

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

**INITIAL STATEMENT OF REASONS**

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

**TITLE 8, CALIFORNIA CODE OF REGULATIONS,  
SECTIONS 9792.24.2 and 9792.24.4**

**1. Introduction**

This Initial Statement of Reasons ("ISOR") identifies the problems the Administrative Director of the Division of Workers' Compensation (DWC) is attempting to address and describes the purpose and necessity of the proposed revisions and new regulations to the existing Medical Treatment Utilization Schedule (MTUS). The ISOR also provides a description of reasonable alternatives to the proposed regulations and the DWC's reasons for not proposing those alternatives.

Pursuant to Labor Code section 4600(a), the employer is required to provide medical treatment to an injured worker that is reasonably required to cure or relieve the effects of an industrial injury. 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." Labor Code section 4604.5 makes it clear that the recommended guidelines set forth in the MTUS "shall be presumptively correct on the issue of extent and scope of medical treatment."

Labor Code section 5307.27 required the Administrative Director of DWC to adopt a Medical Treatment Utilization Schedule (MTUS) that "shall incorporate the evidenced-based, peer-reviewed, and nationally recognized standards of care" and "that shall address, at a minimum, the frequency, durations, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases." The Administrative Director conducted formal rule making and the MTUS was adopted effective June 15, 2007, consisting of sections 9792.20 through 9792.26, title 8 of the California Code of Regulations. Section 9792.24.2 of the MTUS entitled Chronic Pain Medical Treatment Guidelines was last amended on July 18, 2009.

The proposed regulations amend the MTUS by updating the Chronic Pain Medical Treatment Guidelines set forth in section 9792.24.2 and adopt section 9792.24.4 which incorporates by reference the Opioids Treatment Guidelines to the MTUS.

**2. The Problem being addressed, Specific Purpose, and Necessity of Each Section of the proposed revisions and proposed new MTUS regulations (Gov. Code section 11346.2(b)(1)).**

**Section 9792.24.2. Chronic Pain Medical Treatment Guidelines**

Problem Being Addressed:

Section 9792.24.2, which contains the Chronic Pain Medical Treatment Guidelines, was last amended on July 18, 2009, nearly six years ago. These guidelines need to be updated because of the ever evolving nature of medical evidence. Some recommendations found in the current Chronic Pain Medical Treatment Guidelines are outdated in light of new studies that have since been published.

Specific Purpose:

The specific purpose of the proposed amendments to section 9792.24.2 is to update the evidenced-based Chronic Pain Treatment Guidelines of the MTUS. The last time the DWC went through the rulemaking process to amend section 9792.24.2 was July 18, 2009, nearly six years ago. Currently, the Chronic Pain Medical Treatment Guidelines set forth in section 9792.24.2 is based on an October 31, 2007 frozen version of the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic).” It was adapted with the permission of the Work Loss Data Institute, ODG’s publisher, to fit into the MTUS framework.

The proposed regulations are based on a more current version of the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)”. Section 9792.24.2 informs the public that the Chronic Pain Medical Treatment Guidelines, consisting of two parts, is adopted and incorporated by reference into the MTUS. Part 1 is entitled Introduction, and Part 2 is entitled 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, which the DWC has adapted with permission from the publisher. The section further informs the public that a copy of the Chronic Pain Medical Treatment Guidelines may be obtained from the Medical Unit, Division of Workers’ Compensation, P.O. Box 71010, Oakland, CA 94612-1486 or from the DWC web site at <http://www.dwc.ca.gov>.

Necessity:

The MTUS is the primary source of guidance used by treating physicians and reviewing physicians for the evaluation and treatment of injured workers. Labor Code section 5307.27 is the authorizing statute for the MTUS, and it states the MTUS “shall incorporate the evidence-based, peer-reviewed, nationally recognized standards of care”. Pursuant to Labor Code section 4600, the employer is required to provide medical treatment to the injured worker that is reasonably required to cure or relieve the

effects of the industrial injury. Labor Code section 4600(b) provides that the 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 on the MTUS. Labor Code section 4604.5 makes it clear the MTUS is presumptively correct on the issue of extent and scope of medical treatment. Section 9792.24.2 of the MTUS contains the Chronic Pain Medical Treatment Guidelines which has not been amended in nearly six years. It is necessary to amend the MTUS because some recommendations found in the current Chronic Pain Medical Treatment Guidelines are outdated as a result of newer studies.

