the October 23, 2008 version of ODG chapter on pain to remove recommendations for acute treatments.** The editing of acute recommendations was consistent with separating "acute recommendations" from "chronic recommendations," in order to insure that the guidelines were applicable only to chronic pain. However, the editing of the text took into consideration the different meanings of the word "acute" and the context in which the word is used. For example, the word "acute" was not removed when used in the text of the supporting evidence-based reviews. Further, in the instances where the word "acute" was used in the context of "acute exacerbations," "acute flares," or "acute breakthrough pain" for chronic pain conditions, the use of the word was left intact in the text of the guidelines as written because the use of the word in this context is for chronic pain; it is not a recommendation for acute treatment.

**Further, DWC edited the entire text of the October 23, 2008 version of ODG chapter on pain to clarify recommendations for subacute treatments.** DWC conducted a word search in the guidelines and in each instance the word "subacute" was found a determination was made to insure that the reference related to a "chronic" recommendation as opposed to an "acute" recommendation. The purpose of this editing was to insure that the recommendation would not conflict with the clinical topics sections. When there was conflict, the "subacute" references were removed.

**2. Individual treatment topics determined by the October 23, 2008 version of ODG chapter on pain to be "under study."**

The ODG chapter on pain uses the term "under study" for some individual treatment topics" or relevant portions of the topic. The term "under study" indicates that the evidence was reviewed but ODG was unable to make a recommendation either in support or against the treatment based on the insufficiency of the evidence in certain circumstances. DWC determined that the determination "under study" without a recommendation does not meet the statutory requirement that the guidelines be "scientific and evidence-based." (Lab. Code, § 4604.5(b); See also, Item

No. 5. Individual treatment topics determined by the ODG chapter on pain to be “under study,” Appendix A, June 2008, page 12, related to the October 31, 2007 ODG chapter on pain version.)

(a) Individual treatment topics “under study” in the October 31, 2007 ODG chapter on pain version now with recommendations in the October 23, 2008 ODG chapter on pain version.

Originally, in Appendix A, accompanying the 45-day notice (June 2008), DWC identified certain individual treatment topics in the October 31, 2007 version of ODG’s chronic pain chapter, which ODG determined to be “under study.” As noticed in Appendix A (June 2008), the individual treatment topics were removed from the DWC chronic pain medical treatment guidelines as not meeting the requirements of the statute. Following the 45-day notice, ODG updated its chronic pain chapter and made recommendations on these individual treatment topics, thus they were no longer considered “under study.” In view of ODG’s update, the public was noticed that the these individual treatment topics, which were omitted from the noticed June 2008 chronic pain medical treatment guideline, were added to the proposed version of the Chronic Pain Medical Treatment Guidelines (as noticed in November 2008). The individual treatment guideline topics were identified as follows: (1) Chronic pain programs, early intervention; (2) Chronic pain programs, intensity; (3) Chronic pain programs, opioids; (4) Massage therapy; (5) CRPS, Diagnostic Criteria.

(b) Individual treatment topics “under study” in the October 23, 2008 ODG chapter on pain version.

The public was further noticed that certain individual treatment topics, or portions of topics, which were found in the updated October 23, 2008 version of ODG chapter on pain, were determined by ODG to be “under study” without a specific recommendation either in support or against the treatment. The public was informed that DWC needed to conduct evidence-based reviews (EBR) of these indicated topics. In the absence of an EBR and a DWC recommendation, DWC removed these individual treatment topics, or portions of such topics from the DWC Chronic Pain Medical Treatment Guidelines, as adapted from the October 23, 2008 version of ODG chapter on pain, and noticed in the 1<sup>st</sup> 15-day notice. The basis for removing the individual treatment topics is that they do not meet the statutory requirement that the guidelines be “scientific and evidence-based.” (Lab. Code, § 4604.5(b) The individual treatment guideline topics were identified as follows: (1) Buprenorphine for chronic pain; and (2) 5-hydroxytryptophan under medical foods.

(c) Individual treatment topics concerning investigational technologies which are equivalent to “under study” in the October 23, 2008 ODG chapter on pain version.

The public was informed that DWC further determined that the October 23, 2008 version of ODG chapter on pain contained individual treatment topics concerning investigational technologies which are equivalent to “under study.” However, DWC independently examined these individual treatment guidelines topics to determine whether there was a conflict with the statute.

The public was noticed that the DWC examined the ODG’s recommendations found in the individual treatment topics on **Functional imaging of brain responses to pain, fMRI (functional magnetic resonance imaging), and Functional MRI**. In these individual treatment topics, ODG states that this technology is investigational, used as a research tool, and therefore there is no scientific evidence base to support its general use. Although, these individual treatment topics are equivalent to “under study,” they were kept in the DWC Chronic Pain Medical Treatment Guidelines because ODG provides a recommendation.

The public was further noticed that in **Functional imaging of brain responses to pain**, the ODG’s October 23, 2008 version states, “Not recommended except in research settings.” Because the MTUS is presumptively correct, this recommendation would mean that that functional imaging of the brain would be recommended in research settings. However, use of fMRI in a research setting is investigational and therefore, this use of the technology is not evidence-based.

DWC noticed the public that it was its determination that it was appropriate to apply the DWC previously noticed guideline (October 31, 2007) instead of the ODG October 23, 2008 guideline, which states, in relevant part as follows:

**“Functional imaging of brain responses to pain** Not recommended. Functional neuroimaging is helping to identify the sensory and emotional components of pain and its autonomic responses, and may help in the design of more rational treatments for pain. However, this test is only useful in a research setting at this time and does not have a role in the evaluation or treatment of patients.”

The public was informed that the October 23, 2008 version of ODG chapter on pain includes references to fMRI in “other individual treatment topics,” where the heading is not about fMRI. The public was noticed that these portions, where fMRI is mentioned in these “other topics,” were removed because the text concerning the technology may be construed as a recommendation for the use of the technology under that ODG topic heading.

The public was provided an example of this modification. For example, under Biofeedback, there is language pertaining to “Functional MRI has been proposed as a method to control brain activation of pain. See Functional imaging of brain responses to pain.” However, Functional MRI, if used for “feedback” purposes is completely different from “biofeedback.” Furthermore, the ODG topic **Function**

**imaging responses to pain** does not mention this therapeutic use of the technology.

The public was further informed that DWC removed text from the ODG topic entitled, “Psychological evaluations,” where ODG states “Chronic pain may harm the brain, based on using functional magnetic resonance imaging (fMRI), whereby investigators found individuals with chronic back pain (CBP) had alterations in the functional connectivity of their cortical regions – areas of the brain that are unrelated to pain – compared to healthy controls. Conditions such as depression, anxiety, sleep disturbances, and decision-making difficulties, which affect the quality of life of chronic pain patient as much as the pain itself, may be directly related to altered brain function as a result of chronic pain (Baliki, 2008).” DWC noted that this article is part of a rapidly growing scientific research base on fMRI, which still is a research tool and its day to day clinical use remains to be determined (i.e., “under study”). DWC removed the text as not pertinent to the topic of psychological evaluations.

### **3. Deletion of an ODG individual treatment topic when the treatment is addressed in another ODG chapter which has not been adopted.**

The public was informed that DWC deleted from the proposed DWC chronic pain medical treatment guidelines, as adapted from the October 23, 2008 version of ODG chapter on pain, individual treatment guideline topics wherein the text under the topic heading referred to other ODG chapters for the guidelines and/or the evidence review. DWC noticed the public that the reason for deleting these references was that DWC had not adopted other ODG chapters. The public was informed that DWC cannot make references to documents which are not formally adopted by reference in the rulemaking or are not part of the documents relied upon and made available to the public during the formal rulemaking process. (See also, Appendix A, June 2008, p. 6.) The individual treatment guideline topics removed were as follows: (1) Colchicine; (2) Etanercept (Enbrel®); (3) Facet blocks; (4) Infliximab (Remicade®); (5) Oral corticosteroids; (4) Piriformis injections; and (5) Restless legs syndrome (RLS).

### **4. Deletion of an ODG individual treatment topic or relevant portions of a topic when the treatment recommendation does not relate to chronic pain**

The public was noticed that certain individual treatment topics, or relevant portions of a topic, were omitted from the proposed chronic pain medical treatment guidelines when the treatment recommendation and text in the guidelines did not directly relate to chronic pain. The public was also noticed that DWC removed individual treatment topics, or relevant portions of individual treatment topics, when they pertained to sleep disorders and psychiatric disorders although they may represent important co-morbidities to manage the treatment of a patient with chronic pain. The public was informed that they were removed because DWC believes that these treatment topics belong to specific special topic treatment areas such as sleep disorders and psychiatric and mental health conditions. The public was further informed that DWC intends to develop guidelines addressing these special topics in the future. DWC noted, that, in the interim, Section 9792.23(b) applied to provide treatment in these areas. The public was also informed that deleted individual treatment guidelines topics related to medical foods. DWC noted that in the October 23, 2008 version of ODG chapter on pain, ODG did not specify how these medical foods are used for chronic pain conditions, and without such specification, these medical foods were deleted. The individual treatment guidelines topics deleted were as follows: (1) Alprazolam

(Xanax®); (2) Ambien® (zolpidem tartrate); (3) Antianxiety drugs; (4) Anti-anxiety drugs; (5) Anxiety medications in chronic pain; (6) Behavioral interventions [(a) ODG Psychotherapy Guidelines]; (7) Insomnia; (8) Insomnia treatment; (9) Medical Foods [(a) Choline; (b) Glutamic Acid; (c) Gamma-aminobutyric acid (GABA); (d) L-Serine; (e) L-Arginine]; (10) Modafinil (Provigil®); (11) Provigil® (modafinil); (12) Restless legs syndrome (RLS); (13) Sedative hypnotics; (14) Xanax® (Alprazolam); (15) Zolpidem (Ambien®).

## **5. Replaced ODG individual treatment topic recommendations**

The public was noticed that the individual treatment topic on Honey & Cinnamon recommendation, as contained in the October 23, 2008 version of ODG chapter on pain, was replaced with DWC's recommendation. The public was informed that the replacement of this individual treatment topic guideline was based on the requirement that the Administrative Director adopt an MTUS that incorporates evidence-based, peer-reviewed, nationally recognized standards of care, and that addresses the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases. (Lab. Code, §5307.27.) DWC noticed the public that ODG listed Honey and Cinnamon as medical food, and indicated that DWC disagreed with the determination. DWC explained in the notice that pursuant to a definition by the Food and Drug Administration (FDA), Honey and Cinnamon are not considered to be a medical food or drug but rather a nutritional supplement. According to the FDA a medical food "is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube. (<http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.9>) DWC indicated that the Federal Drugs Administration (FDA) does not regulate the manufacturing of foods or dietary supplements. (See, Appendix A, at pp. 15-16.) DWC determined, and so informed the public, that the recommended individual treatment topic on Honey & Cinnamon did not conform to the requirements of the Labor Code section 5207.27, requiring that the MTUS address the "intensity" of treatment. DWC noted that the MTUS will be revised when the FDA issues regulations on good manufacturing practices that will focus on practices that ensure the identity, purity, quality, strength, and composition of dietary supplements.

## **6. ODG individual treatment topics that were not previously included in the chronic pain medical treatment guidelines because they were informative and/or educational in nature are now included in the DWC Chronic Pain Medical Treatment Guidelines**

The public was informed that previously in the June 2008 Appendix A, at page 7, paragraph b, DWC had indicated that there were various ODG individual treatment topics that were informative and/or educational in nature. DWC had removed these individual treatment guideline topics from the chronic pain medical treatment guidelines on the basis that although informative, the concepts were not treatment topics and did not substantively added to the overall utility of the chronic pain medical treatment guidelines. Public comments were received during the 45-day comment period, stating that it is necessary to include the topics related to the diagnosis of Complex Regional Pain Syndrome and related conditions as these concepts do substantively add to the overall utility of the guidelines. DWC agreed with the public comments and the following ODG individual treatment topics were included in the DWC chronic pain medical treatment guidelines: (1) CRPS (complex regional pain syndrome); (2) CRPS,

diagnostic criteria; (3) Diagnostic criteria for CRPS; (4) RSD (reflex sympathetic dystrophy); (5) Sympathetically independent pain (SIP); (6) Sympathetically maintained pain (SMP).

