

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

**FINAL STATEMENT OF REASONS**

**Workers' Compensation: Medical Treatment Utilization Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS,**

**SECTIONS 9792.23(b)(1), 9792.24.2 AND 9792.24.4**

The Acting Administrative Director of the Division of Workers' Compensation (hereinafter "Acting Administrative Director") pursuant to the authority vested in him by Labor Code Sections 59, 133, 4600, 4604.5, 5307.3 and 5307.27, has amended and adopted the following regulations:

Amend Section 9792.23(b)(1)	Clinical Topics
Amend Section 9792.24.2	Chronic Pain Medical Treatment Guidelines
Adopt Section 9792.24.4	Opioids Treatment Guidelines

**REQUEST AND GOOD CAUSE FOR EFFECTIVE DATE UPON FILING WITH THE SECRETARY OF STATE**

The proposed regulations amend Title 8, California Code of Regulations sections 9792.23(b)(1) and 9792.24.2, and adopt section 9792.24.4 of the Medical Treatment Utilization Schedule (MTUS). The proposed regulations will incorporate by reference an updated Chronic Pain Medical Treatment Guidelines and incorporate by reference a stand-alone comprehensive Opioids Treatment Guidelines. The Division provides the following reasons why there is good cause for the effective date of these regulations to become effective upon filing with the Secretary of State.

First, the proposed Opioids Treatment Guidelines addresses the national concern regarding adverse health impacts and other unintended consequences due to opioid misuse. The Centers for Disease Control and Prevention (CDC) has declared a national opioid epidemic. According to the CDC, deaths associated with prescription opioids rose from 4,000 in 1999 to over 14,000 in 2008 (CDC 2011). Moreover, these deaths peaked in the age group of 25-55 years, constituting a large premature loss of productive life. Additionally, an increasing number of emergency department visits and hospitalization have been associated with prescription opioids.

Coinciding with the increases in opioid-associated deaths and opioid misuse and abuse has been a substantial escalation in opioid prescribing and dosage between 2000 and 2010. Opioids are currently the second most widely prescribed class of medications (statins for lowering cholesterol are the first). Efforts to encourage safer prescribing of opioid pain relievers should be strengthened and it is a primary goal of the proposed Opioids Treatment Guidelines to significantly reduce the rate of opioid-related adverse events and substance misuse and abuse.

Currently, the MTUS only provides guidance for the use of opioid medications for the treatment of chronic non-cancer pain in the MTUS' Chronic Pain Guidelines. The MTUS does not have a stand-alone opioids guideline. The proposed stand-alone Opioids Treatment Guidelines comprehensively addresses the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative as well as chronic non-cancer pain. A set of best practices for safe and effective prescribing of opioids are provided for acute, subacute, post-operative and chronic pain due to a work-related injury that promotes functional restoration. Included in the proposed Opioids Treatment Guidelines are universal precautions for the safe prescribing of opioids including an 80 milligram per day morphine equivalency dosage (MED) threshold that, if reached, triggers a consultation with a pain specialist. The proposed guidelines also contain screening recommendations for risk of addiction, misuse, abuse and psychosocial factors that should be monitored. Finally, the proposed guidelines contain recommendations for proper tapering or weaning methods to safely discontinue use of opioids. The proposed Opioids Treatment Guidelines provides much needed guidance to prevent and reduce opioid-related substance misuse and abuse and long-term disability, morbidity, and mortality. The urgency for these regulations to become effective upon filing with the Secretary of State could not be much clearer.

Second, updating the Chronic Pain Medical Treatment Guidelines and adding a comprehensive Opioids Treatment Guidelines is needed to efficiently deliver medical care to California's injured workers. The MTUS' Chronic Pain Medical Treatment Guidelines has not been updated since 2009 and, as already mentioned, there has never been a stand-alone opioids guideline in the MTUS.

Pursuant to Labor Code section 5307.27, the MTUS must contain medical guidelines that comprehensively address all treatment procedures and modalities commonly performed in workers' compensation cases. Labor Code section 4600(b) states, "...medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Section 5307.27." The recommended guidelines in the MTUS is presumptively correct on the issue of extent and scope of medical treatment and is the primary source of guidance for treating physicians and physician reviewers for the evaluation and treatment of injured workers.

If a medical condition or injury is not addressed by the MTUS or if the MTUS' presumption of correctness is being challenged because a differing recommendation is supported by new medical evidence, then our current regulations allow

recommendations found outside of the MTUS to be considered. However, to do this, physicians and reviewing physicians need to search through the voluminous medical literature to find a recommendation that he or she believes applies to the injured worker's injury or condition and is supported by the best available medical evidence. This process often leads to disputes because competing recommendations may be viewed as guiding the injured worker's medical condition or injury. Disputes regarding the medical necessity of a requested treatment are resolved by the utilization review process (UR) or by the independent medical review process (IMR). If a utilization review decision denies a treating physician's request for treatment, then a request for a review by an Independent Medical Reviewer can be filed. Going through the utilization review process and then the independent medical review process is expensive, but most importantly it is time consuming, potentially delaying important medical treatment to injured workers.