Since the MTUS is presumptively correct on the issue of extent and scope of medical treatment, it must be kept up-to-date. To properly guide treating physicians, reviewing physicians and members of the public on issues related to the evaluation and treatment of injured workers suffering from chronic pain, the Chronic Pain Medical Treatment Guidelines must contain recommendations supported by the most current, best available medical evidence.

#### Consideration of Alternatives:

Alternative #1: Allow the most current version of the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” to be automatically incorporated by reference into the MTUS without having to go through the time consuming rulemaking process.

Analysis: This alternative was suggested by several members of the public during preliminary rulemaking activities because they understand that medical evidence is constantly evolving. The need to update medical guidelines is a never ending process because new studies may be published that compels changes to a medical recommendation. The “Official Disability Guidelines (ODG) Treatment in Workers Compensation – Pain (Chronic)” is updated by ODG’s publisher on a regular basis without having to go through the time consuming rule-making process. At best, the rulemaking process takes a few months but usually takes approximately one year to complete. Although this alternative makes practical sense, the ability for members of the public to make comments, both in writing and orally in a public hearing, and to voice their concerns about proposed regulatory changes will be stripped away. This alternative is not feasible because it bypasses the rulemaking process and constitutes an unlawful transfer of the DWC’s regulatory power.

Alternative #2: The DWC should create its own chronic pain treatment guideline instead of adapting the “Official Disability Guidelines (ODG) Treatment in Workers Compensation – Pain (Chronic),” which is an existing proprietary guideline.

Analysis: In order for the DWC to create its own chronic pain treatment guideline, it must conduct a search of the medical literature covering the broad topic of chronic pain. This would require a large investment of the DWC’s resources that would, in essence, be duplicative of the work that has already been done by many guideline makers,

including ODG's publisher. Rather than use its resources duplicating the work already done by ODG's publisher, the DWC focused its resources on reviewing existing chronic pain guidelines to determine which guideline provides a framework for the most effective treatment for work related injuries or conditions. The DWC determined that the "Official Disability Guidelines (ODG) Treatment in Workers Compensation – Pain (Chronic)" fulfills this goal.

In addition, during the preliminary rulemaking activities, concerns were raised about the motives and potential bias of proprietary guidelines and whether or not they can be trusted. Labor Code section 5307.27 requires the Administrative Director to adopt a Medical Treatment Utilization Schedule (MTUS) that "shall incorporate the evidenced-based, peer-reviewed, and nationally recognized standards of care". The DWC created the MTUS by using a patch-work approach. Most of the existing guidelines in the MTUS were derived from three sources: ODG, the American College of Occupational Medicine (ACOEM), and the state of Colorado's medical treatment guideline. Both ODG and ACOEM are proprietary guidelines. In their respective methodologies, bias and conflicts of interests were factored in by both ODG and ACOEM when evaluating medical evidence for their recommendations. The DWC, with the assistance of the advisory recommendations made by the Medical Evidence Evaluation Advisory Committee (MEEAC), vetted both proprietary guidelines and is satisfied with the trustworthiness of both ODG and ACOEM's guidelines.

No more effective alternative to the Chronic Pain Medical Treatment Guidelines, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time. The public is invited to submit such alternatives during the public comment process.

#### **Section 9792.24.4. Opioids Medical Treatment Guidelines**

##### Problem Being Addressed:

Currently, the MTUS addresses the use of opioids in the Chronic Pain Medical Treatment Guidelines. Although opioids may be useful as an adjunct in the treatment of pain, opioid misuse remains a national concern due to adverse health impacts and other unintended consequences. According to the US Centers for Disease Control and Prevention (CDC), deaths associated with prescription opioids rose from 4,000 in 1999 to over 14,000 in 2008 (CDC 2011). As a result of the ongoing national concern, the topic of opioids deserves its own separate stand-alone guidelines that cover the use of opioids not just for the treatment of chronic pain conditions but also for the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain with the goal of improving function.