## **7. Modification of ODG chapter on pain's individual treatment topic heading**

The public was informed that the following individual treatment topic heading were modified for two reasons: (1) some of the headings were modified pursuant to ODG's October 23, 2008 update, and (2) other modifications resulted from DWC removing the "[DWC]" and "[ODG]" labels where necessary as no longer applicable: (1) Acetaminophen (APAP); (2) Actiq® (fentanyl lollipop); (3) Antispasticity drugs; (4) Botulinum toxin (Botox®, Myobloc®); (5) Capsaicin, topical; (6) Chronic pain programs (functional restoration programs); (7) Clonidine, Intrathecal; (8) CRPS; (9) Cymbalta® (duloxetine); (10) Cytokine DNA Testing for Pain; (11) Dynatron STS; (12) Effexor® (venlafaxine); (13) Electrical stimulators (E-stim); (14) Electroceutical therapy (bioelectric nerve block); (15) Functional imaging of brain responses to pain; (16) Glucosamine (and Chondroitin Sulfate); (17) H-Wave stimulation (HWT); (18) Injection with anaesthetics and/or steroids; (19) Interferential Current Stimulation (ICS); (20) Intravenous regional sympathetic blocks (for RSD/CRPS, nerve blocks); (21) Ketamine; (22) Microcurrent electrical stimulation (MENS devices); (23) Milnacipran (Ixel®); (24) Muscle relaxants (for pain); (25) Neurontin® (gabapentin); (26) Occupational therapy (OT); (27) Percutaneous electrical nerve stimulation (PENS); (28) Physical Medicine; (28) Physical Therapy (PT); (30) RS-4i sequential stimulator; (31) Salicylate topicals; (32) Sympathetic therapy; (33) TENS, chronic pain (transcutaneous electrical nerve stimulation); (34) TENS, post operative pain (transcutaneous electrical nerve stimulation); (34) Testosterone replacement for hypogonadism (related to opioids); (35) Topical Analgesics, compounded; (36) Transcutaneous electrotherapy [DWC]; (37) TENS, chronic pain (transcutaneous electrical nerve stimulation); (38) TENS, post operative pain (transcutaneous electrical nerve stimulation); (39) Dynatron STS; (40) Electroceutical Therapy (bioelectric nerve block); (41) H-wave stimulation (HWT); (42) Interferential Current Stimulation (ICS); (43) Microcurrent electrical stimulation (MENS devices); (44) Neuromuscular electrical stimulation (NMES devices); (45) RS-4i sequential stimulator; and (46) Sympathetic therapy.

## **8. ODG sections on diagnostic tests that were not previously included in the chronic pain medical treatment guidelines because they have broader uses beyond chronic pain medical treatment are now included in the DWC Chronic Pain Medical Treatment Guidelines**

The public was noticed that previously, in the June 2008 Appendix A, at page 6, paragraph 3a, that the individual treatment guideline on the topic of Autonomic test battery was not included in the chronic pain medical treatment guidelines because the guideline represented a diagnostic test that is not exclusive to the diagnosis of chronic pain. After further review of the guidelines, and because of public comments submitted, the individual treatment guideline on the topic of Autonomic test battery was placed back in the chronic pain medical treatment guidelines. The reason for restoring the guidelines into the chronic pain medical treatment guidelines is because this topic is specific to chronic pain and the diagnosis of CRPS 1, and also because these tests do not appear elsewhere in the medical treatment utilization schedule. Thus, upon further review, DWC concluded that there was no internal conflict in the MTUS. (See also, Appendix A, June 2008, at p. 6.)

## **9. Non-substantive changes**

The public was further informed that DWC made non-substantive changes in adapting the October 23, 2008 version of ODG chapter on pain to the DWC chronic pain medical treatment guidelines as follows: (1) In certain circumstances, links were edited to reflect when certain individual treatment topics were omitted or referred to in another ODG chapter; (2) Typographical and grammatical errors in the ODG October 23, 2008 revised chapter on pain were corrected if encountered; (3) Medical foods individual treatment topic heading was removed as all the items listed below the heading were removed; (4) Where ODG referenced “Physical therapy” without mention of “Occupational therapy,” DWC modified “Physical therapy” to “Physical medicine” to conform to DWC’s decision to list Physical therapy and Occupational therapy under the heading “Physical medicine; (5) The individual treatment topic “Oral morphine” was moved to its proper location in alphabetical order; and (6) The individual treatment topic of “Galvanic stimulation” was moved to its proper location in alphabetical order under “Transcutaneous electrotherapies.”

### **B. Specific Modifications Made by DWC to the ODG Version Dated October 23, 2008 as Adapted Into the DWC Chronic Pain Medical Treatment Guidelines.**

**The individual treatment guideline topic for Acetaminophen (APAP), at pp. 11-12, was modified to strike** the last two sentences of the guideline, wherein ODG discusses two Manchikanti et al. articles. The guideline was modified because the text provided commentary which is off-topic and not pertinent to ODG’s recommendations in the specific treatment guideline on Acetaminophen. Further, in modifying the individual treatment guideline on the topic of “Acetaminophen (APAP)”, DWC noted that ODG, via its internal updating process, completed and expanded its evidence base in this guideline on November 4, 2008. ODG, however, did not change the basic recommendation for Acetaminophen. (See, ODG Updates Change Log, November, 2008, added to the Rulemaking file.) In order to properly update this guideline, the entire updated guideline was adapted into the current version of the regulations for the benefit of the regulated public. (See, ODG Acetaminophen Guideline Update, January 21, 2009, added to the rulemaking file). The modified individual treatment topic guideline for Acetaminophen (APAP) provides:

#### **Acetaminophen (APAP)**

“Recommended for treatment of chronic pain & acute exacerbations of chronic pain. With new information questioning the use of NSAIDs, acetaminophen should be recommended on a case-by-case basis. The side effect profile of NSAIDs may have been minimized in systematic reviews due to the short duration of trials. On the other hand, it now appears that acetaminophen may produce hypertension, a risk similar to that found for NSAIDs.

“Osteoarthritis (hip, knee, and hand): Recommended as an initial treatment for mild to moderate pain, in particular, for those with gastrointestinal, cardiovascular and renovascular risk factors. (Laine, 2008) If pain is inadequately treated or there is evidence of inflammation, alternate pharmacologic treatment should be

considered. In patients with moderate to severe disease, initial treatment with an NSAID may be warranted. The decision to use either class of drugs should be made on a case-by-case basis, incorporating factors including side effect profile and patient preferences. Current guidelines note that evidence is limited to make an initial recommendation with acetaminophen, and that NSAIDs may be more efficacious for treatment. In terms of treatment of the hand it should be noted that there are no placebo trials of efficacy and recommendations have been extrapolated from other joints. (Zhang, 2007) The selection of acetaminophen as a first-line treatment appears to be made primarily based on side effect profile in osteoarthritis guidelines. (Zhang, 2008) The most recent Cochrane review on this subject suggests that non-steroidal anti-inflammatory drugs (NSAIDs) are more efficacious for osteoarthritis than acetaminophen in terms of pain reduction, global assessments and improvement of functional status. No significant difference was found between overall safety, although patients taking NSAIDs were more likely to experience an adverse GI event. It is important to note that the median trial duration was only 6 weeks. (Towheed, 2008) See NSAIDs; NSAIDs, GI symptoms & cardiovascular risk; & NSAIDs, hypertension and renal function.

“Low back pain (acute and chronic): Both acetaminophen and NSAIDs have been recommended as first-line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by-case basis based on weighing efficacy vs. side effect profile. In the past many low back pain guidelines recommended acetaminophen as a first-line treatment but recent systematic reviews either failed to find evidence to support the view that acetaminophen was effective for the treatment of non-specific low back pain (Davies, 2008) or found that there was only “fair” quality evidence to support use vs. “good” quality evidence for NSAIDs. (Chou, 2007) Problems with research in this area include a lack of large high quality trials, inadequate reporting of methods and results, and choice of treatment contrasts. Further research on this topic has been suggested. It appears that part of the reason that acetaminophen was recommended as a first-line treatment over NSAIDs in most guidelines, in part, was that acetaminophen appeared to have less adverse effects. (Roelofs-Cochrane, 2008) See adverse effects below.

“Adverse effects: Hepatotoxicity: Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. (Hunt, 2007) A warning is given on all acetaminophen products that patients that consume  $\geq 3$  alcoholic drinks a day should discuss use with their physician, although a systematic review of acetaminophen use in alcoholic subjects concluded that there was little credible evidence to implicate therapeutic doses as a cause of fulminant hepatotoxicity in alcoholics. (Dart, 2007) Recent RCTs found that short-term treatment (3-5 days) of acetaminophen in newly abstinent alcoholic patients did not cause hepatic injury. (Kuffner, 2007) (Bartels, 2008) Acetaminophen, when used at recommended maximum doses, may induce ALT elevations  $>3\times$  ULN in up to nearly 40% of subjects. Renal toxicity: Renal insufficiency occurs in 1 to 2% of patients with overdose. (Mazer, 2008) Hypertension and cardiovascular risk: Cohort analysis reveals that acetaminophen

use is associated with hypertension but evidence from randomized controlled trials is limited. This risk is similar to that found for NSAIDs. (Forman, 2007) (Montgomery, 2008) An increased cardiovascular risk was found in the Nurse's Health Study. (Chan, 2006) (Laine, 2007) (Laine, 2008)

“Dose: The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day.”

**The individual treatment guideline topic for Topical Analgesics, at pp. 116-118, was modified** based on review of the public comments received during the 1<sup>st</sup> 15-day comment period. After reviewing the public comments, ODG was consulted to evaluate the scientific evidence pertaining to Topical Analgesics and more specifically to the compounding pharmacy practice of preparing topically applied analgesics by mixing more than one active ingredient. ODG conducted its own evidence-based reviews, and determined that it was appropriate to modify its Topical Analgesics guidelines to include clarifying language that “any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.” Moreover, the clarifying language was added to state that for “*Other muscle relaxants*” “there is no evidence for use of any other muscle relaxant” as a topical product. Further the guideline was modified to clarify that for “*other antiepilepsy drugs*” “there is no evidence for use of any other antiepilepsy drug as a topical product.” (See, ODG Topical Analgesics Guideline Update, January, 21, 2009, and ODG Updates Change Log, December, 2008, added to the Rulemaking file.) The modified individual treatment topic guideline for Topical Analgesics, compounded, provides:

### **Topical Analgesics**

“Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\gamma$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic® (fentanyl transdermal system).]

“***Non-steroidal anti-inflammatory agents (NSAIDs):*** The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small

and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) *Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment:* Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. *Neuropathic pain:* Not recommended as there is no evidence to support use. *FDA-approved agents: Voltaren® Gel 1% (diclofenac):* Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. *Non FDA-approved agents: Ketoprofen:* This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000)

**“Lidocaine Indication: Neuropathic pain** Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm<sup>®</sup>) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007)

(Knotkova, 2007) (Lexi-Comp, 2008) *Non-neuropathic pain*: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)

**“Capsaicin:** Recommended only as an option in patients who have not responded or are intolerant to other treatments. *Formulations:* Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. *Indications:* There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-*BMJ*, 2004) See also **Capsaicin**.

**“Baclofen:** Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen.

“Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product.

**“Gabapentin:** Not recommended. There is no peer-reviewed literature to support use.

Other antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product.

**“Ketamine:** Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also **Glucosamine (and Chondroitin Sulfate); & Topical analgesics, compounded.**”

**Moreover, the individual treatment topic guideline for Topical Analgesics, compounded, at pp 118-119, was modified to reference the individual treatment topic guideline Topical Analgesics, and by striking the entire text of the guideline.** During the 15-day comment period, many comments were received from the regulated public arguing that the guideline would completely ban all topical compounded drug treatments. This was not the intention of the guideline. After reviewing the comments, ODG was consulted to evaluate the scientific evidence pertaining to the compounding pharmacy practice of mixing more than one active ingredient. From this evidence-based review, as conducted through its formal internal review, ODG determined that it was appropriate to modify its Topical Analgesics guidelines to include language addressing compounding more than one topical analgesics, as set forth above. (See, ODG Topical Analgesics, compounded Guideline Update, January, 21, 2009.) The modified individual treatment topic guideline for Topical Analgesics, compounded provides:

### **Topical Analgesics, compounded**

“See Topical analgesics.”

**The text of the individual treatment topic guideline for Interferential Current Stimulation (ICS) was modified,** at page 126, for clerical error, to insert the phrase “as an isolated intervention” at the second full paragraph. The phrase was left out from the October 23, 2008 ODG version due to inadvertence, and it was brought to the attention of DWC by public comment during the 1<sup>st</sup> 15-day comment period. The revised text of the individual treatment topic guideline for Interferential Current Stimulation (ICS), at page 126, second paragraph, provides:

“While not recommended as an isolated intervention, Patient selection criteria if Interferential stimulation is to be used anyway:”

### **C. Clerical errors corrected on the DWC chronic pain medical treatment guidelines as Adapted Into the DWC Chronic Pain Medical Treatment Guidelines.**

**The following clerical errors appeared in the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period,** and are corrected as reflected below. Further, the following identified paragraphs/sentences were erroneously inserted into the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. These paragraphs/sentences were not included in the initial proposed guidelines: The Division has no intention of adopting these paragraphs/sentences. We are deleting these paragraphs/sentences as reflected below as they should not be considered part of the rulemaking file.

### **Antidepressants for chronic pain**

Page 12, first paragraph, the last sentence, stating “Also see Comorbid psychiatric disorders,” which appears in a double strike-out should have not been included in the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. The sentence already appeared in a double strike-out format in the middle of the paragraph, and it was included at the end of the paragraph due to clerical error.

### Antiepilepsy drugs (AEDs)

Page 22, first paragraph, line 7: Under Other Antiepileptic Drugs, *Topiramate (Topamax®)*, *no generic available*, the “no generic available” phrase was not double-underlined as new language. Thus, it is corrected for clerical error as follows: *Topiramate (Topamax®)*, *no generic available*.

### Antispasticity drugs

Page 22, last sentence: The sentence under the individual treatment guideline for the topic “Antispasticity drugs,” which states, See Muscle relaxants is reflected as new language by double-underscore. The language was not new language during the 1<sup>st</sup> 15-day notice as it was contained in the proposed guidelines in the 45-day comment period. Thus, it is corrected for clerical error to remove the double-underscore as follows: “See Muscle relaxants.”

