

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
Division of Workers' Compensation**

NOTICE OF PROPOSED RULEMAKING

Subject Matter of Regulations: Medical Treatment Utilization Schedule

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

NOTICE IS HEREBY GIVEN that the Administrative Director of the Division of Workers' Compensation (hereinafter "Administrative Director") pursuant to the authority vested in her by Labor Code sections 59, 133, 4604.5, 5307.3 and 5307.27, proposes to amend and adopt the proposed regulations contained in Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, sections 9792.24.2 and 9792.24.4, relating to the Medical Treatment Utilization Schedule (MTUS). These proposed amendments and additions do the following: amend section 9792.24.2 to incorporate by reference an updated Chronic Pain Medical Treatment Guidelines to the MTUS based on a frozen version of the "Official Disability Guidelines (ODG) Treatment in Workers' Compensation – Pain (Chronic)" published by the Work Loss Data Institute on April 6, 2015; adopt a new section 9792.24.4 to incorporate by reference a separate Opioids Treatment Guidelines to the MTUS that comprehensively covers the use of opioids for the treatment of pain prescribed for patients on a chronic non-cancer pain basis but also for the use of opioids prescribed for patients with acute pain, sub-acute pain, and for perioperative situations.

PROPOSED REGULATORY ACTION

The Department of Industrial Relations, Division of Workers' Compensation, proposes to amend Article, 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, by amending existing section 9792.24.2 and adopting a new section 9792.24.4.

Amend Section 9792.24.2 Medical Treatment Utilization Schedule – Chronic Pain
Medical Treatment Guidelines
Adopt Section 9792.24.4 Medical Treatment Utilization Schedule – Opioids Treatment
Guidelines

TIME AND PLACE OF PUBLIC HEARING

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, oral or in writing, with respect to the proposed regulatory action, on the following date:

Date: September 1, 2015
Time: 10:00 a.m. to 5:00 p.m., or until conclusion of business
Place: Elihu Harris State office Building - Auditorium
1515 Clay Street
Oakland, CA 94612

The State Office Building and its Auditorium are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or other type of reasonable accommodation to facilitate effective communication for persons with disabilities, are available upon request. Please contact the State Wide Disability Accommodation Coordinator, Maureen Gray, at 1-866-681-1459 (toll free), or through the California Relay Service by dialing 711 or 1-800-735-2929 (TTY/English) or 1-800-855-3000 (TTY/Spanish) as soon as possible to request assistance.

Please note that public comment will begin promptly at 10:00 A.M. and will conclude when the last speaker has finished his or her presentation or 5:00 P.M., whichever is earlier. If public comment concludes before the noon recess, no afternoon session will be held.

The Administrative Director requests, but does not require, that any persons who makes oral comments at the hearing also provide a written copy of their comments. Equal weight will be accorded to oral comments and written materials.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department of Industrial Relations, Division of Workers' Compensation. The written comment period closes at 5:00 P.M., on September 1, 2015. The Division of Workers' Compensation will only consider comments received at the Department of Industrial Relations, Division of Workers' Compensation by that time. Equal weight will be accorded to oral comments presented at the hearing and written materials.

Submit written comments concerning the proposed regulations prior to the close of the public comment period to:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
P.O. Box 420603
San Francisco, CA 94612

Written comments may be submitted via facsimile transmission (FAX), addressed to the above-named contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: dwcrules@dir.ca.gov.

Unless submitted prior to or at the public hearing, Ms. Gray must receive all written comments no later than 5:00 P.M., on September 1, 2015.

AUTHORITY AND REFERENCE

The Administrative Director is undertaking this regulatory action pursuant to the authority vested in her by Labor Code sections 59, 133, 4600, 4604.5, 5307.3 and 5307.27. Reference is to Labor Code sections 4600, 4604.5 and 5307.27, Labor Code.

INFORMATIVE DIGEST/POLICY OVERVIEW

Pursuant to Labor Code section 4600(a), the employer is required to provide medical treatment to the injured worker that is reasonably required to cure or relieve the effects of an 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 upon the MTUS.

Labor Code section 5307.27 required 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” and “that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers’ compensation cases.” The Administrative Director conducted formal rulemaking 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. Currently, the MTUS addresses the use of opioids in the Chronic Pain Medical Treatment Guidelines; however, it only provides guidance for the use of opioids for the treatment of chronic pain conditions.

This notice amends section 9792.24.2 of the MTUS and adds section 9792.24.4 to the MTUS. Section 9792.24.2 is amended and the Chronic Pain Medical Treatment Guidelines is updated by adapting and freezing a current version of the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)”. The last time the Administrative Director 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 is necessary to amend section 9792.24.2 and update the Chronic Pain Medical Treatment Guidelines because some recommendations found in the current Chronic Pain Medical Treatment Guidelines are outdated as a result of new studies that have since been published that support revisions to these recommendations. Section 9792.24.4 is added to the MTUS as a separate Opioids Treatment Guidelines. 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 that comprehensively covers the use of opioids. It is necessary to add section 9792.24.4 as a separate Opioids Treatment Guidelines to provide guidance for the use of opioid medications, not just for the treatment of chronic pain conditions but also as part of an overall multidisciplinary treatment regimen for acute, sub-acute, post-operative, and chronic non-cancer pain and with the goal of improving function.