### Specific Purpose:

The purpose of this section is to add a separate, stand-alone Opioids Treatment Guidelines to the MTUS. Currently the Chronic Pain Medical Treatment Guidelines set forth in section 9792.24.2 addresses the use of opioids for chronic pain conditions. The proposed regulations would add section 9792.24.4 entitled Opioids Treatment Guidelines to the MTUS to comprehensively cover the use of opioids. Section 9792.24.4(a) informs the public that the Opioids Treatment Guidelines consisting of two parts are adopted and incorporated by reference into the MTUS. Part 1 contains the executive summary, abbreviated treatment protocols, background information, complete recommendations, and appendices with useful tools for clinicians. Part 2 contains supplemental information consisting of a discussion of the medical evidence supporting the recommendations and a summary of recommendations from other guidelines that were reviewed. These guidelines will replace the existing parts of the MTUS that refer to opioid use. A copy of the Opioids Treatment Guidelines may be obtained from the Medical Unit, Division of Workers' Compensation, P.O. Box 71010, Oakland, CA 94612-1486, or from the DWC web site at <http://www.dwc.ca.gov>.

Section 9792.24.4(b) describes the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain. The Opioids Treatment Guidelines apply when alternative therapies do not provide adequate pain relief, and opioid medications are being considered as part of the treatment regimen.

### Necessity:

It is necessary to create a separate, stand-alone guideline that provides clearer, more comprehensive guidance for the use of opioids in the California workers' compensation system. As a result of opioid misuse, injured workers have suffered from adverse health impacts and other unintended consequences. Yet the use of opioids may be useful as an adjunct in the treatment of pain. The more detailed, comprehensive guidance of the proposed MTUS' Opioids Treatment Guidelines, supported by current, best available evidence, provides a balance between appropriate treatment of pain among injured workers and safety in the use of opioids for that purpose.

### Consideration of Alternatives:

Alternative #1: This alternative would adopt the most current version of the "Official Disability Guidelines (ODG) Treatment in Workers Compensation – Pain (Chronic)" without deleting the sections on opioids. To avoid confusion and reduce complexity, this alternative would maintain the status quo format and would not create a separate Opioids Treatment Guidelines in the MTUS.

Analysis: In the interest of ease of use for physicians and members of the public, this alternative prefers the ODG as a single-source that covers the topic of chronic pain and

opioids. Although the Chronic Pain Medical Treatment Guidelines currently covers the topic of opioids, it lacks specificity to comprehensively cover the use of opioids for injured workers in the workers' compensation system. In addition to providing guidance for the use of opioids prescribed for chronic pain patients, the proposed Opioids Treatment Guidelines also provides comprehensive guidance for the use of opioids prescribed for patients to assist in safer, more judicious and effective use of opioids, if they are prescribed for acute pain, sub-acute, and perioperative situations with the goal of improving function.

Alternative #2: Adopt the recently published 2014 ACOEM (March 2014) Opioid Treatment Guideline in lieu of the proposed Opioids Treatment Guidelines.

Analysis: This alternative proposes the adoption of ACOEM's Opioids Treatment Guideline recently published on March 2014 in lieu of the proposed Opioids Treatment Guidelines. The DWC began working on the MTUS' Opioids Treatment Guidelines in November 2012. At that time, ACOEM's Guidelines for the Chronic Use of Opioids had already been published and was one of the guidelines evaluated by MEEAC and the DWC. The DWC was unaware that ACOEM had plans to update their opioids guideline to develop more detailed and comprehensive guidance for treatment of acute, sub-acute, chronic and postoperative pain with opioids. By the time the DWC found out that ACEOM was in the process of drafting an updated opioids guideline, the DWC had already invested many hours and resources in its efforts to draft its own separate opioids guideline. When the DWC initially published its proposed regulations during the preliminary rulemaking activities in April 2014, it had not yet reviewed ACOEM's Opioids Treatment Guideline published one month earlier. Since then, the DWC has evaluated and incorporated ACOEM's Opioids Treatment Guideline published on March 2014 into these proposed regulations. However, the DWC will not adopt ACOEM's guideline in lieu of the proposed MTUS Opioids Treatment Guidelines for the following reasons: ACOEM's Opioids Treatment Guideline will need to be adapted to the MTUS and formatting changes will likely need to be made; the time and effort to draft the Opioids Treatment Guideline has already been expended by MEEAC and the DWC; and finally, although both guidelines are substantively very similar, they differ in the recommended morphine equivalent dose that should trigger a consultation with a specialist. The ACOEM Opioids Treatment Guideline contains a morphine equivalency threshold dose of 50 mg per day whereas the proposed MTUS Opioids Treatment Guidelines contain a morphine equivalency dose of 80 mg per day. The morphine equivalency threshold dose of 80 mg per day is based on the most recent evidence and represents the nuanced and balanced approach that is both scientifically accurate and implementable in the state of California. No other guideline considered contained this dose. In November 2014 after the DWC published the proposed MTUS Opioids Treatment Guidelines during preliminary rulemaking activities, the Medical Board of California published its "Guidelines for Prescribing Controlled Substances for Pain" which also contains a recommended morphine equivalency dose of 80 mg per day that should trigger a consultation with a specialist. Adopting the proposed MTUS Opioids Treatment