### CRPS, sympathetic and epidural blocks

Page 41, first full paragraph, subtitle, “**Recommendations (based on consensus guidelines) for use of sympathetic blocks;**” should have not been included the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. The paragraph was not contained in the proposed guidelines in the 45-day comment period. Accordingly, the paragraph is stricken from the final draft of the chronic pain medical treatment guidelines for clerical error as follows:

~~**Recommendations (based on consensus guidelines) for use of sympathetic blocks:** (1) In the initial diagnostic phase if less than 50% improvement is noted for the duration of the local anesthetic, no further blocks are recommended. (2) In the initial therapeutic phase, maximum sustained relief is generally obtained after 3 to 6 blocks. These blocks are generally given in fairly quick succession in the first two weeks of treatment with tapering to once a week. Continuing treatment longer than 2 to 3 weeks is unusual. (3) In the therapeutic phase repeat blocks should only be undertaken if there is evidence of increased range of motion, pain reduction and increased tolerance of activity and touch in physical therapy/occupational therapy. (4) There should be evidence that physical or occupational therapy is incorporated with the duration of symptom relief of the block during the therapeutic phase. (5) In acute exacerbations, 1 to 3 blocks may be required for treatment. (5) A formal test of the block should be documented (preferably using skin temperature). (6) Documentation of motor and/or sensory block should occur. This is particularly important in the diagnostic phase to avoid overestimation of the sympathetic component of pain. (Burton, 2006) (Stanton-Hicks, 2004) (Stanton-Hicks, 2006) (International Research Foundation for RSD/CRPS, 2003) (Colorado, 2006) (Washington, 2002) (Rho, 2002)~~

### Epidural steroid injections (ESIs)

Page 48, Item No 7, the word “be” should not have been double underlined as new language. Thus, it is corrected for clerical error and it should be reflected in the final text of the regulations (chronic pain medical treatment guidelines) as follows: “(7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007)”

## Medications for acute pain (analgesics)

Page 62 should have shown the individual treatment guideline on the topic of “Medications for acute pain (analgesics)” on “double strike-out” form to represent that it was being removed from the chronic pain treatment guidelines as a guideline applicable to acute pain and not applicable to chronic pain. Thus:

## ~~Medications for acute pain (analgesics)~~

~~Recommended as indicated below. Pharmacologic agents are the main treatment of acute pain.~~

~~Acetaminophen is the initial choice for treatment of acute pain in a dose of 1,000 mg. A recent study found that in a single dose, aspirin was similar to acetaminophen (mg to mg comparison) for treatment of acute pain, although aspirin is more likely to produce GI side effects. (Edwards, 2006) (Sachs, 2005) The maximum daily dose of acetaminophen is 4,000 mg. There should be caution about daily doses of acetaminophen and liver disease if over 4,000 mg per day or in combination with other NSAIDs. (Watkins, 2006)~~

~~NSAIDs are superior to acetaminophen for some types of pain, and can provide analgesia similar to opioids in some settings, including post-operatively. (Mason, 2006) They suffer from a ceiling effect above which no additional analgesic effect can be obtained. They also suffer from side effects such as GI disturbance, renal dysfunction, increased edema, and increased blood pressure. NSAIDs, and the Cox-2 NSAIDs in particular, also are associated with thrombotic cardiovascular events.~~

~~Opioids are appropriate analgesics for somatic, neuropathic and visceral pain. Hydrocodone is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). (Quigley, 2006) Side effects include sedation, nausea, vomiting and constipation. There is no evidence that supports the addition of pentazocine (Talwin) or butorphanol (Stadol) to decrease side effects. (Sachs, 2005) This study found a negative association between receipt of early opioids for acute LBP and outcomes (disability duration, medical costs, subsequent surgery), but severity was also a strong predictor (confounding variable) of all the outcomes and may explain the early opioid use. (Webster, 2007) Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/acetaminophen. There is also no evidence that it has a safer adverse event profile. (Turturro, 1998)~~

### **Medications for chronic pain**

Page 62, the title of the individual treatment guideline on the topic of “Medications for chronic pain” is corrected for clerical error with double strike-through to the word “subacute” in the title, thus: “**Medications for ~~subacute~~ & chronic pain.**” The corrected title is reflected in the final text of the regulations (chronic pain medical treatment guidelines).

### **Norepinephrine serotonin reuptake inhibitors (NSRIs)**

Page 70, the individual treatment guideline on the topic of “Norepinephrine serotonin reuptake inhibitors (NSRIs)” was moved to follow its proper alphabetical place under the individual treatment guideline on the topic of “Nonprescription medications.” However, the change, due to clerical error, was not noticed to the public.

### **Topical Analgesics**

Page 116, first full paragraph, the phrase “Neuropathic Pain” should have appeared on double strike-through format before the word “Lidocaine.” Thus: Neuropathic Pain

### **Transcutaneous electrotherapy [DWC]**

Originally in Appendix A, the public was notified that DWC restructured the individual treatment topics related to electrotherapy and listed them in alphabetical order grouped under the heading “transcutaneous electrotherapy.” (See, Appendix A, June 2008, pp. 9-10.) Consistent with this reorganization, DWC examined the individual treatment topics related to electrotherapy in the October 23, 2008 version of the ODG chapter on pain, and again conducted further alphabetical reorganization of the topics related to electrotherapy, but did not reflect this in Appendix A1. Accordingly, the modifications are noted below:

Page 121, the individual treatment guideline on the topic of “Dynatron STS” related to electrotherapy, was moved and placed under the individual treatment guideline on the main topic of “TENS, chronic pain (transcutaneous electrical nerve stimulation).” The guideline was originally contained out of order following the individual treatment guideline on the topic of “Sympathetic therapy.” However, this modification was not reflected in the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. The moved guideline should have been double underlined, and the deleted guideline should have been in double strike-through format. This is corrected for clerical error in the text of the final text of the regulations (chronic pain medical treatment guidelines) as follows:

### **“~~Dynatron STS [ODG]~~**

**See Sympathetic therapy.”**

Page 121, the individual treatment guideline on the topic of “Electroceutical Therapy (bioelectric nerve block)” related to electrotherapy was moved and placed in alphabetical order under the individual treatment guideline on the topic of “Dynatron STS.” It was originally contained out of order following the individual treatment guideline on the topic of “RS-4i sequential stimulator.” However, this modification was not reflected in the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. The moved guideline should have been double underlined, and the deleted guideline should have been in double strike-

through format. This is corrected for clerical error in the text of the final text of the regulations (chronic pain medical treatment guidelines) as follows:

**“Electroceutical Therapy (bioelectric nerve block) ~~{ODG}~~**

Not recommended. Electroceutical therapy (also known as bioelectric nerve block) is experimental and investigational for the treatment of ~~acute pain or~~ chronic pain (e.g., back pain, diabetic pain, joint pain, fibromyalgia, headache, and CRPS) because there is a lack of scientific evidence regarding the effectiveness of this technology. In addition, electroceutical treatments use much higher electrical frequencies than TENS units and may only be prescribed and administered under the supervision of a healthcare provider experienced in this method of treatment. (Aetna, 2005)”

Page 126, the individual treatment guideline on the topic of “RS-4i sequential stimulator” related to electrotherapy was moved and placed in alphabetical order under the individual treatment guideline on the topic of “Neuromuscular electrical stimulation (NMES devices).” It was originally contained out of order following the individual treatment guideline on the topic of “Microcurrent electrical stimulation (MENS devices).” However, this modification was not reflected in the revised regulations (chronic pain medical treatment guidelines) proposed in the 1<sup>st</sup> 15-day comment period. The moved guideline should have been double underlined, and the deleted guideline should have been in double strike-through format. This is corrected for clerical error in the text of the final text of the regulations (chronic pain medical treatment guidelines) as follows:

**“RS-4i sequential stimulator ~~{ODG}~~**

**See Interferential current stimulation (ICS).”**

**Ultram® (tramadol)**

Page 128, the individual treatment guideline topic for “Ultram® (tramadol)” is a new guideline and should have been double underlined as new language thus: **“Ultram® (tramadol)** Ultram® is a brand of tramadol supplied by Ortho-McNeil Pharmaceutical. See Tramadol (Ultram®).”

**Subdivision 9792.24.2(e)** was added to section §9792.24.2 to reflect that Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers’ Compensation and Official Disability Guidelines References—is incorporated by reference into the MTUS as supplemental part of the Chronic Pain Medical Treatment Guidelines. This subdivision also provides that a copy of Appendix D may be obtained from the Medical Unit, Division of Workers’ Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>. These references are incorporated into the MTUS as supplemental part of the Chronic Pain Medical Treatment Guidelines. **Appendix D was adopted and incorporated into the regulations** pursuant to requests by the regulated public that the references should be available to the public as part of the regulations. Because the references are voluminous and it would cumbersome and impractical to publish them in the regulations, DWC will incorporate them by reference into the regulations, and make them available to the public as set forth above. This allows the regulated public to have access to the Division of Workers’ Compensation and

Official Disability Guidelines’ chronic pain medical treatment guidelines’ references, if interested.

### **Modifications to Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers’ Compensation and Official Disability Guidelines References**

At the outset, it is noted that **Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers’ Compensation and Official Disability Guidelines References** is a separate, self-contained new document, consisting of 559 pages. The document contained its own original format, wherein certain titles and subtitles were single-underlined, certain references and citations were single-underlined, and page 202 contained an informational table. It would have been difficult for the regulated public to read and analyze the document had DWC single-underlined the entire document. Because the entire document was **all new** text/language, DWC noticed the document without the single-underlying. However, when further changes were made to the document (i.e., the document was adopted and incorporated into the regulations), DWC noticed those changes accordingly and the public was properly informed of the format of the changes.

**The header of Appendix D was modified** to delete the phrases “Initial Statement of Reasons,” and “(DWC 2008).” The header of Appendix D was further modified to insert the date of the version of the ODG Chapter of Pain being adapted, thus “October 23, 2008 version of ODG Chapter on Pain.” The footer of Appendix D was modified to delete the phrase “(DWC 2008),” and to substitute the month “June” with the month “November.” Further because the Chronic Pain Medical Treatment Guidelines version was being updated to the October 23, 2008 ODG version, the entire document was replaced to ensure that it contains all the revised ODG references. The modifications was intended to make the document current for incorporation into the regulations as explained under section 9792.24.2(e), above.

**Appendix D further was modified to delete references to two *Manchikanti, et al.* articles** in Appendix D, at pages 342, 343, and 344. The reason for deleting these references was set forth in the explanation for the modifications to the individual treatment topic guideline for Acetaminophen (APAP), above.

**Appendix D was also modified to add new references** relating to the expansion of evidence base in the individual treatment topic guideline for Acetaminophen (APAP) as set forth above, at pages 93, 94, 157, 181, 182, 207, 208, 271, 307, 357, 371, 490, and 548 in that document.

### **Modifications to Section 9792.24.3. Postsurgical Treatment Guidelines**

The title of the section was modified to delete the phrase “DWC 2008.” The phrase was deleted to avoid confusion as to the date of applicability of the guidelines. The date when the regulations becomes effective is the date when the guidelines becomes applicable as approved by OAL.

**Subdivision 9792.24.3(a)1.** was modified for clerical purposes to delete the period after number 1 and to place the number in parenthesis, thus (1). The subdivision as corrected now reads, subdivision 9792.24.3(a)(1).

**Subdivision 9792.24.3(a)2.** was modified for clerical purposes to delete the period after number 2 and to place the number in parenthesis, thus (2). The subdivision as corrected now reads, subdivision 9792.24.3(a)(2).

**Subdivision 9792.24.3(a)3.** was modified for clerical purposes to delete the period after number 3 and to place the number in parenthesis, thus (3). The subdivision as corrected now reads, subdivision 9792.24.3(a)(3).

**Subdivision 9792.24.3(a)4.** was modified for clerical purposes to delete the period after number 4 and to place the number in parenthesis, thus (4). The subdivision as corrected now reads, subdivision 9792.24.3(a)(4).

**Subdivision 9792.24.3(a)5.** was modified for clerical purposes to delete the period after number 5 and to place the number in parenthesis, thus (5). The subdivision as corrected now reads, subdivision 9792.24.3(a)(5).

**Subdivision 9792.24.3(b)1.** was modified for clerical purposes to delete the period after number 1 and to place the number in parenthesis, thus (1). The subdivision as corrected now reads, subdivision 9792.24.3(b)(1).

**Subdivision 9792.24.3(c)1.** was modified for clerical purposes to delete the period after number 1 and to place the number in parenthesis, thus (1). The subdivision as corrected now reads, subdivision 9792.24.3(c)(1).

**Subdivision 9792.24.3(c)1.** was further corrected for clarification purposes to delete the comma after the phrase “a nurse practitioner.” The comma was removed pursuant to a public comment that it was not clear whether the nurse practitioner would need to be working with the surgeon who performed the operation and whether this provision would expand the scope of practice of the nurse practitioner. The intention of the subdivision is to have the nurse work with the surgeon as part of the surgical team. The comma was removed to avoid misinterpretation of this provision. This language is also consistent with the language set forth in subdivision 9792.24.3(c)(5)(A).

**Subdivision 9792.24.3(c)2.** was modified for clerical purposes to delete the period after number 2 and to place the number in parenthesis, thus (2). The subdivision as corrected now reads, subdivision 9792.24.3(c)(2).

**Subdivision 9792.24.3(c)3.** was modified for clerical purposes to delete the period after number 3 and to place the number in parenthesis, thus (3). The subdivision as corrected now reads, subdivision 9792.24.3(c)(3).