The proposed amendments to the regulations are intended to implement, interpret or make specific the applicable Labor Code sections as follows:

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

- Subdivision (a) is amended to delete the “May 2009” effective date and reinsert the effective date of these regulations upon approval. In addition, the title to Part 2 “Pain Interventions and Treatments” is deleted and replaced with the “Official Disability Guidelines (ODG) Treatment in Workers’ Compensation – Pain (Chronic)” which consists of an edited version of the Official Disability Guidelines published on April 6, 2015, which the Division of Workers’ Compensation has adapted with permission from the publisher. The sentence that references Chapter 6 of the ACOEM Practice Guidelines is deleted and the following sentence that references the “pain chapter” or “pain assessment” is deleted because they are no longer applicable. Capital letters replace the lower case letters in the title “Chronic Pain Medical Treatment Guidelines” in the title chronic pain medical treatment guidelines.
- In subdivisions (b), (c) and (d), capital letters replace the lower case letters in the title “Chronic Pain Medical Treatment Guidelines” whenever the title chronic pain medical treatment guidelines appear.
- Subdivision (e) is deleted as unnecessary because the scientific literature references are already incorporated in Parts 1 and 2 of the Chronic Pain Medical Treatment Guidelines.

Proposed Adoption of Section 9792.24.4. Medical Treatment Utilization Schedule – Opioids Treatment Guidelines

- Subdivision (a) provides that the Opioids Treatment Guidelines, consisting of two parts, are adopted and incorporated by reference into the MTUS. It indicates that 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. It further informs the public that these guidelines will replace the existing parts of the MTUS that refer to opioid use and that a copy of the guideline 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>.

- Subdivision (b) provides that the Opioids Treatment Guidelines describe 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. In addition it mandates these guidelines apply when alternative therapies do not provide adequate pain relief and opioid medications are being considered as part of the treatment regimen.

Objective and Anticipated Benefits of the Proposed Regulations:

The objectives of the proposed regulations are to update the Chronic Pain Medical Treatment Guidelines and to add a separate Opioids Treatment Guidelines to the MTUS. Updating the Chronic Pain Medical Treatment Guidelines is necessary because they were last amended July 2009, nearly six years ago. Because of the ever evolving nature of medical evidence, some of the recommendations found in the current Chronic Pain Medical Treatment Guidelines are outdated in light of newer studies that support revisions to these recommendations. A separate Opioids Treatment Guidelines is necessary because the use of opioids is currently addressed in the Chronic Pain Medical Treatment Guidelines but that guidance is limited to opioid use for the treatment of chronic pain conditions. The proposed Opioids Treatment Guidelines comprehensively covers the use of opioids not just for chronic pain, but also for the appropriate use of opioid medications as part of an overall multidisciplinary treatment regimen for acute, sub-acute, and post-operative pain and with the goal of improving function.

The proposed regulations will be beneficial to the health and welfare of injured workers, save costs for impacted businesses and reduce workers' compensation costs for California's employers as a result of the clearer, more comprehensive guidance supported by the most current medical evidence.

Determination of Inconsistency/Incompatibility with Existing State Regulations:

The Administrative Director has determined that these proposed regulations are not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would relate to or affect this area, the Administrative Director has concluded that these are the only regulations that provide guidance for the treatment of chronic pain conditions and for the safe and efficacious prescription of opioid medications for California's injured workers.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Administrative Director has made the following initial determinations:

- Mandate on local agencies and school districts: None.

- Cost or savings to any state agency: To the extent that the state is a self-insured employer (i.e. California's State Agencies including the public enterprise fund State Compensation Insurance Fund) and has employees handling its own workers' compensation claims, minor costs will be incurred associated with the time expenditure needed to familiarize its employees adjusting workers' compensation claims with the new Chronic Pain Treatment Guidelines and the Opioids Treatment Guidelines. However, these costs will be offset by the clearer, more up-to-date guidelines because of the more efficient delivery of state-of-the art treatment, when appropriate, and the avoidance of inappropriate medical treatment resulting in the reduction of workers' compensation claims costs. In addition, the comprehensive guidance should reduce disputes over the reasonableness and necessity of many treatment requests for the treatment of chronic pain conditions and the prescribing of opioids.
- Cost to any local agency or school district which must be reimbursed in accordance with Government Code section 17500 through 17630: None.
- Other nondiscretionary cost or savings imposed on local agencies: None.
- Cost or savings in federal funding to the state: None.
- Cost impacts on a representative private person or business: The Administrative Director has determined that the proposed regulations will not have a significant adverse economic impact on representative private persons or directly affected businesses. These representative private persons or directly affected businesses are treating physicians, Utilization Review physicians, Independent Medical Review physicians, and claims administrators which include insurers, third-party administrators and self-insured employers. As is the case whenever there are new regulations, businesses will be impacted because of the time needed to familiarize its employees with the new regulations. 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. However, the costs associated with the time expenditure 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 (see Benefits of the Proposed Action, below).
- Statewide adverse economic impact directly affecting businesses and individuals:

Although the proposed action will directly affect business statewide, specifically treating physicians, reviewing physicians and claims administrators, the Administrative Director concludes that the adverse economic impact including the ability of California businesses to compete with business in other states, will not be significant because the initial costs associated with the time expenditure to familiarize its employees with the new regulations will be quickly recuperated with the anticipated system-wide savings (see Benefits of the Proposed Action, below).

- Significant effect on housing costs: None.

Results of the Economic Impact Analysis/Assessment:

- The Administrative Director concludes that it is (1) unlikely the proposal will create jobs within the State of California, (2) unlikely that the proposal will eliminate any jobs within the State of California, (3) unlikely that the proposal will create some new businesses within the State of California, (4) unlikely that the proposal will eliminate any existing businesses within the State of California, and (5) unlikely the proposal would cause the expansion of the businesses currently doing business within the State of California although the anticipated improved health outcomes for affected injured workers may allow some businesses to expand because of a more productive, healthy, work-force (see Benefits of the Proposed Action, below).
- Benefits of the Proposed Action: 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 from performing time consuming and costly medical literature research to find recommendations addressing a treatment request that 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 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 the lesser amount in Temporary Disability. 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.

- **Small Business Determination:** The Administrative Director has determined that the proposed regulations will not affect small businesses to a significant degree. As already stated, minor costs associated with the time needed to familiarize employees with the new guidelines may be incurred by treating physicians, reviewing physicians, and claims administrators; but those minor costs will likely be offset by the anticipated savings 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.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Administrative Director must determine that no reasonable alternative considered or brought to the attention of the Administrative Director's attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Administrative Director invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period, or at the public hearing.

CONTACT PERSON FOR GENERAL QUESTIONS

Non-substantive inquiries concerning this action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed regulations, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file may be requested in writing at the same address. The contact person is:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
P.O. Box 420603
San Francisco, CA 94612
E-mail: mgray@dir.ca.gov
Telephone: (510) 286-7100

CONTACT PERSON FOR SUBSTANTIVE QUESTIONS

In the event the contact person is unavailable, or for questions regarding the substance of the proposed regulations, inquiries should be directed to:

John Cortes
Division of Workers' Compensation
P.O. Box 420603
San Francisco, CA 94142
Email: jcortes@dir.ca.gov
Telephone: (510) 286-7100

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

An Initial Statement of Reasons and the text of the proposed regulations in plain English have been prepared and are available from the contact person named in this Notice. The entire rulemaking file will be made available for inspection and copying at the address indicated below.

As of the date of this Notice, the rulemaking file consists of the Notice, the Initial Statement of Reasons, proposed text of the regulations, pre-rulemaking comments and the Economic Impact Statement (Form STD 399). In addition, the Notice, Initial Statement of Reasons, and proposed text of the regulations being proposed may be accessed and downloaded from the Division's website at www.dir.ca.gov. To access them, click on the "Proposed Regulations – Rulemaking" link and scroll down the list of rulemaking proceedings to find the Medical Treatment Utilization Schedule (MTUS) link. Any interested person may inspect a copy or direct questions about the proposed regulations and any supplemental information contained in the rulemaking file. The

rulemaking file will be available for inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 17th Floor, Oakland, California 94612, between 9:00 A.M. and 4:30 P.M., Monday through Friday. Copies of the proposed regulations, Initial Statement of Reasons and any information upon which the proposed rulemaking file is based may be requested in writing to the contact person.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Administrative Director may adopt the proposed regulations substantially as described in this notice. If the Administrative Director makes modifications which are sufficiently related to the originally proposed text, the Administrative Director will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Administrative Director adopts the regulations as received.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Upon its completion, the Final Statement of Reasons will be available and copies may be requested from the contact person named in this Notice or may be accessed on the Division's website at: www.dir.ca.gov.

AUTOMATIC MAILING

A copy of this Notice, the Initial Statement of Reasons, and the text of the regulations, will automatically be sent to those interested persons on the Administrative Director's mailing list.

If adopted, the regulations as amended will appear in the California Code of Regulations, title 8, commencing with section 9792.24.2. The text of the final regulations also may be available through the website of the Office of Administrative Law at www.oal.ca.gov.