Guidelines ensures statewide coordination and consistency with the Medical Board of California.

No more effective alternative to the Chronic Pain Medical Treatment Guidelines, nor equally effective and less burdensome alternative, has been identified by the Administrative Director at this time. The public is invited to submit such alternatives during the public comment process.

**3. Technical, Theoretical, or Empirical Studies, Reports, or Documents upon which the Division relied upon:**

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#### **4. Specific Technologies or Equipment.**

None.

**5. Duplication or Conflicts with Federal Regulations (Gov. Code section 11346.2(c)).**

The proposed regulations do not duplicate or conflict with any federal regulations. There are no federal regulations that prescribe rules for the guidance of the treatment and evaluation of chronic pain conditions or opioid medication prescriptions as it pertains to the California workers' compensation system.

**6. Facts, evidence, documents, testimony, or other evidence on which the agency relies to support an initial determination that the action will not have a significant adverse economic impact on business. (Gov. Code section 11346.2(b)(5)(A)).**

The Administrative Director has determined that the proposed regulations will not have a significant, statewide adverse economic impact directly affecting business. The proposed regulations will update the Chronic Pain Medical Treatment Guidelines and will set forth a separate Opioids Treatment Guidelines to provide more detailed and comprehensive guidance for the use of opioids in the California workers' compensation system.

As is the case whenever there are new regulations, businesses will be impacted because of the costs associated with the time expenditure to familiarize their employees with the regulatory changes. Businesses that will be affected by these proposed regulations include treating medical providers, Utilization Review physicians, Independent Medical Review physicians and claims administrators, which include insurers, third-party administrators and self-insured employers. It is unnecessary for businesses affected by these proposed regulations to require each employee to read every treatment recommendation discussed in the guidelines. Rather, in order to properly utilize both guidelines, it is necessary to understand the format and how to navigate through the guidelines to find treatment recommendations for the evaluation and treatment of injured workers. The DWC has estimated it will take approximately two hours for each employee to become familiar with both the Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines.

The Chronic Pain Medical Treatment Guidelines and the Opioids Treatment Guidelines will be posted on the Division's website and will be available to all members of the public free of charge. Even though the Chronic Pain Guidelines are adapted from the "Official Disability Guidelines (ODG) Treatment in Workers' Compensation – Pain (Chronic)" a proprietary guideline published by the Work Loss Data Institute (WLDI), the DWC has an agreement with the WLDI that permits the publishing of the Chronic Pain Medical Treatment Guidelines of the MTUS on DWC's website free of charge. Members of the public may make copies of the MTUS Chronic Pain Guidelines as necessary in connection with the use and application of the MTUS. In addition, because the separate

Opioids Treatment Guidelines was created by the DWC with the assistance from the advisory recommendations provided by MEEAC, The MTUS' Opioids Treatment Guidelines will also be published on DWC's website free of charge and members of the public may make copies as necessary in connection with the use and application of the MTUS.

Despite the large number of businesses that will be impacted by these new regulations, there will be no significant economic impact because the costs associated with the time expenditure to familiarize its employees with the new regulations will likely be offset by the savings from the avoidance of inappropriate medical treatment as a result of the clearer guidance for the evaluation and treatment of injured workers, the delivery of state-of-the-art treatment when appropriate for the patient, improved health outcomes, and reduced overall costs of caring for chronic conditions and the prescribing of opioids.