The best way to curtail these disputes is to make sure the recommendations in the MTUS are comprehensive and current. The proposed regulations will affect a staggering number of medical treatment requests, utilization review decisions and independent medical review decisions. There are approximately 550,000 to 650,000 new workers' compensation claims every year requiring medical treatment. Data reported to the Division's Workers' Compensation Information System for 2013 indicated there were 26.2 million treatment request bills. Representatives of claims administrators and utilization review organizations estimate 25% of requests for treatment required a physician's review through UR. With these figures, approximately 17,945 treatment requests are sent to utilization review physicians each day.

With regards to Independent Medical Review, in 2014 there were 377,000 treatment requests reviewed through IMR. There were 145,000 IMR final determinations which included 2.6 treatment disputes per IMR application. With these figures, approximately 1,032 treatment requests are reviewed through IMR each day, resulting in 397 IMR final determinations issued by independent medical review physicians each day.

Granted, the data provided above is for all medical treatment requests, utilization review decisions and independent medical review decisions and the proposed regulations only cover issues related to chronic pain and opioids. Nevertheless, the numbers are high regardless of the ratio of medical treatment requests, utilization review decisions and independent medical review decisions specifically related to the issue of chronic pain and the use of opioids. Once the proposed regulations become effective, the MTUS will contain up-to-date, comprehensive recommendations addressing chronic pain and the use of opioids. Since the recommendations in the MTUS are considered presumptively correct, there will be fewer disputes and the delivery of medical care to California's injured workers will be much more efficient.

Accordingly, for all the reasons mentioned above, there is good cause for the effective date of these regulations to be effective upon filing with the Secretary of State.

## UPDATE OF INITIAL STATEMENT OF REASONS AND INFORMATION DIGEST

As authorized by Government Code section 11346.9(d), the Acting Administrative Director hereby incorporates by reference the entire Initial Statement of Reasons prepared in this matter. Unless a specific basis is stated below for any modification to the regulations as initially proposed, the necessity for the amendments to existing regulations and for the adoption of new regulations as set forth in the Initial Statement of Reasons continues to apply to the regulations as now adopted.

### Updated Informative Digest:

The Informative Digest/Policy Overview is updated because this rulemaking also amends the California Code of Regulations, title 8, section 9792.23(b)(1) by deleting the phrase “that persists beyond the anticipated time of healing” and replacing it with the phrase “lasting three or more months from the initial onset of pain” to consistently apply the definition of chronic pain set forth in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines and Opioids Treatment Guidelines. The proposed amendment to section 9792.23(b)(1) was published during the 15-Day comment period from December 4, 2015 to December 19, 2015, and the regulated public had an opportunity to comment on this change.

### Updated Technical, Theoretical, Or Empirical Studies, Reports, Or Documents Upon Which The Division Relied Upon:

All modifications from the Initial Statement of Reasons, item number 3, list of “Technical, Theoretical, or Empirical Studies, Reports, or Documents Upon Which the Division Relied Upon” are listed below.

The following documents are added to the documents relied upon list:

Backonja M. Chapter 19: Painful Neuropathies, in Loeser JD. *Bonica's Management of Pain*. Lippincott Williams & Wilkins, Philadelphia, 2001.

Singh J., Dohm M., Borkhoff C. Total joint replacement surgery versus conservative care for knee osteoarthritis and other non-traumatic diseases. *Cochrane Database of Systematic Reviews* 2013, Issue 9. Art. No: CD010732. doi: 10.1002/14651858.CD010732

Smith ES, Lewin GR. (2009) Nociceptors: a phylogenetic view. *J. Comp Physiol A Neuroethol Sens Neural Behav Physiol*;195(12): 1089-1106. doi: 10.1007/s00359-009-0482-z

Backonja M, is added to the list because Chapter 19: Painful Neuropathies is the chapter the DWC relied upon in the book *Bonica's Management of Pain*. Lippincott Williams & Wilkins, Philadelphia, 2001. In the Initial Statement of Reasons we referenced in error the entire book under Loeser, J. D., & Bonica, J. J. (2001). *Bonica's management of pain* (3rd ed.). Philadelphia: Lippincott Williams & Wilkins. Note, the correct reference to Backonja, M., was included in the proposed Chronic Pain Medical

Treatment Guidelines, in the “References for Introduction” section (pages 12-13), and published for public comment in both the 45-Day Comment Period and the 15-Day Comment Period.

Singh J, Dohm M, Borkhoff C. is added to the list because this is the citation to the document used to define “conservative care” which was added after the 45-Day Comment Period and the regulated public was notified and had the opportunity to provide comments to the changes during the 15-Day Comment Period.

Smith ES, Lewin GR is added to the list because the DWC inadvertently omitted it from the Initial Statement of Reasons. However, Smith ES, Lewin GR. Nociceptors: a phylogenetic view. *J Comp Physiol A Neuroethol Sens Neural Behav Physiol*, 2009;195(12): 1089-1106. doi: 10.1007/s00359-009-0482-z was referenced in the proposed Chronic Pain Medical Treatment Guidelines, in the “References for Introduction” section (pages 12-13), and published for public comment in both the 45-Day Comment Period and the 15-Day Comment Period.