**Subdivision 9792.24.3(c)4.** was modified for clerical purposes to delete the period after number 4 and to place the number in parenthesis, thus (4). The subdivision as corrected now reads, subdivision 9792.24.3(c)(4).

**Non-Substantive Correction of Clerical Error to Subdivision 9792.24.3(d)(1)  
Postsurgical Treatment Guidelines**

The notice of the proposed regulations issued June 2008 clearly informed the public that the “the physical medicine treatment recommendations (listed alphabetically)” were “adapted from Official Disability Guidelines (ODG) except where developed by the Division of Workers’ Compensation and indicated as ‘[DWC].’ ” The notice further clearly informed the public that “[t]he postsurgical physical medicine period [was] identified by an asterisk [\*] as also developed by DWC.” The draft of the proposed text of the regulations, which was served with the notice, contained a clerical error at Section 9792.24.3(d)(1), wherein specific postsurgical treatment guidelines following the adoption language in the section—which was single-underlined—were not single-underlined to indicate new text/language. Although the entire postsurgical treatment guidelines were **all new** text/language, the text/language should have been single-underlined to be consistent with the rest of the section which was single-underlined as new text/language. The clerical error is corrected in the final text of the regulations.

**Modifications to Subdivision 9792.24.3(d)(1)**

**Subdivision 9792.24.3(d)(1)** was modified to delete the last sentence of the subdivision which states, “A copy of citations listed in the postsurgical treatment guidelines may be obtained from the Medical Unit, Division of Workers’ Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.” The sentence was deleted because that information is moved to new subdivision 9792.24.3(d)(3) which incorporates by reference into the MTUS Appendix E containing the Postsurgical Treatment Guidelines references, and informs the public where these references may be obtained.

**Modifications to the specific guidelines in Section 9792.24.3(d)(1). Postsurgical Treatment Guidelines as adapted from the ODG’s Postsurgical Treatment Guidelines Chapters, version dated October 23, 2008, are reflected below.**

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Ankle & Foot topic** was modified pursuant to the ODG revised October 23, 2008 version to add the following sentence at the end of the text: “This RCT supports early motion (progressing to full weight bearing at 8 weeks from treatment) as an acceptable form of rehabilitation in surgically treated patients with Achilles tendon ruptures. (Twaddle, 2007).” Further, the text was corrected for clerical error to delete the word “physical” immediately preceding the word “therapist” in the second sentence. The modification is to clarify that a therapist can be either a “physical therapist” or an “occupational therapist” because “physical medicine” in these regulations encompasses both physical therapy and occupational therapy. The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Ankle & Foot topic provides:

## **Ankle & Foot**

Exercise program goals should include strength, flexibility, endurance, coordination, and education. Patients can be advised to do early passive range-of-motion exercises at home by a therapist. (Colorado, 2001) (Aldridge, 2004) This RCT supports early motion (progressing to full weight bearing at 8 weeks from treatment) as an acceptable form of rehabilitation in surgically treated patients with Achilles tendon ruptures. (Twaddle, 2007)

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Burns** topic was modified pursuant to the ODG revised October 23, 2008 version to add the word “Recommended” at the beginning of the paragraph, and to add the following sentence at the end of the text: “As with any treatment, if there is no improvement after 2-3 weeks the protocol may be modified or re-evaluated.” The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Burns topic provides:

### **Burns**

Recommended. Occupational therapy and physical therapy for the patient with burns may include respiratory management, edema management, splinting and positioning, physical function (mobility, function, exercise), scar management, and psychosocial elements. (Simons, 2003) As with any treatment, if there is no improvement after 2-3 weeks the protocol may be modified or re-evaluated.

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Carpal Tunnel Syndrome** topic was modified pursuant to the ODG revised October 23, 2008 version to add the following first five sentences at the beginning of the text: “Recommended as indicated below. There is limited evidence demonstrating the effectiveness of PT or OT for CTS. The evidence may justify 3 to 5 visits over 4 weeks after surgery, up to the maximums shown below. Benefits need to be documented after the first week, and prolonged therapy visits are not supported. Carpal tunnel syndrome should not result in extended time off work while undergoing multiple therapy visits, when other options (including surgery for carefully selected patients) could result in faster return to work.” The subsequent sentence (sixth) was modified to insert the word “Furthermore,” at the beginning of the sentence and to change the letter “C” to lower case “c.” Moreover, a new sentence was inserted following the citation “(Cook, 1995)” as follows: “Continued visits should be contingent on documentation of objective improvement, i.e., VAS improvement greater than four, and long-term resolution of symptoms.” Further the introductory text was corrected for clerical error to delete the word “physical” immediately preceding the word “therapy” in three instances in the introductory text. The modification was to clarify that “therapy” in these guidelines can be either a “physical therapy” or “occupational therapy” because “physical medicine” in these regulations encompasses both physical therapy and occupational therapy. The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Carpal Tunnel Syndrome topic provides:

## **Carpal Tunnel Syndrome**

Recommended as indicated below. There is limited evidence demonstrating the effectiveness of PT or OT for CTS. The evidence may justify 3 to 5 visits over 4 weeks after surgery, up to the maximums shown below. Benefits need to be documented after the first week, and prolonged therapy visits are not supported. Carpal tunnel syndrome should not result in extended time off work while undergoing multiple therapy visits, when other options (including surgery for carefully selected patients) could result in faster return to work. Furthermore, carpal tunnel release surgery is a relatively simple operation that also should not require extended multiple therapy office visits for recovery. Of course, these statements do not apply to cases of failed surgery and/or misdiagnosis (e.g., CRPS I instead of CTS). (Feuerstein, 1999) (O'Conner-Cochrane, 2003) (Verhagen-Cochrane, 2004) (APTA, 2006) (Bilic, 2006) Post surgery, a home therapy program is superior to extended splinting. (Cook, 1995) Continued visits should be contingent on documentation of objective improvement, i.e., VAS improvement greater than four, and long-term resolution of symptoms. Therapy should include education in a home program, work discussion and suggestions for modifications, lifestyle changes, and setting realistic expectations. Passive modalities, such as heat, iontophoresis, phonophoresis, ultrasound and electrical stimulation, should be minimized in favor of active treatments.

**The post-replantation surgery specific postsurgical physical medicine guideline** under Traumatic Amputation of Arm (ICD9 887), Elbow & Upper Arm topic was modified for clerical error to delete the abbreviations “ODG” in the brackets (i.e., [ODG]) as only the guidelines developed by DWC are the ones identified in brackets in the postsurgical guidelines. The modified post-replantation surgery specific postsurgical physical medicine guideline provides:

### **Elbow & Upper Arm**

#### **Traumatic amputation of arm (ICD9 887):**

Post-replantation surgery: 48 visits over 26 weeks

\*Postsurgical physical medicine treatment period: 12 months

The **Forearm, Wrist, & Hand** postsurgical guideline was modified pursuant to the ODG revised October 23, 2008 version as set forth below.

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Forearm, Wrist, & Hand topic was corrected for clerical error** to delete the word “physical” immediately preceding the word “therapist” in the introductory text. The modification was to clarify that a therapist can be either a “physical therapist” or an “occupational therapist” because “physical medicine” in these regulations encompasses both physical therapy and occupational therapy. Further the sentence “Hand function significantly improved in patients with rheumatoid arthritis after completion of a course of occupational therapy (p<0.05),” and supporting study “(Rapoliene, 2006)” was deleted as the subject of the reference and the study do not relate to surgery. The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Forearm, Wrist, & Hand topic and added surgery, provides:

## **Forearm, Wrist, & Hand**

(Not including Carpal Tunnel Syndrome –see separate post surgical guideline.)

Used after surgery and amputation. During immobilization, there was weak evidence of improved hand function in the short term, but not in the longer term, for early occupational therapy, and of a lack of differences in outcome between supervised and unsupervised exercises. Post-immobilization, there was weak evidence of a lack of clinically significant differences in outcome in patients receiving formal rehabilitation therapy, passive mobilization or whirlpool immersion compared with no intervention. There was weak evidence of a short-term benefit of continuous passive motion (post external fixation), intermittent pneumatic compression and ultrasound. There was weak evidence of better short-term hand function in patients given therapy than in those given instructions for home exercises by a surgeon. (Handoll-Cochrane, 2002) (Handoll-Cochrane, 2006)

**The post-replantation surgery specific postsurgical physical medicine guideline** under the Amputation of Hand (ICD9 887) surgery, Forearm, Wrist, & Hand topic was modified for clerical error to delete the abbreviations “ODG” in the brackets (i.e., [ODG]) as only the guidelines developed by DWC are the ones identified in brackets in the postsurgical guidelines. The modified post-replantation surgery specific postsurgical physical medicine guideline provides:

### **Amputation of hand (ICD9 887):**

Post-replantation surgery: 48 visits over 26 weeks

\*Postsurgical physical medicine treatment period: 12 months

A postsurgical physical medicine guideline for the “Sprains and strains of elbow and forearm (ICD9 841)” surgery was added pursuant to the revised October 23, 2008 version to the Forearm, Wrist, & Hand topic as follows:

### **Sprains and strains of elbow and forearm (ICD9 841):**

Post-surgical treatment/ligament repair: 24 visits over 16 weeks

\*Postsurgical physical medicine treatment period: 6 months

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Head topic was corrected for clerical error** to delete the word “physical” immediately preceding the word “therapy” in three instances in the introductory text. The modification was to clarify that “therapy” in these guidelines can be either “physical therapy” or “occupational therapy” because “physical medicine” in these regulations encompasses both, physical therapy and occupational therapy. Further, letter “t” in the word “therapy” has been changed to upper case because it is now in the beginning of the sentence. The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Head topic provides:

## Head

Patient rehabilitation after traumatic brain injury is divided into two periods: acute and subacute. In the beginning of rehabilitation therapist evaluates patient's functional status, later he uses methods and means of treatment, and evaluates effectiveness of rehabilitation. Early ambulation is very important for patients with coma. Therapy consists of prevention of complications, improvement of muscle force, and range of motions, balance, movement coordination, endurance and cognitive functions. Early rehabilitation is necessary for traumatic brain injury patients and use of therapy methods can help to regain lost functions and to come back to the society. (Colorado, 2005) (Brown, 2005) (Frankeviciute, 2005) (Driver, 2004) (Shiel, 2001)

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Hip, Pelvis and Thigh (femur)** topic was modified pursuant to the ODG revised October 23, 2008 version to delete the phrase “injury or” in the first sentence, to delete the word “a” in between the words “coordinated” and “multidisciplinary,” and to add the following sentence at the end of the introductory text: “Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense physical therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008)” Further, the introductory text was corrected for clerical error to delete the word “physical” immediately preceding the word “therapy” in two instances in the introductory text. The modification was to clarify that “therapy” in these guidelines can be either “physical therapy” or “occupational therapy” because “physical medicine” in these regulations encompasses both physical therapy and occupational therapy. Moreover, a postsurgical physical medicine guideline for the new surgery of “Osteoarthritis and allied disorders (ICD9 715)” was added pursuant to the ODG revised October 23, 2008 version. The revisions are as follows:

### **Hip, Pelvis and Thigh (femur)**

A therapy program that starts immediately following hip surgery allows for greater improvement in muscle strength, walking speed and functional score. (Jan, 2004) (Jain, 2002) (Penrod, 2004) (Tsao, 2005) (Brigham, 2003) (White, 2005) (National, 2003) A weight-bearing exercise program can improve balance and functional ability to a greater extent than a non-weight-bearing program. (Expert, 2004) (Binder, 2004) (Bolglia, 2005) (Handoll, 2004) (Kuisma, 2002) (Lauridsen, 2002) (Mangione, 2005) (Sherrington, 2004) Patients with hip fracture should be offered a coordinated multidisciplinary rehabilitation program with the specific aim of regaining sufficient function to return to their pre-fracture living arrangements. (Cameron, 2005) Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008)

#### **Osteoarthritis and allied disorders (ICD9 715):**

Post-surgical treatment: 18 visits over 12 weeks

\*Postsurgical physical medicine treatment period: 6 months

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Knee topic was corrected for clerical error** to delete the word “physical” immediately preceding the word “therapy” in two instances in the introductory text. The modification was to clarify that “therapy” in these guidelines can be either “physical therapy” or “occupational therapy” because “physical medicine” in these regulations encompasses both, physical therapy and occupational therapy. The text was further modified pursuant to the ODG revised October 23, 2008 version to add the following sentence at the end of the introductory text: “Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense physical therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008)” The modified introductory text leading to the specific postsurgical physical medicine guidelines in the Knee topic provides:

### **Knee**

Controversy exists about the effectiveness of therapy after arthroscopic partial meniscectomy. (Goodwin, 2003) Functional exercises after hospital discharge for total knee arthroplasty result in a small to moderate short-term, but not long-term, benefit. In the short term therapy interventions with exercises based on functional activities may be more effective after total knee arthroplasty than traditional exercise programs, which concentrate on isometric muscle exercises and exercises to increase range of motion in the joint. (Minns Lowe, 2007) Accelerated perioperative care and rehabilitation intervention after hip and knee arthroplasty (including intense therapy and exercise) reduced mean hospital length of stay (LOS) from 8.8 days before implementation to 4.3 days after implementation. (Larsen, 2008)

