

TITLE 8, CALIFORNIA CODE OF REGULATIONS, SECTION 9792.20 ET AL.  
NOTICE OF MODIFICATION TO TEXT OF PROPOSED RULEMAKING  
APPENDIX A1—CHRONIC PAIN MEDICAL TREATMENT GUIDELINES

Appendix A supplemented the Notice of Proposed Rulemaking/Initial Statement of Reasons issued June 2008 and explained the Chronic Pain Medical Treatment Guidelines. Appendix A1—**Chronic Pain Medical Treatment Guidelines** serves as the Supplement of Notice of Modification of the Text of the Division of Workers' Compensation's (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 new version adapted is dated **October 23, 2008**. The Notice of Proposed Rulemaking issued June 2008 proposed to adapt a previous version dated October 31, 2007. The new proposed version is 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 Medical Treatment Utilization Schedule (MTUS) to reflect the most recent advances in the science of medicine. (See further explanation at page 2, Item No. 2, below.) The Work Loss Data Institute has provided its ODG chapter on pain version to the DWC at no cost. As previously noticed, the Chronic Pain Medical Treatment Guidelines, Section 9792.24.2, et al., consists of two parts. Part 1: Introduction, and Part 2: Pain Interventions and Treatments. The chronic pain medical treatment guidelines replace the ACOEM's Practice Guidelines' Chapter 6—*Pain, Suffering, and the Restoration of Function* (Chapter 6) relating to chronic pain.

### **Part 1: Introduction**

**The Chronic Pain Medical Treatment Guidelines are modified as follows:**

**Part 1: Introduction** of the Chronic Pain Medical Treatment Guidelines is modified as set forth below. The deletions in the text of the Introduction are reflected by double strike-through, thus: ~~deleted language~~. Additions to the Introduction are reflected by a double underline, thus: added language. The changes to the Introduction are summarized as follows:

**1. The first paragraph, third sentence of the Introduction**, at page 1, is 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 is modified to delete the phrase “during this interval” immediately after the word “persists.” The fifth sentence is 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 is 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,” is stricken and replaced with the phrase “continues to have pain that persists beyond the anticipated time of healing,” and the phrase “plans for” is inserted between the words “without” and “definitive.” The sentence is completed by inserting the last phrase, “the chronic pain medical treatment guidelines apply.”

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**In summary, the modifications in the first paragraph of the Introduction** removes a defined time frame for reassessment of the patient after ruling out a potentially serious condition as this time frame may vary depending on the case. Further, DWC agrees with public comments submitted that the interval or clinical circumstances for reassessment should be left to the judgment of the physician. The modifications in the paragraph clarify when the chronic pain guidelines apply in relation to the clinical topics and other guidelines. Thus, as modified, the sentences 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 definitive treatment, such as surgical options, the chronic pain medical treatment guidelines apply.”

**2. The second paragraph, fifth sentence, of the Introduction,** at page 1, is modified to delete the date “October 31, 2007” and to substitute it with the date “*October 23, 2008.*” This date reflects the new date of the new ODG version of the chronic pain chapter which is being adapted in the DWC Chronic Pain Medical Treatment Guidelines. This new version is 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.) In this regard, 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)

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“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. Thus, as modified, the sentence states, “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, is corrected for clerical error for the reasons set forth under **Subdivision 9792.20(c)** in the Notice of Modification of Text of Proposed Rulemaking (November 2008) In that Notice, it is stated: “**Subdivision 9792.20(c)** is corrected for clerical error to delete the word “tissue” from the definition of “chronic pain.” The definition is 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.)”**

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**4. The first paragraph, fourth sentence under the subject *Overview***, at page 1, is 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” is not correct because we cannot be certain in any given case that a worse outcome would have occurred absent the intervention. However, the term suggested by the public comment was “abatement” which raised similar issues. Thus, DWC believes that the concept of “management” is a better concept because early recognition of chronicity does change the management approach in treating the chronic condition. Thus, as modified, the sentence states, “Therefore, effective early care is paramount in managing chronic pain.”