The following documents are removed from the documents relied upon list:

Loeser, J. D., & Bonica, J. J. (2001). *Bonica's management of pain* (3rd ed.). Philadelphia: Lippincott Williams & Wilkins

Manchikanti, L., Malla, Y., Wargo, B. W., & Fellows, B. (2011b). Comparative evaluation of the accuracy of benzodiazepine testing in chronic pain patients utilizing immunoassay with liquid chromatography tandem mass spectrometry (LC/MS/MS) of urine drug testing. *Pain Physician*, 14(3), 259-270.

Loeser, J. D., & Bonica, J. J. (2001). *Bonica's management of pain* (3rd ed.). Philadelphia: Lippincott Williams & Wilkins is removed because it incorrectly references the entire book instead of the specific chapter the DWC relied upon. As noted above, the DWC specifically relied upon Backonja M Chapter 19: Painful Neuropathies instead of the entire book. This reference to the entire book is removed and replaced with the reference to Backonja M Chapter 19: Painful Neuropathies which was correctly referenced and included in the proposed Chronic Pain Medical Treatment Guidelines, in the “References for Introduction” section (pages 12-13), and published for public comment in both the 45-Day Comment Period and the 15-Day Comment Period.

Manchikanti, L., Malla, Y., Wargo, B. W., & Fellows, B. was inadvertently duplicated in the Initial Statement of Reasons and the identical duplicate reference is removed to correct a typographical error.

## **ALL MODIFICATIONS FROM THE INITIALLY PROPOSED TEXT OF THE REGULATIONS ARE SUMMARIZED BELOW.**

### **Proposed Amendments to Section 9792.23. Medical Treatment Utilization Schedule - Clinical Topics.**

- Subdivision (b)(1) is amended by deleting the phrase “that persists beyond the anticipated time of healing” and replacing it with the phrase “lasting three or more months from the initial onset of pain” to consistently apply the definition of chronic pain set forth in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines.

**Proposed Amendments to Section 9792.24.2. Medical Treatment Utilization Schedule – Chronic Pain Medical Treatment Guidelines**

- Subdivision (b) is amended by deleting the phrase “as determined by following the clinical topics” and replacing it with the phrase “as defined in section 9792.20” to clarify the proposed Chronic Pain Medical Treatment Guidelines applies when the patient has pain lasting three or more months from the initial onset of pain.
- Subdivision (c) is amended by deleting the phrase “is diagnosed with” chronic pain and replacing it with the word “has” chronic pain because the definition of “Chronic Pain” set forth in section 9792.20 is not triggered by a treating physician’s diagnosis of chronic pain, but rather, if the pain lasts three or more months from the initial onset of pain. The lower case letters “c” and “t” are capitalized to “C” and “T” in the phrase “Clinical Topics” both times it is referenced because this is the name of a section in the MTUS. The letter “s” is deleted from the word “sections” to make it singular instead of plural and the phrase “of the MTUS” is added for clarity.
- Subdivision (d) is amended by adding the phrase “a patient has chronic pain and” for clarification and consistency with the language in subdivision (c). The lower case letters “c” and “t” are capitalized to “C” and “T” in the phrase “Clinical Topics” because this is the name of a section of the MTUS. The phrase “or if the treatment is only addressed in the Chronic Pain Medical Treatment Guidelines, then” is added to address this additional situation when the Chronic Pain Medical Treatment Guidelines shall apply.

**Proposed Amendments to the Chronic Pain Medical Treatment Guidelines incorporated by reference in Section 9792.24.2.**

- Title page for the Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines is amended by deleting “July 2015” and replacing it with “[Insert Effective Date of Regulations]” because the Chronic Pain Medical Treatment Guidelines will be incorporated by reference into section 9792.24.2 on the effective date of these regulations.
- Table of Contents is amended by deleting the page numbers because page numbers inserted in the Table of Contents before the completion of the rulemaking process will not accurately reflect the page of the corresponding sections. The correct page numbers will be re-inserted into the Table of Contents when the final version is submitted to the Office of Administrative Law which will accurately reflect

the page of the corresponding sections consistent with any changes made during the rulemaking process.

- Part 1: Introduction is amended by deleting the phrase “beyond the anticipated time of healing” and replacing it with the phrase “three (3) months or longer from the initial onset of pain (i.e., 12 weeks or longer)” to be consistent with the definition of “Chronic Pain” as set forth in in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines. The phrase “clinical topics” is deleted and replaced with the phrase “Clinical Topics section of the MTUS (8 CCR § 9792.23)” to clarify that the term “Clinical Topics” refers to other guidelines in the Medical Treatment Utilization Schedule (MTUS) and to avoid confusion with the procedure/topics section of the Chronic Pain guideline. The phrase “Upon ruling out a potentially serious condition, the physician should provide conservative management”, is clarified by adding the phrase “that is, a treatment approach designed to avoid surgical and other medical and therapeutic measures with higher risk of harm compared to benefit” in order to clearly define what is meant by “conservative management”. The reference “(Singh, 2013)” is also added here and the full citation for the Singh, 2013 reference is added in the Reference for Introduction section. The letters “C” and “T” are capitalized in the phrase “Clinical Topics” in order to specify that the term refers to the Clinical Topics section of the MTUS.
- Part 1: Introduction, Definitions, Pain is amended by deleting the word “intensity” to clarify that there is no objective measurement or physiologic biomarkers for pain itself, not just pain intensity.
- Part 1: Introductions, Definitions, Types of Pain (Acute vs Chronic) is amended by deleting the phrase “more than” and replacing it with the phrase “(3) or more” months “from the initial onset of pain (i.e., over 12 weeks)” to be consistent with the definition of “Chronic Pain” as set forth in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines. The phrase “following an injury” is deleted and replaced with the phrase “from the initial onset of pain” The word “also” is added to clarify the definition of chronic pain is consistently defined in the MTUS Opioids Treatment Guidelines as “pain lasting three or more months from the initial onset of pain”.
- Part 1: Introductions, Pain Mechanisms is amended to bold the section topic for emphasis, consistency of format and ease of reading.
- Part 1: Introduction, Models is amended by deleting the word “standards” and replacing it with the phrase “guidance for” care to make clear these models are to assist providers by offering an analytical framework for the evaluation and treatment of injured workers but is not intended to mandate specific clinical practices.