**The Low Back postsurgical guideline was modified pursuant to the ODG revised October 23, 2008 version** to add introductory text leading to the specific postsurgical physical medicine guidelines. The modified introductory text provides:

### **Low Back**

As compared with no therapy, therapy (up to 20 sessions over 12 weeks) following disc herniation surgery was effective. Because of the limited benefits of therapy relative to massage, it is open to question whether this treatment acts primarily physiologically, but psychological factors may contribute substantially to the benefits observed. (Erdogmus, 2007)

**The postsurgical physical medicine guideline for Intervertebral disc disorders without myelopathy** (ICD9 722.1; 722.2; 722.5; 722.6; 722.8) under the specific postsurgical physical medicine guidelines in the Low Back topic was corrected for clerical error to add a specific postsurgical physical medicine guideline for arthroplasty, which was inadvertently left out from the October 23, 2008 ODG version. A document entitled “Intervertebral disc disorder without myelopathy” was added to the rulemaking file as a document relied upon, reflecting that the surgery was originally contained in the ODG October 23, 2008 version. The modified postsurgical physical medicine guideline for Intervertebral disc disorders without myelopathy for arthroplasty provides:

**Intervertebral disc disorders without myelopathy (ICD9 722.1; 722.2; 722.5; 722.6; 722.8):**

Postsurgical treatment (arthroplasty): 26 visits over 16 weeks

\*Postsurgical physical medicine treatment period: 6 months

The **Neck & Upper Back** postsurgical guideline was modified pursuant to the ODG revised October 23, 2008 version to insert the phrase “after graft maturity” after the word “fusion inside of the parenthesis, as set forth below:

### **Neck & Upper Back**

**Displacement of cervical intervertebral disc (ICD9 722.0):**

Postsurgical treatment (fusion, after graft maturity): 24 visits over 16 weeks

**Subdivision 9792.24.3(d)(2)** was added to incorporate by reference into the MTUS, **Appendix C—Postsurgical Treatment Guidelines Evidence-Based Reviews (EBRs)** as a supplemental part of the Postsurgical Treatment Guidelines. This section also informs the public that a copy of Appendix C may be obtained from the Medical Unit, Division of Workers’ Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>. Appendix C is incorporated by reference into the regulations pursuant to requests by the regulated public that the references should be available to the public as part of the regulations. This document represents the evidence-based reviews that support the Postsurgical Medical Treatment Guidelines with a description of the DWC’s Methodology used. Because DWC intends to continue to incorporate the most recent scientific advances in medicine to this document via formal rulemaking, this document will continue to grow; it will become cumbersome and impractical in the future to publish it in the regulations. Thus, DWC will incorporate the document by reference into the regulations, and make it available to the public as set forth above.

At the outset, it is noted that **C—Postsurgical Treatment Guidelines-Evidence-Based Reviews** is a separate, self-contained new document, consisting of 24 pages. The document contained is in its original format, wherein certain titles and subtitles were single-underlined, and certain references and citations were single-underlined. It would have been difficult for the regulated public to read and analyze the document had DWC single-underlined and/or double-underlined the entire document. Because the entire document was **all new** text/language, DWC noticed the document without the single-underlining. However, when further changes were made to the document (i.e., the document was adopted and incorporated into the regulations), DWC noticed those changes accordingly and the public was properly informed of the format of the changes.

### **Modifications to Appendix C—Postsurgical Treatment Guidelines-Evidence-Based Reviews**

The header of Appendix C was modified to delete the phrases “Initial Statement of Reasons,” and “(DWC 2008).” The footer of Appendix C was modified to delete the phrase “(DWC 2008),” and to substitute the month “June” with the month “November.” These modifications

were intended to make the document current for incorporation into the regulations. The document was incorporated as section 9792.24.3(d)(2).

**Subdivision 9792.24.3(d)(3)** was added to incorporate by reference into the MTUS, **Appendix E— Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References**. These references are incorporated into the MTUS as a supplemental part of the Postsurgical Treatment Guidelines. This section also informs the public that a copy of Appendix E may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>. Appendix E is incorporated into the regulations pursuant to requests by the regulated public that the references should be available to the public as part of the regulations. Because the references are voluminous and it would be cumbersome and impractical to publish them in the regulations, DWC will incorporate them by reference into the regulations, and make them available to the public as set forth above.

At the outset, it is noted that **Appendix E—Postsurgical Treatment Guidelines—Official Disability Guidelines References** is a separate, self-contained new document, consisting of 59 pages. The document is in its own original format, wherein certain titles and subtitles were single-underlined, and certain references and citations were single-underlined. It would have been difficult for the regulated public to read and analyze the document had DWC single-underlined and/or double-underlined the entire document. Because the entire document was **all new** text/language, DWC noticed the document without the single-underlining. However, when further changes were made to the document (i.e., the document was adopted and incorporated into the regulations), DWC noticed those changes accordingly and the public was properly informed of the format of the changes.

### **Modifications to Appendix E—Postsurgical Treatment Guidelines—Official Disability Guidelines References**

**The header of Appendix E was modified** to delete the phrases “Initial Statement of Reasons,” and “(DWC 2008).” The header of Appendix E was further modified to insert the date of the version of the ODG Physical Medicine Guidelines being adapted, thus “October 23, 2008 ODG version of Physical Medicine Guidelines.” The top of the first page of Appendix E was modified to delete the title of the Appendix, “Work Loss Data Institute Official Disability Guidelines’ References,” as superfluous language, as this information was already contained in the header of the Appendix.

**The list of postsurgical areas** contained on the top of Appendix E (i.e., (Ankle & Foot (Acute & Chronic), Burns, Carpal Tunnel Syndrome (Acute & Chronic), Elbow (Acute & Chronic), Forearm, Wrist, & Hand, Head, Hip & Pelvis (Acute & Chronic), Knee & Leg (Acute & Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Neck and Upper Back (Acute & Chronic), Pain (Chronic), Shoulder (Acute & Chronic)) was deleted as superfluous.

**Names for the postsurgical areas** in Appendix E were modified to match the names of the postsurgical areas in the regulations.

**Postsurgical areas for Hernia, Neck & Upper Back, and Shoulder** were modified to reflect that no postsurgical physical medicine references were found.

**References which did not relate to postsurgical were removed.** References which were duplicated in the document were removed.

**The footer of Appendix E** was modified to delete the phrase “(DWC 2008),” and to substitute the month “June” with the month “November.” Further because the Postsurgical Treatment Guidelines version was being updated to the October 23, 2008 ODG version, the entire document was replaced to ensure that it contained all the revised ODG references. The modifications were intended to make the document current for incorporation into the regulations. The document was incorporated as section 9792.24.3(d)(3).

### **Modifications to the FISCAL IMPACTS as originally noticed in the Notice of Proposed Rulemaking issued June 2008**

The Fiscal Impacts noticed in the Notice of the Proposed Rulemaking was modified and set forth in its entirety below:

#### **FISCAL IMPACTS**

- **Costs or savings to state agencies or costs/savings in federal funding to the State:** As an employer that is legally uninsured for workers’ compensation, and whose workers’ compensation claims are administered by the State Compensation Insurance Fund, the State may incur increased medical costs for a subset of its claims as a result of this regulation. However, the State is already providing medical treatment for these claims. These regulations provide greater specificity and clarity to the MTUS which is expected to bring about a reduction in medical and utilization review costs for some claims. As described in Section B, estimated costs of this Form 399 for each part of the regulation (adoption of the ACOEM revised elbow chapter, postsurgical physical medicine guidelines, and chronic pain guidelines), the fiscal impact, if any, is difficult if not impossible to estimate.
- **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 potential costs imposed on all public agency employers by these proposed regulations, although not a benefit level increase, are not a new State mandate because the regulations apply to all employers, both public and private, and not uniquely to local governments. The Administrative Director has determined that the proposed regulations will not impose any new mandated programs on any local agency or school district. The California Supreme Court has determined that an increase in workers’ compensation benefit levels does not constitute a new State mandate for the purpose of local mandate claims because the increase does not impose unique requirements on local governments. See *County of Los Angeles v. State of California* (1987) 43 Cal.3d 46. The potential costs imposed on all public agency employers and payors by these proposed regulations, although not a benefit level increase, are similarly not a new State mandate because the regulations apply to all employers and payors, both public and private, and not uniquely to local governments.

Regardless, as an employer, local governments may incur increased medical costs for a subset of its claims as a result of this regulation. However, local governments are already providing medical treatment for these claims. These regulations provide greater specificity and clarity to the MTUS which is expected to bring about a reduction in medical and utilization review costs for some claims. As described in Section B, estimated costs of this Form 399 for each part of the regulation (adoption of the ACOEM revised elbow chapter, postsurgical physical medicine guidelines, and chronic pain guidelines), the fiscal impact, if any, is difficult if not impossible to estimate.

- 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. (See “Local Mandate” section above.)
- Other nondiscretionary costs/savings imposed upon local agencies: None. (See “Local Mandate” section above.)

#### **NON-SUBSTANTIVE REVISIONS TO THE DOCUMENTS RELIED-UPON NOTICED IN THE INITIAL STATEMENT OF REASONS**

All noticed documents relied upon during the 45-day notice period, which referenced articles with two authors, were modified to reflect the proper citation to include an “and” between the names of the two authors, and to include their first initials after their surnames. All those documents titles, which contained three authors were modified to reflect the three authors’ names and initials, separated by “commas.” All those document titles, which contained more than three authors were modified to list the first authors’ surnames followed by their first initials and a “comma” and an “et al.”

The document relied upon listed as “Current Procedural Terminology 2008 (CPT 2008), pp. 47-49” was corrected for clerical error to reflect the correct name as “American Medical Association (AMA), Current Procedural Terminology 2008 (CPT 2008), pp. 47-49.

The document relied upon listed as “Ackermann, L., Follett, K., Rosenquist, R. ‘Long-Term Outcomes During Treatment of Chronic Pain with Intrathecal Clonidine or Clonidine/Opioid Combinations’ *Journal of Pain and Symptom Management*. 2003; July, Volume 26: 668-76,” was corrected for clerical error to reflect the correct page numbers as 668-77.

The document relied upon listed as “Argoff, C. E. Topical agents for the treatment of chronic pain. *Curr Pain Headache Rep*. 2006 Feb; 10 (1):11-9” was corrected for clerical error to spell out the publication, and to correct the page numbers to 11-19.

The document relied upon listed as “Bolona E.R., et al. Testosterone use in men with sexual dysfunction: a systematic review and meta-analysis of randomized placebo-controlled trials. *Mayo Clinical Proceedings*. 2007; 82:20-8” was corrected for clerical error to correct the page numbers to 20-28.

The document relied upon listed as “Carnegie, C., et al. Diagnosis of Hypogonadism: Clinical Assessments and Laboratory Tests. *Rev Urol.* 2006; Volume 6, Supplement 6, S3-S8” was corrected for clerical error to correct the year of publication to 2004.

The document relied upon listed as “Flor, H., Fydrich, T., et al. Efficacy of multidisciplinary pain treatment centers: A meta-analytic flow. *Pain.* 1992; 49(2): 221-230” was corrected for clerical error to correct the title of the article as: A meta-analytic review.

The document relied upon listed as “Goldberg, M, et al. Multi-Day Low Dose Ketamine Infusion for the Treatment of Complex Regional Pain Syndrome. *Pain Physician.* 2005;Volume 8, Number 2: 175-19” was corrected for clerical error to correct the page numbers to 175-79.

The document relied upon listed as “Guzman, J., Esmail R., et al. Multidisciplinary rehabilitation for chronic low back pain: systematic review. *British Medical Journal.* 2001; 322(7301): 1511-6” was corrected for clerical error to correct the page numbers to 1511-16.

The document relied upon listed as “Hanson, R. and Gerber, K. ‘Table 2.1:Constrasting Pain Models’ Coping with Chronic Pain: A Guide to Patient Self-Management. New York, NY, Guilford Press. 1993.30” was corrected for clerical error to correct the year of publication to 1990.

The document relied upon listed as “Hocking, G., et al. Ketamine in Chronic Pain Management. *Anesth. Analg,* 2003; Volume 97: 1730-9” was corrected for clerical error to correct the title of the article as: Ketamine in Chronic Pain Management: An Evidence-Based Review.

The document relied upon listed as “Isidori AM, et al. Effects of testosterone on body composition, bone metabolism and serum lipid profile in middle-aged men: a meta-analysis. *Clin Endocrinol (Oxf).* 2005; 63:280-93” was corrected for clerical error to delete the reference “(Oxf).”

The document relied upon listed as “Isidori A. M., et al. Effects of testosterone on sexual function in men: results of a meta-analysis. *Clin Endocrinol (Oxf).* 2005; 63:381-94” was corrected for clerical error to delete the reference “(Oxf).”

The document relied upon listed as “Jadad, A., et al. Intravenous Regional Sympathetic Blockade for Pain Relief in Reflex Sympathetic Dystrophy: A Systematic Review and a Randomized, Double-Blind Crossover Study. *Journal of Pain Symptom Management.* 1995; Volume 10:13-20” was corrected for clerical error to correct title of the publication: *Journal of Pain and Symptom Management.*

The document relied upon listed as “Lynch, M et al. A Pilot Study Examining Topical Amitriptyline, Ketamine, and a Combination of Both in the Treatment of Neuropathic Pain. *The Clinical Journal of Pain*. 2003; Volume 19: 323-8” was corrected for clerical error to correct the page numbers to 323-28.