**5. The third paragraph, second sentence under the subject *Overview***, at page 2, is modified for clerical error to add a comma to the parenthetical example, thus “(e.g., injury).” Thus, as modified, the sentence states, “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, is modified to insert the phrase “symptoms such as” before the word “lancinating,” and to add two examples of symptoms: “electric shock-like,” and “numbing” as suggested by the regulated public and as contained in the lexicon of neuropathic pain symptoms. Thus, as modified the sentence states, “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, is modified to insert the phrase “but are not limited to” within a parenthetical comma after the introductory phrase, “These conditions include.” The phrase is 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 acknowledges that there may be other chronic pain conditions that have a large centralized component, such as diabetic neuropathy. Thus, the sixth paragraph, third sentence under the subject Pain Mechanisms, at page 3, as modified states, “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, is 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

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first sentence. The paragraph is further modified to insert the phrase, “These are helpful” before the phrase, “for physicians” in the second sentence. The second sentence is further modified by substituting the word “facilities” with the word “providers” and by deleting the end of the sentence which states, “for understanding pain.” The following sentence which states, “Models help to establish parameters for reasonable outcomes and acceptable standards of care” is deleted.” The last sentence is modified by deleting the last phrase of the sentence, “insights and limitations” and inserting the phrase, “strengths and weakness” in its place. The paragraph is rewritten essentially to clarify what models are and how they are used. Thus, as modified, the 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, is modified to insert the word “protective” before the word “warning.” 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. Accordingly, the first paragraph, second sentence, and third paragraph, second sentence, have been amended respectively. Thus, as modified, the sentence 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, is 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, DWC agrees that most acute pain is self-limited. It is also true that most acute pain responds to short term administration of analgesics and conservative therapies. Since both are true, one does not exclude the other, and therefore the use of the word “or” in this sentence is incorrect. There may be instances, however, where acute pain is self-limited, but may not respond to short term administration of analgesics and conservative therapies. Thus using the phrase “and may” is a more accurate description. Thus, as modified the 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, is modified to substitute the word “poor” with

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the phrase “less than adequate.” The language “less than adequate” is substituted because DWC agreed with a public comment that the phrase “less than adequate” better expresses 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. Using the phrase “less than adequate” better reflects the challenges of controlling pain. Poor pain control, as it was previously stated, represents a more extreme clinical situation. It is important to target adequate pain control as the desired goal. Moreover, the sentence is also modified to delete the phrase “leading to a neuropathic pain state.” This phrase is deleted as superfluous because it carries the same meaning as the phrase “lead to peripheral and central sensitization” which is already used in the sentence. Thus, the sentence as modified 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, is modified to insert the word “protective” before the word “warning.”** 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. Thus, the sentence as modified 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, is deleted.** The sentence is deleted as superfluous.

**14. The third paragraph, last sentence, under the subject *Acute vs. Chronic Pain Model*, at page 4, is modified to insert the word “and/” before the words “or anxiety.”** The word “and/” was inserted prior to the word “or” following a public comment to clarify the sentence that chronic pain may be associated with depression and/or anxiety independently or concurrently because these complications may occur together. Thus, the sentence as modified states, “To complicate matters, unremitting pain may be associated with depression and/or anxiety.”

**15. The fourth paragraph, under the subject *Acute vs. Chronic Pain Model*, at page 4, is amended by inserting a second sentence which states, “The Division of Workers’ Compensation definition of chronic pain, ‘any pain that persists beyond**

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the anticipated time of healing,' is derived from Bonica's Management of Pain (Turk and Okifuji, 2001)." This new sentence clarifies that the source of the definition of chronic pain is from Bonica's Management of Pain. (Turk and Okifuji, 2001)

**16. The first paragraph, last sentence, under the subject *Illness Behavior Model*, at page 4, is modified to include the phrase "but are not limited to" within a parenthetical comma before the phrase "a tendency toward anxiety." This 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. Thus, as modified the 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, is modified to delete the first two sentences of the last paragraph but to include the same substantive information in one sentence which is written in a more comprehensive manner. The complete last paragraph, under the subject Biomedical vs. Biopsychosocial Model, at page 5, as modified 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, is modified to place the word "cured" in quotation marks. The placement in quotation marks results 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. The quotation marks help to 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." Thus, the sentence as modified 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, is modified for clerical error to add an "s" to the word "failure" thus, "failures." Thus, the sentence as modified 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."**

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**20. The first paragraph, last sentence, under the subject *Subacute Delayed Recovery***, at page 6, is 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 clarifies the treating physician has the option to refer the patient to a multi-disciplinary program or to specialists if necessary. Thus, the sentence as modified 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, is modified to by inserting the following phrase at the end of the first sentence, “and includes a review of medical records.” The sentence is modified because 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. 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. Thus, the sentence as modified 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, is modified 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 are inserted to follow the first two sentences of the first paragraph under the same subject. The first paragraph discusses obtaining a history from the patient that includes record review to identify previously unknown or undocumented medical and/or psychosocial issues. Based on the history, a physical examination is performed to establish and confirm the diagnosis and to observe and understand pain behavior. Thereafter, a doctor-patient relationship is established. Thus, these sentences as modified 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, is modified by inserting three new sentences in the middle of the paragraph. The three new sentences clarify the language of the paragraph and address public comments expressing concern that complexities of the patient’s conditions and circumstances that warrant additional