- Part 1: Introduction, Models, Acute vs. Chronic Pain Model is amended by deleting the phrase “recognizes that the most clinically useful definition might be” and replacing it with the word “states” so that the ACOEM definition of chronic pain is clearly stated yet does not conflict with the definition of “Chronic Pain” as set forth in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines. The phrase “The MTUS defines chronic pain lasting three or more months from the initial onset of pain” is added and the phrase “Therefore, it is a clinical decision to recognize chronicity or persistence of pain” is deleted to maintain consistency with the definition of “Chronic Pain” as set forth in in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines. The phrase “Additional clinical factors that aid in the diagnosis of chronic pain are:” is added to clarify the subsequent list of clinical factors aid in diagnosis but do not replace the definition of “Chronic Pain” as set forth in in section 9792.20. The phrase “It often takes a number of months for the clinician to recognize when pain has become chronic” is deleted because it conflicts with the definition of “Chronic Pain” as set forth in in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines.
- Part 1: Introduction, Models, Acute vs. Chronic Pain Model and Illness Behavior Model is amended by deleting the extra space between the two sections to delete a typographical error.
- Part 1: Introduction, Risk Stratification, Importance of early identification is amended by changing the capital “S” in the word “Section” to a lower case “s” to correct a typographical error.
- Part 1: Introduction, Risk Stratification, Importance of early identification and Subacute Delayed Recovery is amended by deleting an extra space between the two sections to delete a typographical error.
- Part 1: Introduction, Pain Outcomes and Endpoints is amended by deleting “(“ before the word “Therefore” to correct a typographical error. The word “pain” is deleted in the second paragraph to correct a grammatical error.
- Part 1: References for Introduction is amended by adding the reference “Singh J, Dohm M, Borkhoff C. Total joint replacement surgery versus conservative care for knee osteoarthritis and other non-traumatic diseases. *Cochrane Database of Systematic Reviews* 2013, Issue 9. Art. No: CD010732. doi: 10.1002/14651858.CD010732” because this is the citation to the document used to define “conservative care.”
- Part 1: References for Introduction is amended by deleting the extra space between the reference “Turk D, Okifuji” and “Ung H. Brown” and between the reference “Ung H. Brown” and “Younger J. Shen” to correct a typographical error.

- Part 2: Procedure Summary – Pain, Procedure/Topic, Functional improvement measures is amended by deleting a comma between the words “Oswestry” and “pain” to correct a typographical error. A period is added after “etc.” on two of the three occasions it is used to correct a typographical error. A space is added between the period and the word “Approach” to correct a typographical error.
- Part 2: Procedure Summary – Pain, Procedure/Topic, Home health care services is amended by deleting the extra space between the sentence that ends in “documentation of:” and the sentence that begins “(1) The medical condition” which was inadvertently omitted. A bullet point is added before the phrase “The individual has trouble leaving the home without help” and a bullet point is deleted before the phrase “Leaving the home isn’t recommended because of the occupational illness or injury AND” to match ODG’s language and to be consistent with the Centers for Medicare & Medicaid Services’ (CMS) definition of “Homebound” that one of two conditions needs to be present in the first bullet in addition to the two conditions in the second bullet.
- Part 2: Procedure Summary – Pain, Procedure/Topic, Hospital length of stay (LOS) is amended by deleting the phrase “See also MTUS chapters on specific body parts” and replacing it with “Refer to the relevant Clinical Topics section of the MTUS for additional recommendations” as this more accurately and specifically describes the applicable section of the MTUS.
- Part 2: Procedure Summary – Pain, Procedure/Topic, Muscle relaxants (for pain) is amended by deleting the phrase “See recommendations in specific body parts” and replacing it with “Refer to the relevant Clinical Topics section of the MTUS for recommendations” as this more accurately and specifically describes the applicable section of the MTUS.
- Part 2: Procedure Summary – Pain, Procedure/Topic, Surgery is amended by deleting the phrase “See specific entries in body parts chapters in the MTUS” and replacing it with “Refer to the relevant Clinical Topics section of the MTUS for recommendations” as this more accurately and specifically describes the applicable section of the MTUS.
- Part 2: Procedure Summary – Pain, Procedure/Topic, TENS, chronic pain (transcutaneous electrical nerve stimulation) is amended by deleting the phrase “See also MTUS chapters on specific body parts” and replacing it with “Refer to the relevant Clinical Topics section of the MTUS for recommendations for additional recommendations” as this more accurately and specifically describes the applicable section of the MTUS.
- Part 2: Procedure Summary – Pain, Procedure/Topic, Topical analgesics, Lidocaine is amended by deleting the phrase “See also MTUS chapters on specific body parts” and replacing it with “Refer to the relevant Clinical Topics section of the MTUS for

recommendations” as this more accurately and specifically describes the applicable section of the MTUS.