The document relied upon listed as “Lynch, M, et al. Topical Amitriptyline and Ketamine in Neuropathic Pain Syndromes: An Open-Label Study. *The Clinical Journal of Pain*. 2005; Volume 6, Number 10, October: 644-49” was corrected for clerical error to correct title of the publication: *Journal of Pain*, and the word “October” is deleted from the citation.

The document relied upon listed as “Lynch, M., et al. Topical 2% Amitriptyline and 1% Ketamine in Neuropathic Pain Syndromes: A Randomized, Double-blind, Placebo-controlled Trial. *Anesthesiology*. 2005; Volume 103:140-6” was corrected for clerical error to correct the page numbers to 140-46.

The document relied upon listed as “Martin, T., et al. Pharmacology of Opioid and Nonopioid Analgesics in Chronic Pain. *The Journal of Pharmacology and Experimental Therapeutics*. 2001; Volume 299, Number 3: 811-7” was corrected for clerical error to correct the title of the article to reflect: Pharmacology of Opioid and Nonopioid Analgesics in Chronic Pain States, and to correct the page numbers to 811-17.

The document relied upon listed as “McCleane, G. Topical application of doxepin hydrochloride, capsaicin and a combination of both produces analgesia in chronic human neuropathic pain: a randomized, double-blind, placebo-controlled study. *British Journal Clinical Pharmacology*. 2000 June; Volume 49, Issue 6, Page 574-9” was corrected for clerical error to correct the page numbers to 574-79.

The document relied upon listed as “Merskey, H. and N. Bogduk (1994). Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. Seattle, WA, IASP Press:210” was corrected for clerical error to correct the name of the second author as Bogduk, N., and to indicate the correct edition as Second Edition.

The document relied upon listed as “Nakazawa, R., et al. Hormone Profiles after Intramuscular Injection of Testosterone Enanthate in Patients with Hypogonadism. *Endocrine Journal*, 2006; Volume 53, Number 3, 305-103” was corrected for clerical error to correct the page numbers to 305-10.

The document relied upon listed as “Page, S., et al. Exogenous Testosterone (T) alone or with Finasteride Increases Physical Performance, Grip Strength, and Lean Body Mass in Older Men with Low Serum T. *Journal of Clinical Endocrinology & Metabolism*. 2005; Volume 90, Number 3, 1502-1510” was corrected for clerical error to correct the page numbers to 1502-10, and to capitalize the word “Alone” in the title of the article.

The document relied upon listed as “Rabben, T. Prolonged Analgesic Effect of Ketamine, a N-Methyl-D-Aspartate Receptor Inhibitor, in Patients with Chronic Pain. *The Journal of Pharmacology and Experimental Therapeutics*. 1999; Volume 289:1060-66” to correct “Aspartate” in the title of the article.

The document relied upon listed as “Rauck, R., et al. Epidural Clonidine Treatment for Refractory Reflex Sympathetic Dystrophy” *Anesthesiology*. 1993; Volume 79:1163-9” was corrected for clerical error to correct the page numbers to 1163-69.

The document relied upon listed as “Reuben, S. and Buvandendran, A. Preventing the Development of Chronic Pain after Orthopedic Surgery with Preventive Multimodal Analgesic Techniques. *Journal of Bone and Joint Surgery*. 2007. Volume 89: 1343-58” was corrected for clerical error to correct the second author’s name as Buvanendran.

The document relied upon listed as “Roberts, L.J, et al. Sex hormone suppression by intrathecal opioids: a prospective study. *Clin J Pain*. 2002; 18:144-8” was corrected for clerical error to correct the page numbers to 144-48.

The document relied upon listed as “Sheffler, L. and Chae, J. Neuromuscular Electrical Stimulation in Neurorehabilitation. *Muscle Nerve Volume* 2007; 35: 562-90” was corrected for clerical error to correct title of the publication: *Muscle Nerve*.

The document relied upon listed as “Siddall P. J. and Cousins, M. J. Persistent pain: a disease entity. *Journal of Pain Symptom Management*. 2007; 33(2 Suppl): S4-S10” was corrected for clerical errors as follows: Siddall P. J. and Cousins, M. J. Persistent pain as a disease entity: Implications for Clinical Management. *Anesth Analg*. 2004; 99:510-20.

The document relied upon listed as “Siddall, P., et al. The efficacy of Intrathecal Morphine and Clonidine in the Treatment of Pain After Spinal Cord Injury. *Anesh. Analg*, 2000; Number 91:1493-8” was corrected for clerical error to correct the page numbers to 1493-98.

The document relied upon listed as “Tracz, M. J., et al. “Testosterone use in men and its effects on bone health. A systematic review and meta-analysis of randomized placebo-controlled trials” *J Clin Endocrinol Metab*. 2006;91:2011-6” was corrected for clerical error to correct title of the article: Clinical Review: Testosterone use in men and its effects on bone health. A systematic review and meta-analysis of randomized placebo-controlled trials, and to correct the page numbers to 2011-16.

The document relied upon listed as “Turk, D. and A. Okifuji, “Chapter 2 Pain Terms and Taxonomies of Pain” in Loeser JD. Bonica’s Management of Pain, 3rd edition. Philadelphia, PA, Lippincott Williams and Wilkins: 17-72” was corrected for clerical error to correct the page numbers to 17-25.

The document relied upon listed as “Visser, E. and Shurg, S.A. ‘The role of ketamine in pain management’ *Biomedicine and Pharmacotherapy* 2006; Volume 60: 341-348” was corrected for clerical error to correct the second author’s name as Schug, S.A.

The document relied upon listed as “Wang, C., et al. New Testosterone Buccal System (Striant) Delivers Physiological Testosterone Levels: Pharmacokinetics Study in Hypogonadal Men. *The Journal of Clinical Endocrinology & Metabolism*. 2004; Volume 89, Number 8, 381-29” was corrected for clerical error to correct the page numbers to 3821-29.

The document relied upon listed as “Wood, P. A Reconsideration of the Relevance of Systemic Low-Dose Ketamine to the Pathophysiology of Fibromyalgia. *The Journal of Pain*. 2006 Volume 7, Number 9: 611-14” was corrected for clerical error to correct the author’s name as Wood, P.B.

The document relied upon listed as “Yu, D., et al. Intramuscular Neuromuscular Electrical Stimulation for Poststroke Shoulder Pain: A Multicenter Randomized Clinical Trial. *Archive of Physical Medicine and Rehabilitation*. 2004; Volume 85, May: 695-704” was corrected for clerical error to correct title of the article: Intramuscular Neuromuscular Electric Stimulation for Poststroke Shoulder Pain: A Multicenter Randomized Clinical Trial.”

The document relied upon listed as “Zorn, C., et al. Effects of neuromuscular electrical stimulation of the knee extensor muscles on muscle soreness and different serum parameters in young male athletes: preliminary data. *British Journal of Sports Medicine*. 2007; Volume 41: 914-6” was corrected for clerical error to correct the page numbers to 914-16.

#### **FINAL NON-SUBSTANTIVE REVISIONS TO THE REGULATIONS TEXT**

The Original Notice of Proposed Rulemaking issued June 2008 contained clerical errors in the listing of the Sections involved in the Proposed Regulatory Action which are corrected as follows: **Section 9792.22** was originally noticed as an adopted section due to clerical error. The section number was already contained in the code of regulations. The section is corrected to indicate that the section is being amended, not adopted as originally contained in the notice. **Section 9792.23** was originally noticed as an adopted section due to clerical error. The section number was already contained in the code of regulations. The section is corrected to indicate that the section is being amended, not adopted as originally contained in the notice. **Section 9792.24.1** was originally noticed as an amended section. The section number was not contained in the code of regulations. The section is corrected to indicate that the section is being adopted, not amended as originally contained in the notice. **Section 9792.25** was originally noticed as an amended section. The section number was not contained in the code of regulations. The section is corrected to indicate that the section is being adopted, not amended as originally contained in the notice. **Section 9792.26** was originally noticed as an amended section. The section number was not contained in the code of regulations. The section is corrected to indicate that the section is being adopted, not amended as originally contained in the notice.

#### **Modifications to Section 9792.20(b)**

Proposed Section 9792.20(b) is modified for clerical error to delete the second sentence stating “The Administrative Director incorporates the ACOEM Practice Guidelines by reference.” as superfluous. The definition of the term does not need this sentence and not removing the sentence may cause confusion. Sections 9792.22 and 9792.23.1 et seq. make it clear that the ACOEM Practice Guidelines (2<sup>nd</sup> Edition, 2004) is not being incorporated entirely, but is being incorporated on a chapter by chapter basis.

## **Modifications to Section 9792.20(f)**

Proposed Section 9792.20(f) is modified for clerical error to delete the single underlining placed under the word “s” after the word “section” which was intended to make the word plural as opposed to singular. Upon revision, the word as contained in the original text of the regulations is already plural and it does not need to be modified.

## **Modifications to Section 9792.24.2(a) Chronic Pain Medical Treatment Guidelines**

Proposed Section 9792.24.2(a) is modified for clerical error to add the date “(May 2009)” immediately after the title of the document, “Chronic Pain Medical Treatment Guidelines.” This modification complies with the requirements of 1 Cal. Code of Regs. Sec. 20(c)(4), which requires the text of the regulations to identify the document being incorporated by title and date.

**Part 2 – Pain Interventions and Treatments** of the chronic pain medical treatment guidelines is modified on a non-substantive basis to add language taken directly from **Part 1 – Introduction** of the chronic pain medical treatment guidelines clarifying the applicable principles for those individual treatment guideline topics where the frequency, duration and intensity of the treatment topic is not addressed. The added language is set forth at page 11 of the guidelines, following immediately the introductory sentence, stating “All of the following (listed alphabetically) treatment recommendations are adapted from ODG except those labeled ‘[DWC]’.” The added language provides: “For those individual treatment guideline topics where the frequency, duration and intensity of the treatment is not addressed, the following principles apply as set forth in the Introduction of these guidelines. Duration of the treatment shall be consistent with the definition of chronic pain as set forth in Section 9792.20(c) and page 1 of these guidelines, and the treatment shall be provided as long as the pain persists beyond the anticipated time of healing and throughout the duration of the chronic pain condition. The duration of continued medication treatment for chronic pain depends on the physician’s evaluation of progress toward treatment objectives, efficacy, and side effects as set forth in the Introduction of these guidelines at page 8. With regard to the frequency and intensity requirements, the treating physician is required, as stated in the Introduction of these guidelines at page 7, to exercise clinical judgment by “tailor[ing] medications and dosages to the individual taking into consideration patient-specific variables such as comorbidities, other medications, and allergies.” The physician shall be “knowledgeable regarding prescribing information and adjust the dosing [i.e. how often {frequency} and how much {intensity}] to the individual patient” as stated in these guidelines at page 7 of the Introduction. Clinical judgment shall be applied to determine frequency and intensity and “[s]election of treatment must be tailored for the individual case” as stated in the Introduction of these guidelines at page 8.”

**The individual treatment guideline on the topic of “Acetaminophen (APAP)”** at page 11, is modified for clerical error at the third paragraph, first sentence, to delete the phrase “acute and.” This modification makes the individual treatment guideline on the topic of “Acetaminophen (APAP)” consistent with all the other guidelines in the chronic pain medical treatment guidelines wherein references to application of the guidelines to acute conditions were removed from all the guidelines during the various notices periods as the guidelines are intended to apply only to chronic conditions.

**The individual treatment guideline on the topic of “Flector patch”** at page 47 is removed for clerical error. The guideline references the Non-steroidal antiinflammatory agents (NSAIDs) entry under Topical analgesics. However, the language referencing the topic of “Flector patch” had been removed from the October 23, 2008 ODG guidelines because the treatment addressed acute conditions. See Appendix A1, pp. 11-12, Item No. 1, regarding removal of recommendations for acute treatments.

**The individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications”** at page 54, is modified for clerical error at the third paragraph under the subtitle, “*Recommended 3rd stage.*” The second sentence in that paragraph is corrected to substitute the word “and” with the word “or.” The corrected sentence states: “See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).” This correction reflects the same language as contained in the individual treatment guideline on the topic of “Ziconotide (Prialt®),” wherein the guideline indicates “Recommended for use after there is evidence of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid), and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects.” The clerical error consisted in the failure to transmit this change, which was made to the individual treatment guideline on the topic of “Ziconotide (Prialt®)” during the 1<sup>st</sup> 15-day comment period to the individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications,” where in reference to specific recommendations for “Ziconotide (Prialt®),” it is stated: “See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine and hydromorphone (Dilaudid).” Due to clerical error the word “or” as contained in the individual treatment guideline on the topic of “Ziconotide (Prialt®)” was not transmitted to the individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications.” The individual treatment guideline on the topic of “Intrathecal drug delivery systems, medications” is corrected for clerical error in the final text of the regulations (chronic pain medical treatment guidelines) to state: “See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).”

**The individual treatment guideline on the topic of “Physical Medicine”** at page 98, is modified for clerical error to correct the number of visits from 26 to 24 under the “Physical Medicine Guidelines.” The number of visits is reduced to 24 because pursuant to Labor Code section 4604.5(d)(1), DWC has no authority to allow more than 24 visits, and the number 26 visits, as set forth in the guideline as adapted from ODG, exceeds the authority of the statute. Thus, the number of visits are corrected for clerical error to be consistent with the statute to reflect the appropriate number of visits:

### **Physical Medicine Guidelines –**

Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine.