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treatment should be taken into consideration in providing medical treatment if the treatment is evidence-based. 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, the clarifying language set forth in this paragraph also addresses 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 should 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. Thus, this information is also included in this paragraph for the benefit of the public. Thus, the fifth paragraph, under the subject Functional Restoration Approach to Chronic Pain Management, at page 8, is modified to insert three new sentences in the middle of the paragraph. The new fourth, fifth, and sixth sentences state as follows: "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." The eighth sentence is modified to delete the phrase "or neuropathic" at end of the sentence; 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, is modified by inserting a new second sentence, stating: "Selection of treatment must be tailored for the individual case." This new sentence is added because it is important to take into consideration the patient's conditions 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, are modified. The first paragraph is modified by deleting the last sentence, which states: "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, is modified at the beginning of the first sentence for clerical error to change the word "Physicians" to its singular form, thus "The physician." The**

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sentence as modified 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.”

Moreover, comments were submitted and the DWC agrees that there are situations where further functional improvement is no longer possible for the patient. DWC also agrees 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 further clarifying the language in this paragraph is necessary to address the purpose of the treatment plan for a chronic condition to maintain the patient’s level of function. Language from the California Medical Board was used to define the treatment plan for chronic pain and the need for periodic review. The second paragraph is further modified by inserting the following new language, thus: “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)).”

Further, a third clarifying paragraph emphasizing the importance of this goal is 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, is modified for clerical error to delete the word “neuropathic” and substitute it with the word “chronic.” Thus, the sentence as modified 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 is 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.” Thus, the sentence as modified 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

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the recently injured patient, (2) identify the “at risk” patient, and (3) refer the patient with intractable chronic pain to the appropriate resources.” These modifications are made for clarification purposes.

## **Part 2: Pain Interventions and Treatments**

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

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 will be noticed to the public by DWC as follows. The deletions in the text **Part 2-Interventions and Treatments** are reflected by double strike-through, thus: ~~deleted language~~. Additions to **Part 2-Interventions and Treatments** are reflected by a double underline, thus: added language. Because the modifications are not those of DWC and because they are numerous they will not be summarized in Appendix A1; a copy of **Part 2-Interventions and Treatments** will correspondingly not be served with this Notice of Modification to Text of Proposed Rulemaking and Appendix A1. The entire Chronic Pain Medical Treatment Guidelines (**Part 1-Introduction and Part 2–Pain Interventions and Treatments**) will be made available in DWC’s website at the DWC web site at <http://www.dwc.ca.gov>. If any member of the public is interested in obtaining a hard copy of **Part 2–Pain Interventions and Treatments**, please contact DWC’s Rulemaking coordinator at the contacting information provided in the accompanying Notice and arrangements will be made to make a copy available to the requesting party.

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

### **B. Modifications Made by DWC to the ODG Version Dated October 23, 2008**

The specific modifications to **Part 2-Interventions and Treatments** as revised in the ODG October 23, 2008 version and as adapted by the DWC in its Chronic Pain Medical Treatment Guidelines are noticed to the public as follows.

#### **1. Modifications to the Entire Guidelines**

**In adapting the October 23, 2008 ODG chapter on Pain version, DWC edited the text of the entire guideline to remove recommendations for acute treatments. The**

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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” is 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, in adapting the October 23, 2008 ODG chapter on Pain, DWC edited the text of the entire guideline to clarify recommendations for subacute treatments.** A word search was conducted 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 that would not conflict with the clinical topics. In those instances, the “subacute” references were removed.

**2. Individual treatment topics determined by the 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. 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.) In Appendix A, June 2008, DWC identified certain individual treatment topics in the October 31, 2007 ODG chapter on pain version which ODG determined to be “under study.” Those individual treatment topics were removed from the DWC chronic pain medical treatment guidelines. ODG has updated its chapter on pain and it no longer considers these topics to be “under study,” and makes a recommendation. The following individual treatment topics which were omitted from the June 2008 chronic pain medical treatment guideline have now been added to the proposed version of the Chronic Pain Medical Treatment Guidelines (November 2008).