#### **Proposed Amendments to Section 9792.24.4. Medical Treatment Utilization Schedule – Opioids Treatment Guidelines**

- Subdivision (b) is amended by deleting the phrase “alternative therapies do not provide adequate pain relief and” because its inclusion was being misinterpreted to mean opioids cannot be prescribed until a clinical history established inadequate pain relief after a trial of all the alternative therapies listed in the proposed Opioids Treatment Guidelines. The amendment clarifies the Opioids Treatment Guidelines apply when the use of opioid medication is being considered as part of the treatment regimen.

#### **Proposed Amendments to the Opioids Treatment Guidelines incorporated by reference in Section 9792.24.4.**

- Title page for the Medical Treatment Utilization Schedule (MTUS) Opioids Treatment Guidelines Part 1 is amended by deleting “July 2015” and replacing it with “[Insert Effective Date of Regulations]” because the Opioids Treatment Guidelines will be incorporated by reference into section 9792.24.4 on the effective date of these regulations.
- Table of Contents is amended by deleting the page numbers because page numbers inserted in the Table of Contents before the completion of the rulemaking process will not accurately reflect the page of the corresponding sections. The page numbers will be re-inserted into the Table of Contents when the final version is submitted to the Office of Administrative Law which will accurately reflect the page of the corresponding sections consistent with any changes made during the rulemaking process.
- Table of Contents, A. Summary Information is amended by adding the section title “A. Summary Information” to correct a formatting error in the Table of Contents.
- Table of Contents, A. Summary Information is amended by deleting the letter “A” from the section title and is replaced with “1. Executive Summary” to be consistent with the format of the document.
- Table of Contents, A. Summary Information is amended by deleting the letter “A” from the section title and is replaced with “2. Abbreviated Treatment Protocols” to be consistent with the format of the document.
- Table of Contents, A. Summary Information is amended by deleting the letter “A” from the section title and is replaced with “3. Background” to be consistent with the format of the document.

- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.1 Burden of Pain” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended adding “3.2 Workers’ Compensation Context” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.3 Evidence of Effectiveness of Opioids Use in the Acute Period” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.4 Evidence of Effectiveness of Long-Term Use” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.5 Opioid Safety: Overdose, Serious Adverse Events, and Substance Misuse/Abuse” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.6 Scope and Target Audience for the Opioids Treatment Guidelines” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.7 Core Concepts” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.8 Goals and Objectives” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.9 Evidence-Based Methods” to be consistent with the format of the document.
- Table of Contents, A. Summary Information, 3. Background is amended by adding “3.10 Guidelines Evaluated” to be consistent with the format of the document.
- Table of Contents is amended by adding the section title “B. Recommendations” to correct a formatting error in the Table of Contents.
- Table of Contents, B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1. is amended by adding “3.3.1.1. Screening for Drug Misuse/Abuse” to be consistent with the format of the document.
- Table of Contents, B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1. is amended by adding “3.3.1.2. Screening for Alcohol Misuse/Abuse” to be consistent with the format of the document.

- Table of Contents, B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1. is amended by adding “3.3.1.3. Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse” to be consistent with the format of the document.
- A. Summary Information, 1. Executive Summary first paragraph is amended by deleting the word “Guidelines” and replacing it with the word “Schedule” in the phrase “Medical Treatment Utilization Schedule” to correct a typographical error.
- A. Summary Information, 1. Executive Summary ninth bullet point, the first use of the word “treatment” is deleted to correct a typographical error.
- A. Summary Information, 2. Abbreviated Treatment Protocols is amended by deleting the letter “A” in the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background is amended by deleting the letter “A” in the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background, 3.1 Burden of Pain is amended by deleting the letter “A” from the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background, 3.2 Workers’ Compensation Context is amended by deleting the letter “A” from the section title to be consistent with the format of the document. The phrase “more than” is deleted and replaced with the phrase “(3) or more” months “from the initial onset of pain (i.e., over 12 weeks)” to maintain consistency with the definition of “Chronic Pain” as set forth in in section 9792.20 and used throughout the proposed Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines.
- A. Summary Information, 3. Background, 3.3 Evidence of Effectiveness of Opioid Use in the Acute Period is amended by deleting the letter “A” from the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background, 3.4 Evidence of Effectiveness of Long-Term Opioid Use is amended by deleting the letter “A” from the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background, 3.5 Opioid Safety: Overdose, Serious Adverse Events, and Substance Misuse/Abuse is amended by deleting the letter “A” from the section title to be consistent with the format of the document. The second sentence of the second paragraph is amended by adding the phrase “Alone or” to the beginning of the sentence to clarify that opioids can induce acute respiratory failure either alone or in combination with other central nervous system depressants. The upper case “I” is deleted and replaced with a lower case “i” in the word “in”.