Therefore, these proposed regulations will not have a significant adverse economic impact on business in California.

## **7. Economic Impact Analysis ((Gov. Code section 11346.3(b)(1)(A)-(D)).**

### The Creation or Elimination of Jobs within the State of California

The Administrative Director has determined that the proposed regulations will not have a significant impact on the creation of or elimination of jobs within the State of California. The proposed regulations will provide more up-to-date and comprehensive guidance for the evaluation and treatment of injured workers suffering from chronic pain or using opioid medications. Although improvements will be made to the injured workers' medical care because of the more up-to-date, comprehensive guidance, the proposed regulations will neither create nor eliminate jobs within the State of California.

### Creation of New Businesses or the Elimination of Existing Businesses within the State of California

The Administrative Director has determined that the proposed regulations will not significantly create or eliminate businesses within the State of California. The proposed regulations will provide more up-to-date and detailed guidance for the evaluation and treatment of injured workers suffering from chronic pain or using opioid medications. Although improvements will be made to the injured workers' medical care because of the more up-to-date, comprehensive guidance, the proposed regulations will neither create new businesses nor eliminate existing businesses within the State of California.

### The Expansion of Businesses Currently Doing Business within the State of California

The Administrative Director has determined that the proposed regulations will not significantly expand businesses within the State of California but the proposed regulations will provide more up-to-date and comprehensive guidance for the evaluation

and treatment of injured workers suffering from chronic pain or using opioid medications. The more up-to-day and comprehensive guidance will help reduce medical costs with the avoidance of inappropriate medical care and non-quantifiable savings in disability costs and utilization review. As a result, the expected improved health outcomes for affected injured workers may allow some businesses within California to expand because of a more productive, healthy, work-force.

### Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The more up-to-date, comprehensive Chronic Pain Medical Treatment Guidelines and Opioids Treatment Guidelines are expected to save costs for impacted businesses, reduce workers compensation costs for California's employers, and produce improved health outcomes for affected injured workers.

California businesses impacted by these regulations can quickly expect to recuperate the initial costs associated with the time it will take to familiarize their employees with the proposed regulations. For example, treating physicians and reviewing physicians will have a better idea of what treatment requests are reasonable and necessary for the treatment and evaluation of injured workers. The proposed Opioids Treatment Guidelines now will comprehensively address 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. Currently the MTUS only provides guidance for the use of opioid medications for the treatment of chronic non-cancer pain. This clarity will allow treating physicians to see more patients instead of spending their valuable time defending treatment disputes in depositions or court appearances. On the other hand, reviewing physicians (Utilization Review and Independent Medical Review) can efficiently and confidently make decisions because of the more comprehensive coverage of the proposed guidelines. This would obviate the need for reviewing physicians performing the time consuming and costly medical literature research to find recommendations addressing a treatment request that currently is not found in the MTUS. Finally, claims administrators will be able to make better, more efficient decisions because of the clarity provided for in these proposed guidelines. For example, if a treating physician makes a treatment request for his or her patient to consult with a pain specialist because the patient is currently taking opioids that is greater than 80 mg of morphine equivalency, the claims administrator can confidently approve the request without incurring the costs and time needed to send the request to Utilization Review.

The clarity and comprehensive coverage of these proposed guidelines will also benefit California's employers. Inappropriate medical treatment will be avoided, resulting in savings for employers because of a reduction in workers' compensation costs. Employers will not have to pay for unnecessary medical treatments, and there will be fewer disputes regarding appropriate medical treatments. In addition, a healthier more productive work-force may allow some businesses to reinvest and expand as a result of the expected reduction in workers' compensation costs.

Finally, injured workers may now be approved to receive state-of-the-art treatments if new evidence supports its reasonableness and necessity. This allows injured workers' to return to work sooner and once again reap the benefits of their regular pay instead of receiving a lesser amount in Temporary Disability payments. In addition, the ability to receive state-of-the-art treatments, supported by the best current medical evidence, should improve the health and well-being of California's injured workers.