- (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.
- (1) Chronic pain programs, early intervention
  - (2) Chronic pain programs, intensity
  - (3) Chronic pain programs, opioids

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- (4) Massage therapy
- (5) CRPS, Diagnostic Criteria

The following individual treatment topics, or portions of topics, which are found in the updated October 23, 2008 ODG chapter on pain, have been determined by ODG to be “under study” without a specific recommendation either in support or against the treatment. DWC has yet to conduct an evidence-based review (EBR) of these indicated topics. In the absence of an EBR and DWC recommendation, these individual treatment topics, or portions of such topics, will be removed from the DWC Chronic Pain Medical Treatment Guidelines as adapted from the October 23, 2008 version of the ODG chapter on pain as they do not meet the statutory requirement that the guidelines be “scientific and evidence-based.” (Lab. Code, § 4604.5(b))

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

- (1) Buprenorphine for chronic pain
- (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.

- (1) 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.

However, In **Functional imaging of brain responses to pain**, 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. Therefore it is appropriate to apply the DWC previously noticed guideline instead of the ODG October 23, 2008 guideline, which states, in relevant part as follows:

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**“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.”

- (2) ODG includes references to fMRI in “other individual treatment topics,” where the heading is not about fMRI. 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.

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.

- (3) 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).” 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.**

DWC has deleted from the adaptation the following individual treatment topics from ODG because the text under the topic heading refers to other ODG chapters for the guidelines and/or the evidence review. The reason for deleting these references is that DWC has not adopted other ODG chapters. DWC cannot make references to documents which are not formally adopted by reference in the rulemaking or are not part of the

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documents relied upon and made available to the public during the formal rulemaking process. (See also, Appendix A, June 2008, p. 6.)

- (1) Colchicine
- (2) Etanercept (Enbrel®)
- (2) Facet blocks
- (3) Infliximab (Remicade®)
- (4) Oral corticosteroids
- (4) Piriformis injections
- (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 individual treatment topics, or relevant portions of a topic, when the treatment recommendation do not relate to chronic pain were omitted from the chronic pain medical treatment guidelines as the text in the guidelines was not directly related to chronic pain. DWC removed these 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. 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. DWC intends to develop guidelines addressing these special topics in the future. In the interim, Section 9792.23(b) applies to provide treatment in these areas. Further, with regard to reviewing individual medical foods, ODG did not specify how these medical foods are used for chronic pain conditions. Without such specification, these medical foods are deleted.

- (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
- (9) Insomnia treatment
- (10) Medical Foods
  - (a) Choline
  - (b) Glutamic Acid:
  - (c) Gamma-aminobutyric acid (GABA)
  - (d) L-Serine
  - (e) L-Arginine

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- (11) Modafinil (Provigil®)
- (12) Provigil® (modafinil)
- (13) Restless legs syndrome (RLS)
- (14) Sedative hypnotics
- (15) Xanax® (Alprazolam)
- (16) Zolpidem (Ambien®)

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

As previously indicated in Appendix A, Labor Code section 5307.27 requires the Administrative Director to 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. It is noted that ODG listed Honey and Cinnamon as medical food. DWC disagrees with this determination. 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> )  
The Federal Drugs Administration (FDA) does not regulate the manufacturing of foods or dietary supplements. (See, Appendix A, at pp. 15-16.) The recommended individual treatment topic listed below does not conform to the requirements of the Labor Code section 5207.27 requiring that the MTUS address the “intensity” of treatment. 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. The following individual treatment topic recommendation is replaced with DWC’s recommendation.

- (1) Honey & Cinnamon

**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**

In the June 2008 Appendix A, at page 7, paragraph b., DWC indicated that there were various ODG individual treatment topics that were informative and/or educational in nature. DWC indicated that although informative, these concepts were not treatment topics and did not substantively added to the overall utility of the chronic pain medical treatment guidelines. DWC now agrees with public comments stating that it is necessary

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to include in the Chronic Pain Medical Treatment Guidelines 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. The following ODG individual treatment topics are included in the chronic pain medical treatment guidelines as adapted.

- (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 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®)

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- (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
- (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**

In the June 2008 Appendix A, at page 6, paragraph 3a, DWC indicated that there were ODG sections on diagnostic tests that were omitted from the chronic pain medical treatment guidelines because they represent diagnostic tests that are not exclusive to the diagnosis of chronic pain. The following individual treatment topic is now included in the chronic pain medical treatment guidelines 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. Upon further review, DWC has determined that there is no internal conflict in the MTUS. (See also, Appendix A, June 2008, at p. 6.)

- (1) Autonomic test battery

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**9. Non-substantive changes**

- (1) In certain circumstances, links are 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 are corrected if encountered.
- (3) Medical foods individual treatment topic heading is removed as all the items listed below the heading were removed.
- (4) Where ODG references “Physical therapy” without mention of “Occupational therapy,” DWC modifies “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” is moved to its proper location in alphabetical order.
- (6) The individual treatment topic of “Galvanic stimulation” is moved to its proper location in alphabetical order under “Transcutaneous electrotherapies.”