**Myalgia and myositis, unspecified (ICD9 729.1):** 9-10 visits over 8 weeks

**Neuralgia, neuritis, and radiculitis, unspecified (ICD9 729.2)**

8-10 visits over 4 weeks

**Reflex sympathetic dystrophy (CRPS) (ICD9 337.2):**

24 visits over 16 weeks

**The individual treatment guideline on the topic of “Topical Analgesics”** at page 113, top of the page, is modified for clerical error. The last sentence of the guideline under the subtopic “**Ketamine**,” is corrected to delete the reference to “Topical Analgesics, compounded.” The reference is deleted as superfluous and no longer applicable.

### **Modifications to Section 9792.24.2(e)**

Proposed Section 9792.24.2(e) is modified for clerical error to add the date “(May 2009)” immediately after the title of the document, “Chronic Pain Medical Treatment Guidelines-Division of Workers’ Compensation and Official Disability Guidelines References.” This modification complies with the requirements of 1 Cal. Code of Regs. Sec. 20(c)(4), which requires the text of the regulations to identify the document being incorporated by title and date.

Section 9792.24.2(e) is modified for clerical error to place ODG’s method to evaluate the medical literature at the end of the Appendix D. The document which is entitled: “Explanation of Medical Literature Ratings,” is one of the documents relied upon and noticed during the 1<sup>st</sup> 15-day notice. During the 45-day comment period, a commenter requested that the document be placed together with Appendix D as an explanation of ODG’s methodology, and the DWC agreed as indicated in the 45-day comment chart. Through clerical inadvertence, however, the document was not placed with Appendix D when the document was revised. This is corrected by placing the document at the end of Appendix D. This correction is reflected in the final text of the regulations (Appendix D).

Section 9792.24.2(e) is modified for clerical error to add page 547 to the list of pages in Appendix D, noticed in the 2<sup>nd</sup> 15-day comment period, which were modified to add new references relating to the expansion of evidence base in the individual treatment guideline on the topic of “Acetaminophen (APAP).” This correction is reflected in the final text of the regulations (Appendix D).

### **Modifications to Section 9792.24.3 Postsurgical Treatment Guidelines**

**During the 1<sup>st</sup> 15-day period, Subdivision 9792.24.3(c)(5)** was modified for clerical purposes to delete the period after number 5 and to place the number in parenthesis, thus (5). The modified subdivision was reflected as follows: 9792.24.3(c)(4). The subdivision was further modified to delete the word “quantifiable.” These modifications were contained in the modified text of the proposed regulations, which was served with the 1<sup>st</sup> 15-day notice. The deletion of the word “quantifiable” was necessitated by the modification to the definition of “functional improvement,” as set forth in **Subdivision 9792.20(f)**, wherein the word “quantifiable” was deleted from the definition, as explained in the 1<sup>st</sup> 15-day notice and set forth above. Due to

clerical error these modifications, although reflected in the text of the regulations, were not transferred to and/or reflected in the notice.

### **Modifications to Section 9792.24.3(c)(5)(C)**

Section 9792.24.3(c)(5)(c) is modified for clerical error to reference the definition of the acronym CPT as set forth in the Official Medical Fee Schedule regulations, section 9789.10(d), wherein in CPT is defined, in relevant part, as “the procedure codes set forth in the American Medical Association’s Physicians’ Current Procedural Terminology (CPT).”

### **Modifications to Section 9792.24.3(d)(1)**

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Ankle & Foot topic** is corrected for clerical error to spell out the acronym “RCT” to reflect “randomized controlled trial” in parentheses immediately following the reference.

**The introductory text leading to the specific postsurgical physical medicine guidelines in the Carpal Tunnel Syndrome topic** is corrected for clerical error to spell out the acronyms “PT” to reflect “physical therapy;” “OT” to reflect “occupational therapy;” “CRPS” to reflect “complex regional pain syndrome;” and “VAS” to reflect “visual analog scale” in parentheses immediately following the references in the paragraph.

**The postsurgical physical medicine period for the “Ulnar nerve entrapment/Cubital tunnel syndrome (ICD9 354.2)”** surgery is corrected for clerical error to reflect “6 months” as opposed to “4 months” under the guideline for the body parts of “Forearm, Wrist, & Hand.” The correction is to make the postsurgical physical medicine period consistent with the same surgery which also appears under the guideline for the body parts of “Elbow & Upper Arm,” and reflects a postsurgical physical medicine period of 6 months. The correction is reflected as follows:

#### **Forearm, Wrist, & Hand**

**Ulnar nerve entrapment/Cubital tunnel syndrome (ICD9 354.2):**

Postsurgical treatment: 20 visits over 10 weeks

\*Postsurgical physical medicine treatment period: 6 months

### **Modifications to Section 9792.24.3(d)(1)**

**The adhesive capsulitis surgery** under the postsurgical physical medicine guideline **topic of Shoulder** is corrected for clerical error to insert a “D” to correct the ICD9 code, thus “(ICD9 726.0).”

### **Modifications to Section 9792.24.3(d)(2)**

Proposed Section 9792.24.3(d)(2) is modified for clerical error to add the date “(May 2009)” immediately after the title of the document, “Postsurgical Treatment Guidelines Evidence-Based Reviews.” This modification complies with the requirements of 1 Cal. Code of Regs. Sec. 20(c)(4), which requires the text of the regulations to identify the document being incorporated by title and date.

### **Modifications to Section 9792.24.3(d)(3)**

Proposed Section 9792.24.3(d)(2) is modified for clerical error to add the date “(May 2009)” immediately after the title of the document, “Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References.” This modification complies with the requirements of 1 Cal. Code of Regs. Sec. 20(c)(4), which requires the text of the regulations to identify the document being incorporated by title and date.

Section 9792.24.3(d)(3) is modified for clerical error to add the sentence “No postsurgical physical medicine references” in brackets under the Elbow and Upper Arm guideline in Appendix E—Postsurgical Treatment Guidelines, at pages 1 and 20. The references were deleted during the 1<sup>st</sup> 15-day notice period, and the sentence “No postsurgical physical medicine references” should have been substituted for the deleted text as was done with other guidelines in the same document.

Section 9792.24.2(d)(3) is further modified for clerical error to place ODG’s method to evaluate the medical literature at the end of the Appendix E— Postsurgical Treatment Guidelines. The document which is entitled: “Explanation of Medical Literature Ratings,” was one of the documents relied upon and noticed during the 1<sup>st</sup> 15-day notice. During the 45-day comment period, a commenter requested that the document be placed together with Appendix E as an explanation of ODG’s methodology, and the DWC agreed as indicated in the 45-day comment chart. Through clerical inadvertence, the document was not placed with Appendix E when the document was revised. This is corrected by placing the document at the end of Appendix E. This correction is reflected in the final text of the regulations (Appendix E).

### **Modifications to Section 9792.25(c)(1)**

Section 9792.25(c)(1) is corrected for clerical error. The phrase “for medical treatment and diagnostic services at variance with both subdivisions (a) or (b) above” is corrected for grammatical error to substitute the word “or” with the word “and.” Thus, as corrected the phrase now states: “for medical treatment and diagnostic services at variance with both subdivisions (a) and (b) above.”

**FINAL NON-SUBSTANTIVE REVISIONS TO THE ECONOMIC AND IMPACT STATEMENT (FORM 399)**

The Economic and Fiscal Impact Statement (Form 399) was modified at Paragraph B. Estimated Costs. The last sentence of paragraph No. 4 of Item No. 2, relating to the postsurgical treatment guidelines, was modified for clarification purposes. The numerical figure of “0.043” contained in that sentence was explained in a parenthetical as the “percentage of claims that are surgery claims.” The modified sentence states: “Following the same logic as above, the total maximum increased cost to the system for additional postsurgical chiropractic visits, if one were to return to pre-reform levels, would be: 805,000 (total workers’ compensation claims) x 0.043 (percentage of claims that are surgery claims) x 0.047 (percentage of post-reform surgery claims that received any postsurgical chiropractic manipulation) x 0.352 (percentage of surgery claims that did not receive adequate postsurgical chiropractic manipulation post-reform) x \$1,002 (cost of additional postsurgical chiropractic manipulation visits, if one were to return to pre-reform levels) = \$573,816.

**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.	November 26, 2008 through December 18, 2008 February 4, 2009 through February 20, 2009 February 17, 2009 through March 10, 2009
Pre-Notice comments from DWC First Public Forum (Revised elbow chapter & chronic pain treatment guidelines) Pre-Notice comments from DWC Second Public Forum (Postsurgical treatment guidelines)	August 20, 2007 through September 4, 2007  October 10, 2007 through November 3, 2007

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

- Comments from various interested parties concerning the regulations have been added to the rulemaking file.
- ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM’s Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, page 1
- ACOEM. *Occupational Medicine Practice Guidelines*, 2<sup>nd</sup> Edition., *Chronic Pain* (Revised 2008), 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)), page 29.

- Agency for Health Care Policy and Research Clinical Practice Guideline, “No. 14 Acute Low Back Problems in Adults, Clinical Practice Guideline 14,” AHCPR Publication No. 95-0642; December 1994
- Akermak C, Forsskahl B. “Topical indomethacin in overuse injuries in athletes. A randomized double-blind study comparing Elmetacin with oral indomethacin and placebo.” *Int J Sports Med.* 1990 Oct; 11(5):393-6.
- Albazaz R, Wong YT, Homer-Vanniasinkam S. “Complex regional pain syndrome: a review.” *Ann Vasc Surg.* 2008 Mar-Apr;22(2):297-306.
- Alexander K, Wynn A. “Transdermal Gel in the treatment of Postoperative Pain.” *International Journal of Pharmaceutical Compounding.* May/June 2007, Volume 11, No. 3 181-184.
- Altman RD, Aven A, Holmburg CE, Pfeifer LM, Sack M, Young GT. “Capsaicin Cream 0.025% Monotherapy for Osteoarthritis: A Double-Blind Study” *Seminars in Arthritis and Rheumatism.* Jun 1994. Vol. 23, No. 6, Suppl. 3: 25-33.
- Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument, The AGREE Collaboration, September, 2001.
- Arregger AL, Contreras LN, Tumilasci OR, Aquilanos DR, Cardoso EM. “Salivary testosterone: A reliable approach to the diagnosis of male hypogonadism.”
- Backonja M, Beydoun A, Edwards KR, Schwartz SL, Fonseca V, Hes M, LaMoreaux L, Garofalo. “Gabapentin for the symptomatic treatment of painful neuropathy in patients with diabetes mellitus.” *JAMA* December 2, 1998, Vol. 280, No. 21: 1831-1836.
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- Work Loss Data Institute, Official Disability Guidelines Licensed by Top WC Payors.
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- Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers’ Comp-Chapter on Pain (Chronic), version dated October 23, 2008
- Work Loss Data Institute, Official Disability Guidelines, Treatment in Workers’ Comp-Excerpt from the Chapter Procedures Summaries (ODG Physical Medicine Guidelines), version dated October 23, 2008:
  - Ankle & Foot (Acute & Chronic)
  - Burns
  - Carpal Tunnel Syndrome
  - Elbow (Acute & Chronic)
  - Forearm, Wrist, & Hand (Acute & Chronic)(Not including “Carpal Tunnel Syndrome.)
  - Head (trauma, headaches, etc., not including stress & mental disorders)
  - Hip & Pelvis (Acute & Chronic)
  - Knee & Leg (Acute & Chronic)
  - Low Back – Lumbar & Thoracic (Acute & Chronic)
  - Neck and Upper Back (Acute & Chronic)
  - Shoulder (Acute & Chronic)
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**NON-SUBSTANTIVE REVISIONS TO THE DOCUMENTS RELIED-UPON NOTICED  
IN THE 1<sup>ST</sup> 15-DAY NOTICE**

All noticed documents relied upon during the 1<sup>st</sup> 15-day notice, which referenced articles with two authors, were modified to reflect the proper citation to include an “and” between the names of the two authors, and to include their first initials after their surnames. All those documents titles, which contained three authors, were modified to reflect the three authors’ names and initials, separated by “commas.” All those document titles, which contained more than three authors, were modified to list the first authors’ surnames followed by their first initials and a “comma” followed by a “et al.”

The document relied upon listed as “ACOEM Practice Guidelines, *APG Insights, Fall 2006, ACOEM’s Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*, page 1” was corrected for clerical error to remove the page number reference 1 as not necessary.

The document relied upon listed as “ACOEM. *Occupational Medicine Practice Guidelines*, 2<sup>nd</sup> Edition., *Chronic Pain* (Revised 2008), 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)), page 29” was corrected for clerical error to remove the page number reference 29 as not necessary.

The document relied upon listed as “Akermak C, Forsskahl B. ‘Topical indomethacin in overuse injuries in athletes. A randomized double-blind study comparing Elmetacin with oral indomethacin and placebo.’ *Int J Sports Med*. 1990 Oct; 11(5):393-6” was corrected for clerical error to correct the first author’s name as Akermark, C. and to correct the page numbers to 393-96.

The document relied upon listed as “Albazaz R, Wong YT, Homer-Vanniasinkam S. ‘Complex regional pain syndrome: a review.’ *Ann Vasc Surg*. 2008 Mar-Apr;22(2):297-306” was corrected for clerical error to indicate that it is an “Abstract” and not the complete article referenced.