- A. Summary Information, 3. Background, 3.6 Scope and Target Audience for the Opioids Treatment Guidelines is amended by deleting the letter “A” from the section title to be consistent with the format of the document.
- A. Summary Information, 3. Background, 3.7 Core Concepts is amended by deleting the letter “A” from the section title to be consistent with the format of the document. An extra space is deleted between the end of 3.7 Core Concepts and the beginning of 3.8 Goals and Objectives to correct a formatting error.
- A. Summary Information, 3. Background, 3.8 Goals and Objectives is amended by deleting the letter “A” from the section title to be consistent with the format of the document. The second bullet point is amended to add the phrase “post-operative,” to clarify that the document includes best practices and universal precautions for safe and effective prescribing of opioids for post-operative pain as well.
- A. Summary Information, 3. Background, 3.9 Evidence-Based Methods is amended by deleting the letter “A” from the section title to be consistent with the format of the document. An extra space is deleted between the end of 3.9 Evidence-Based Methods and the beginning of 3.10 Guidelines Evaluated to correct a formatting error.
- A. Summary Information, 3. Background, 3.10 Guidelines Evaluated is amended by deleting the letter “A” from the section title to be consistent with the format of the document.
- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset) is amended by reversing the order of section 1.1 with 1.2 to have a more logical flow of recommendations for opioids with acute injuries, that starts with mild injuries, followed by moderate injuries and then severe acute injuries. Section 1.1 is now “Mild Acute Injuries (e.g., musculoskeletal strains and sprains, muscle pain, tendonitis)” and 1.2 is now “Moderate to Severe Acute Injuries (e.g., severely sprained ligaments, severe sprains, moderate trauma, moderate to severe low back pain, moderate to severe radiculopathy)”.
- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.2 Moderate to Severe Acute Soft Tissue Injuries (e.g., severely strained ligaments, severe sprains, moderate trauma, moderate to severe low back pain, moderate to severe radiculopathy) is amended by deleting the phrase “Soft-Tissue” from the section title to clarify that the recommendations that follow are not limited to soft-tissue injuries.
- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.2. Moderate to Severe Acute Injuries (e.g., severely strained ligaments, severe sprains, moderate trauma, moderate to severe low back pain, moderate to severe radiculopathy) first paragraph, the first use of the word “acute” is deleted to

correct a typographical error. The phrase “soft tissue” is deleted from this section to clarify that the following guidelines are not limited to soft-tissue injuries.

- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.2. Moderate to Severe Acute Injuries (e.g., severely strained ligaments, severe sprains, moderate trauma, moderate to severe low back pain, moderate to severe radiculopathy) item 4 is amended by adding the phrases “particularly sleep apnea,” “cerebrovascular disease,” and “chronic hepatitis, cirrhosis,” to the list of conditions noted as relative contraindications to initiating opioids to maintain consistency with other similar lists of conditions in the document. The word “must” was deleted and replaced with the word “should” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.3. Severe Acute Injuries (e.g., fractures, crush injuries, major trauma, large burns, other injuries with significant tissue damage) item 4 is amended by deleting the word “must” and replacing it with the word “should” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
- B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.4. Opioids for Post-operative Pain first bullet point, first sentence is amended by deleting the phrase “management of” to correct a typographical error.
- B. Recommendations, 2. Opioids for Subacute Pain (1-3 months) item 4.b. is amended by adding the phrases “particularly sleep apnea,” “cerebrovascular disease,” and “chronic hepatitis, cirrhosis,” to the list of conditions noted as relative contraindications to initiating opioids to maintain consistency with other similar lists of conditions in the document.
- B. Recommendations, 2. Opioids for Subacute Pain (1-3 months) item 4.b. is amended by deleting the unnecessary extra space between items 4.b. and 5.
- B. Recommendations, 2. Opioids for Subacute Pain (1-3 months) item 6 is amended by deleting the word “narcotics” and replacing it with the word “opioids” to maintain consistent wording throughout the document.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment is amended by deleting the phrase “longer than” and the word “months” and replacing them with the phrase “or more” twice in this paragraph to maintain consistency with the definition of “Chronic Pain” as set forth in in section 9792.20 and used

throughout the proposed Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines.

- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1. Screening for Risk of Addiction or Adverse Events, Prior to Chronic Opioid Treatment is amended by italicizing the heading to be consistent with the format of this document. Also, the entire section is amended by changing the font from Calibri to Arial to maintain a consistent font throughout the document.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1 Screening for Risk of Addiction or Adverse Events, Prior to Chronic Opioid Treatment, 3.3.1.1. Screening for Drug Misuse/Abuse item 3 is amended by deleting the word “only” and the word “and” followed by adding the phrase “only if” to correct a typographical error.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1 Screening for Risk of Addiction or Adverse Events, Prior to Chronic Opioid Treatment, 3.3.1.3. Screening for Additional Psychosocial Factors Contributing to Substance Misuse/Abuse item 1 is amended by deleting the word “to” and replacing it with the word “and” to correct a typographical error.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.2. Patient Treatment Agreement and Informed Consent is amended by italicizing the heading to conform to the format of the document. Item 3a. is amended by deleting the word “modified” and replacing it with the word “modify” to correct a typographical error. Item 3b. is amended by deleting the phrase “update it” to correct a typographical error.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.3. Initiation of Chronic Opioid Treatment is amended by italicizing the heading to conform to the format of the document. This section is further amended by deleting the bullet points and replacing them with the numbers “1., 2., 3., and 4.” respectively because they denote clinical practices that should be followed for the initiation of chronic opioid therapy. The sentence “The following clinical practices should be followed” is deleted because the previously bulleted points are now combined with the numbered items that follow this sentence. The clinical practices previously numbered “1. – 4.” are renumbered from “5. – 9.” to combine these items with items 1 through 4 which were the previously bulleted points.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.4. Use of CURES to Ensure Safe and Effective Opioid Use is amended by italicizing the heading to conform to the format of the document.

- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.5. Use of Tools to Monitor Patients on Chronic Opioid Treatment is amended by italicizing the heading to conform to the format of the document.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.6. Use of Urine Drug Testing (UDT) is amended by italicizing the heading to conform to the format of the document. This section is further amended by deleting the extra spaces between the first paragraph and item 1, the end of item 3 and the beginning of item 4, and the end of item 4 and the beginning of item 5.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.7. Monitoring Effectiveness of Chronic Opioid Treatment is amended by italicizing the heading to conform to the format of the document.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.7. Monitoring Effectiveness of Chronic Opioid Treatment, 3.3.7.1. Tracking Pain and Function to Monitor Effectiveness of Chronic Opioid Treatment is amended by deleting the extra spaces between “3.3.7.1” and the section heading.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.8. Opioid Titration and Dosing Threshold is amended by italicizing the heading to conform to format of the document. Item 3 is amended by deleting the word “must” and replacing it with the word “should” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices. Item 3.e. is amended by deleting the word “required” and replaced with the word “recommended” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.8. Opioid Titration and Dosing Threshold item 6 is amended by deleting the phrase “Due to lack of sufficient evidence to guide outpatient care, the routine prescription of naloxone to patients on chronic opioid treatment is not recommended” to reflect evolving scientific knowledge regarding recommended use of naloxone to treat opioid overdoses. This change also ensures that the Opioid Treatment Guidelines are consistent with the MTUS Chronic Pain Medical Treatment Guidelines.

- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.9. Maintenance of Chronic Opioid Treatment is amended by italicizing the heading to conform to the format of the document. Item 2.d. is amended by deleting the word “required” and replacing it with the word “recommended” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Pain Treatment, 3.3. Initiating and Monitoring Chronic Pain Treatment, 3.3.10. Treating Breakthrough Pain (BTP) is amended by italicizing the heading to conform to the format of the document.
- B. Recommendations, 4. Tapering Opioids, 4.1 Indications for Tapering Opioids first paragraph is amended by deleting the word “reducing” to correct a typographical error.
- B. Recommendations, 4. Tapering Opioids, 4.1 Indications for Tapering Opioids item 1 is amended by adding an additional bullet point that includes pregnancy as a condition for tapering opioids as indicated by guidelines developed by the Medical Board of California that states, “Pregnancy (refer to the Medical Board of California Guidelines for Prescribing Controlled Substances for pain for additional information).”
- B. Recommendations, 4. Tapering Opioids, 4.1 Indications for Tapering Opioids item 2 is amended to add the phrase “storage and disposal” to correct an omission error.
- B. Recommendations, 9. Managing Peri-Operative Pain in Workers on Chronic Opioid Treatment Undergoing Elective Surgery item 1. an extra space is deleted from items 1d. and 1e. and in item 3 an extra space is deleted from items 3e. and 3f.
- B. Recommendations, 10. Opioid Use in Catastrophic Injuries item 4.c. is amended by deleting the word “must” and replacing it with the word “should” to clarify the Opioids Treatment Guidelines along with the other guidelines set forth in the MTUS are designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers and is not intended to mandate specific clinical practices.
- Appendix A. Brief, Validated Tools is amended by un-italicizing the heading to conform to the format of the document.
- Appendix A2a. Pain Numeric Rating Scale item 4. is amended by adding the visual numeric scale from “0” to “10” to correct an omission error.
- Appendix A2c. Graded Chronic Pain Scale (GCPS)(Longer Survey) items 1., 4., 5., 6., and 7., are amended by deleting the word “facial” to correct a typographical error.

- Appendix B. Written Opioid Treatment Agreement (Sample) is amended by un-italicizing the heading to conform to the format of the document and by deleting the word “or” and replacing it with the word “for” to correct a typographical error in the following listed agreement: “I understand that lack of improvements in function or a later loss of those functional benefit(s) are reasons for my prescriber to discontinue opioid medications.”
- Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT) is amended by un-italicizing the heading to conform to the format of the document and by adding the phrase “Chronic Non-cancer Pain” to clarify the meaning of the acronym “CNCP”. The acronym “CNCP” is amended by placing it in parentheses.
- Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), Clinical Usefulness of UDS, Baseline Measure of Risk is amended by deleting the heading number “2.2.” and replacing it with the number “2.1” to correct a typographical error.
- Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), 2.2. Monitoring for Compliance is amended by adding the phrase “Long-term Opioid Therapy” to clarify the meaning of the acronym “LTOT.” The acronym “LTOT” is amended by placing it in parentheses.
- Appendix C. Guidance on Conducting and Interpreting Urine Drug Testing (UDT), 4. Interpreting Unexpected Results of UDS row 3 in the Table, under the column Possible Explanations is amended by adding the phrase “using medical marijuana” to correct a formatting error that had mistakenly hidden this text from view in the 45-Day Comment Period version.
- Appendix D. Select Black Box Warnings: Important Safety Information on Long-Acting Opioids, Morphine Long Acting Products: Avinza the table is amended by adding a single space between the following words in the second paragraph: between “capsules” and “are” and in the third paragraph: between “on” and “avinza”; “use” and “prescription”; “containing” and “alcohol”; and “alcohol” and “while” to correct typographical errors.
- Appendix E. Opioid Dose and Risk of Morbidity and Mortality is amended by un-italicizing the heading to conform to the format of the document.
- Appendix F. Opioid Dose Calculations is amended by un-italicizing the heading to conform to the format of the document.
- Appendix G. Summary of Screening and Monitoring Recommendations is amended by un-italicizing the heading to conform to the format of the document.
- Acronyms. The list is amended by adding “CNCP Chronic Non-cancer Pain;” and “LTOT Long-term Opioid Therapy” to define acronyms used in the text of the document:

- Title page for the Medical Treatment Utilization Schedule (MTUS) Opioids Treatment Guidelines Part 2 is amended by deleting “July 2015” and replaced with “[Insert Effective Date of Regulations]” because the Opioids Treatment Guidelines will be incorporated by reference into section 9792.24.4 on the effective date of these regulations.

**THE FOLLOWING ADDITIONAL NON-SUBSTANTIVE CORRECTIONS WITHOUT REGULATORY EFFECT WERE MADE TO THE TEXT OF THE PROPOSED GUIDELINES AFTER THE CLOSE OF THE FINAL COMMENT PERIOD**

**Proposed Amendments to the Chronic Pain Medical Treatment Guidelines incorporated by reference in Section 9792.24.2.**

- Part 2: Procedure Summary – Pain, Procedure/Topic, TENS, chronic pain (transcutaneous electrical nerve stimulation) is amended by deleting the letters “los” after the word “recommendations” to correct a typographical error.

**Proposed Amendments to the Opioids Treatment Guidelines incorporated by reference in Section 9792.24.4.**

- Table of Contents, B. Recommendations, 1. Opioids for Acute Pain (up to four weeks after injury or pain onset), 1.2. Moderate to Severe Acute Soft Tissue Injuries is amended by deleting the phrase “Soft Tissue” to make the Table of Contents consistent with the changes made during the 15-Day Comment period to the section heading of 1.2 that clarified the following guidelines are not limited to soft-tissue injuries.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1. Screening for Risk of Addiction or Adverse Events, Prior to Chronic Opioid Treatment is amended by indenting the word “Treatment” in the heading to align with the word “Screening” to correct a typographical indentation error.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.1 Screening for Risk of Addiction or Adverse Events, Prior to Chronic Opioid Treatment, 3.3.1.1 Screening for Drug Misuse/Abuse is amended by deleting spaces to the heading so that the heading aligns with the format of the rest of the document.
- B. Recommendations, 3. Opioids for Chronic Pain and Chronic Opioid Treatment, 3.3. Initiating and Monitoring Chronic Opioid Treatment, 3.3.10 Treating Breakthrough Pain (BTP) is amended by deleting spaces to the heading so that the heading aligns with the format of the rest of the document.

- Appendices Table of Contents, A. Brief, Validated Tools is amended by un-italicizing the heading and underlining it to conform to the format of the document.
- Appendix A2c. Graded Chronic Pain Scale (GCPS)(Longer Survey) item 3 is amended by adding the letter “r” to the word “you” to and the additional “)” close parenthesis is deleted to correct a typographical error.
- Appendix B. Written Opioid Treatment Agreement (Sample) is amended by adding the letter “e” to the word “breath” in Table 1, under Respiratory to correct a typographical error.
- Appendix D. Select Black Box Warnings: Important Safety Information on Long-Acting Opioids, the heading is amended by un-italicizing the heading to conform to the format of the document.

### **JUSTIFICATION FOR INCORPORATION BY REFERENCE**

The “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation-Pain (Chronic)” consisting of an edited version from the Official Disability Guidelines published on April 6, 2015 and “The Guideline for the Use of Opioids to Treat Work-Related Injuries” has been incorporated by reference into the regulations. Incorporation by reference is necessary because these documents incorporated by reference are voluminous and it would be cumbersome and otherwise impractical to publish the entire publication in the California Code of Regulations (1 CCR § 20(c)(1), (c)(2)). The regulations specify how these documents incorporated by reference may be obtained.

### **LOCAL MANDATES DETERMINATION**

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

### **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 Acting 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 and less burdensome to affected private persons and businesses than the regulations that were adopted or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

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

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

The public comment period was as follows:

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

July 17, 2015 – September 1, 2015

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

December 4, 2015 – December 19, 2015