The document relied upon listed as “Alexander K, Wynn A. ‘Transdermal Gel in the treatment of Postoperative Pain.’ *International Journal of Pharmaceutical Compounding*. May/June 2007, Volume 11, No. 3 181-184” was corrected for clerical error to correct the second author’s name as Wynn I.

The document relied upon listed as “Altman RD, Aven A, Holmburg CE, Pfeifer LM, Sack M, Young GT. ‘Capsaicin Cream 0.025% Monotherapy for Osteoarthritis: A Double-Blind Study’ *Seminars in Arthritis and Rheumatism*. Jun 1994. Vol. 23, No. 6, Suppl. 3: 25-33” was corrected for clerical error to correct title of the article to: Capsaicin Cream 0.025% as Monotherapy for Osteoarthritis: A Double-Blind Study.

The document relied upon listed as “Arregger AL, Contreras LN, Tumilasci OR, Aquilanos DR, Cardoso EM. ‘Salivary testosterone: A reliable approach to the diagnosis of male

hypogonadism’ was corrected for clerical error to indicate the title and page number of the publication as: *Clinical Endocrinology* (2007) 67:656-662.

The document relied upon listed as “Bandolier. ‘Health Economics of topical NSAIDs’  
*Bandolier* :1-4. Accessible at  
[www.medicine.ox.ac.uk/bandolier/booth/painpag/topical/HEC1.html](http://www.medicine.ox.ac.uk/bandolier/booth/painpag/topical/HEC1.html) was corrected for clerical error to remove the reference “*Bandolier*:1-4.”

The document relied upon listed as “Bolona ER, Uruga MV, Haddad RM, Tracz MJ, Sideras K, Kennedy CC, Caples SM, Erwin PJ, Montori VM. ‘Testosterone Use in Men with Sexual Dysfunction: A Systematic Review and Meta-analysis of Randomized Placebo-Controlled Trials’ *Mayo Clin Proc.* January 2007, 82(1): 20-8” was corrected for clerical error to correct the page numbers to 20-28.

The document relied upon listed as “Crowley KL, Flores, JA, Hughes CN, Iacono RP. ‘Clinical Application of Ketamine Ointment in the treatment of (Remainder of the title unreadable)’ *International Journal of Pharmaceutical Compounding*, March/April 1998, Vol. 2, No. 2: 122-7” was corrected for clerical error to correct title of the article to: Clinical Application of Ketamine Ointment in the treatment of sympathetically maintained pain.

The document relied upon listed as “Csoka I, Csanyi E, Zapantis G, Nagy E, Feher-Kiss A, Horvath G, Blazso G, Eros I. ‘In vitro and in vivo percutaneous absorption of topical dosage forms: case studies’ *International journal of Pharmaceutics*, 2005, 291:11-9” was corrected for clerical error to correct the page numbers to 11-19.

The document relied upon listed as “Evans JM, McMahon AD, McGilchrist MM, White G, Murray FE, McDevitt DG, MacDonald TM. ‘Topical non-steroidal anti-inflammatory drugs and admission to hospital for upper gastrointestinal bleeding and perforation: a record linkage case-control study.’ *BMJ.* 1995 Jul 1;311(6996):22-6” was corrected for clerical error to correct the page numbers to 22-26.

The document relied upon listed as “Hodges CJ, Jones TH, Willoughby DL. ‘Transdermal Gels in the Treatment of Diabetic Neuropathy.’ *International Journal of Pharmaceutical Compounding* March/April 2000, Vol. 4, No. 2: 91-4” was corrected for clerical error to correct the page numbers to 91-93.

The document relied upon listed as “Lynch ME, Clark AJ, Sawynok J. ‘A Pilot Study Examining Topical Amitriptyline, Ketamine, and a Combination of Both in the Treatment of Neuropathic Pain,’ *The Clinical Journal of Pain* Volume 2003 19: 323-8” was corrected for clerical error to remove the word “Volume.”

The document relied upon listed as “Lynch ME, Clark AJ, Sawynok J. ‘Topical Amitriptyline and Ketamine in Neuropathic Pain Syndromes: An Open-Label Study.’ *The Clinical Journal of Pain.* 2005; Volume 6, Number 10, October: 644-49” was corrected for clerical error to correct title of the publication to: *The Journal of Pain.*

The document relied upon listed as “Machen J, Whitefield M. ‘Efficacy of a proprietary ibuprofen gel in soft tissue injuries: a randomised, double-blind, placebo-controlled study.’ *Int J Clin Pract.* 2002 Mar;56(2):102-6” was corrected for clerical error to indicate that it is an “Abstract” and not the complete article referenced.

The document relied upon listed as “Mason L, Moore RA, Edwards JE, Derry S and McQuay HJ. ‘Topical NSAIDs for acute pain: a meta-analysis’ *BMC Family Practice*, 2004, 5:10 pages” was corrected for clerical error to remove the page numbers referenced.

The document relied upon listed as “Mazieres B. ‘Topical Ketamine Patch’ *Drugs RD*, 2005, 6 (6): 337-44. *Clin J Pain.* 2006 Jun;22(5):425-9” was corrected for clerical error to correct title of the article to: Topical Ketapropfen Patch.

The document relied upon listed as “National Institute of Neurological Disorders and Stroke, NINDS Complex Regional Pain Syndrome Information Page: [http://www.ninds.nih.gov/disorders/reflex\\_sympathetic\\_dystrophy/reflex\\_sympathetic\\_dystrophy.htm](http://www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/reflex_sympathetic_dystrophy.htm) Accessed July 10, 2008” was corrected for clerical error to replace “Accessed” with “Last Updated.”

The document relied upon listed as “Rao RR, Chalasani KB, Chauhan AS, Jain AK, Diwan PV, Ram MK. ‘Controlled Systemic Delivery of Indomethacin Using Membrane-Moderated, Cream Formulation-Based Transdermal Devices’ *Drug Delivery*, 2006, 13:210-213 ” was corrected for clerical error to correct the first author’s name as Rao P.R. and to correct the page numbers to 207-213.

The document relied upon listed as “Roberts LJ, Finch PM, Pullan PT, Bhagat CI, Price LM. ‘Sex Hormone Suppression by Intrathecal Opioids: A Prospective Study’ *The Clinical Journal of Pain*, 18: 144-8” was corrected for clerical error to include the year of the publication as 2002, and to correct the page numbers to 144-48.

The document relied upon listed as “Rolf C, Engstrom B, Beauchard C, Jacobs LD, Liboux AL. ‘Intra-articular absorption and distribution of ketoprofen after topical plaster application and oral intake in 100 patients undergoing knee arthroscopy’ *Rheumatology*, Jun 1999, 38, : 564-7’ was corrected for clerical error to correct the citation to: Jun 1999, 38, 6: 564-7. This citation was noticed twice due to clerical error. One citation was deleted.

The document relied upon listed as “Shin SM, Choi JK. ‘Effect of Indomethacin Phonophoeiss on the Relief of Temporomandibulaar Joint Pain’ *The Journal of Craniomandibular Practice*, October 1997, Vol. 15, No. 4: 345-8” was corrected for clerical error to correct title of the article to: Effect of Indomethacin Phonophoresis on the Relief of Temporomandibular Joint Pain.

The document relied upon listed as “Vadaurri V. ‘Topical Treatment of Neuropathic Pain’ *International Journal of Pharmaceutical Compounding*, May/June 2008, Vol. 12, No. 3: 182-90” was corrected for clerical error to correct the page numbers to 183-90.

The document relied upon listed as “Wetrtheimer A, Levy R, O’Connor T. ‘Too Many Drugs? The Clinical and Economic Value of Incremental Innovations’ *Investing in Health: The Social and Economic Benefits of Health care Innovation*, Volume 14: 77-118” was corrected for clerical error to correct the first author’s name as Wertheimer A., and to indicate the year of the publication as 2001.

The document relied upon listed as “Whitefield M, O’Kane CJ, Anderson S. ‘Comparative efficacy of a proprietary topical ibuprofen gel and oral ibuprofen in acute soft tissue injuries: a randomized, double-blind study.’ *J Clin Pharm Ther.* 2002 Dec;27(6):409-17” was corrected for clerical error to indicate that it is an “Abstract” and not the complete article referenced.

The document relied upon listed as “Ziegler D, Ametov A, Barinov A, Dyck PJ, Gurieva I, Low PA, Munzel U, Yakhno N, Raz I, Novosadova M, Maus J, Samiguillin R. ‘Oral Treatment with Lipoic Acid Improves Symptomatic Diabetic Polyneuropathy: The Sydney 2 trial’ *Diabetes Care*, November 2006, Volume 29, Number 11: 2365-70’ was corrected for clerical error to correct title of the article to: Oral Treatment with  $\alpha$ Lipoic Acid Improves Symptomatic Diabetic Polyneuropathy: The SYDNEY 2 trial.

The documents relied upon listed as “Ziegler D. ‘Painful diabetic neuropathy: treatment and future aspects’ *Diabetes/Metabolism Research and Reviews*, 2008, 24 (Suppl 1); S52-57. Ziegler D. “Thioctic Acid for Patients with Symptomatic Diabetic Polyneuropathy” *Treat Endocrinol*, 2004, 3 (3):173-89” was corrected for clerical error by separating the two references as follows:

Ziegler D. “Painful diabetic neuropathy: treatment and future aspects” *Diabetes/Metabolism Research and Reviews*, 2008, 24 (Suppl 1); S52-57.

Ziegler D. “Thioctic Acid for Patients with Symptomatic Diabetic Polyneuropathy” *Treat Endocrinol*, 2004, 3 (3):173-89.

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

- Comments from various interested parties concerning the regulations have been added to the rulemaking file.
- Intervertebral disc disorder without myelopathy, October 23, 2008 ODG version.
- ODG Acetaminophen Guideline Update, January 21, 2009
- ODG Topical Analgesics and Topical Analgesics, compounded Guidelines Updates, January, 21, 2009
- ODG Updates Change Log, November, 2008
- ODG Updates Change Log, December, 2008

**Documents added to the formal rulemaking file and Noticed in the 3<sup>rd</sup> 15-Day Notice (Notice of Addition of Documents to Rulemaking File [Government Code Section 11347.1])**

- ODG Updates and Comments as a result of the California MTUS Comments dated August 12, 2008.
- ODG Updates & Comments as a result of the California MTUS Comments Later Additions dated August 12, 2008.
- ODG Response to the California MTUS 15-day Comments dated January 5, 2009.
- Work Loss Data Institute Letter to DWC regarding “Process for ODG updates from MTUS Comments dated January 16, 2009.

Written comments were received during the 3<sup>rd</sup> 15-day comment period, and properly considered and addressed in the 3<sup>rd</sup> comment period chart.

**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 potential costs imposed on all public agency employers by these proposed regulations, although not a benefit level increase, are not a new State mandate because the regulations apply to all employers, both public and private, and not uniquely to local governments. The Administrative Director has determined that the proposed regulations will not impose any new mandated programs on any local agency or school district. The California Supreme Court has determined that an increase in workers’ compensation benefit levels does not constitute a new State mandate for the purpose of local mandate claims because the increase does not impose unique requirements on local governments. See *County of Los Angeles v. State of California* (1987) 43 Cal.3d 46. The potential costs imposed on all public agency employers and payors by these proposed regulations, although not a benefit level increase, are similarly not a new State mandate because the regulations apply to all employers and payors, both public and private, and not uniquely to local governments.

- 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. (See “Local Mandate” section above.)
- Other nondiscretionary costs/savings imposed upon local agencies: None. (See “Local Mandate” section above.)

## **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 Tabs L, O, P, and U of the Rulemaking File, which are incorporated by reference.

The public comment period was as follows:

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

June 27, 2008 through August 12, 2008.

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

November 26, 2008 through December 18, 2008.

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

February 4, 2009 through February 20 2009.

### **Third 15-day comment period**

(Notice of Addition of Documents to Rulemaking File [Government Code Section 11347.1])

February 17, 2009 through March 10 2009.

## **INCORPORATION BY REFERENCE**

The Medical Treatment Utilization Schedule regulations incorporate by reference:

- (1) Elbow Disorders Chapter (the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines [ACOEM Practice Guidelines], 2<sup>nd</sup> Edition (Revised 2007), Chapter 10) at Section 9792.23.3(a). A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org) as specified in Section 9792.22 (a)

- (2) The Chronic Pain Medical Treatment Guidelines, Part 1. Introduction, Part 2. Pain Interventions and Treatments at Section 9792.24.2(a). A copy of the chronic pain medical treatment guidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.
- (3) Appendix C—Postsurgical Treatment Guidelines Evidence-Based Reviews at Section 9792.24.3(d)(2). A copy of Appendix C may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.
- (4) Appendix D—Chronic Pain Medical Treatment Guidelines-Division of Workers' Compensation and Official Disability Guidelines References at Section 9792.24.2(e). A copy of Appendix D may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.
- (5) Appendix E— Postsurgical Treatment Guidelines Work Loss Data Institute-Official Disability Guidelines References at Section 9792.24.3(d)(3). A copy of Appendix E may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.

Incorporation by reference is necessary because all the documents incorporated by reference are voluminous and it would be cumbersome and otherwise impractical to publish the entire publications in the California Code of Regulations. (1 CCR § 20(c)(1), (c)(2)) The regulations specify at specific sections how the documents may be obtained. Moreover, copies of the documents were made available to the public as part of the rulemaking record throughout this rulemaking.