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

### NOTICE OF PROPOSED RULEMAKING

Subject Matter of Regulations: Medical Treatment Utilization Schedule

# <u>TITLE 8, CALIFORNIA CODE OF REGULATIONS,</u> SECTIONS 9792.20 – 9792.26

NOTICE IS HEREBY GIVEN that the Acting Administrative Director of the Division of Workers' Compensation (hereinafter "Acting 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 9792.20 through 9792.26, relating to the medical treatment utilization schedule (MTUS). These proposed amendments do the following: revise regulatory definitions and add new definitions primarily for terms used in the strength of evidence section, clarify that the MTUS constitutes the standard for the provision of medical care in accordance with Labor Code section 4600, set forth the process to determine if medical care is reasonable and necessary when the MTUS is silent on a particular medical condition or diagnostic test or when the MTUS is successfully rebutted, establish a minimum standard for conducting a medical literature search, explicitly set forth a systematic methodology to determine the strength of evidence used to support the recommendations of a medical condition, and finally, amend the composition of the Medical Evidence Evaluation Advisory Committee (MEEAC) to include two additional members, one from the pharmacology field and one from the nursing field.

#### 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, Sections 9792.20 through 9792.26, and adopt Article 5.5.2 of Chapter 4.5, Subchapter 1, of Title 8, California Code of Regulations, and Sections 9792.20 through 9792.26.

Amend Section 9792.20	Medical Treatment Utilization Schedule - Definitions
Amend Section 9792.21	Medical Treatment Utilization Schedule; Medical Literature
	Search Sequence
Amend Section 9792.25	Strength of Evidence – Definitions
Adopt Section 9792.25.1	Strength of Evidence – Method for Evaluating the Quality of
	Evidence Used to Support a Recommendation; MTUS Hierarchy
	of Evidence for Different Clinical Questions
Amend Section 9792.26	Medical Evidence Evaluation Advisory Committee

### 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 follow date:

**Date: July 1, 2014** 

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 Acting 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 July 1, 2014. 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 abovenamed contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: <a href="mailto:dwcrules@dir.ca.gov">dwcrules@dir.ca.gov</a>.

Unless submitted prior to or at the public hearing, Ms. Gray must receive all written comments no later than 5:00 P.M., on July 1, 2014.

#### **AUTHORITY AND REFERENCE**

The Acting 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 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 upon the MTUS.

Labor Code section 5307.27 required the Administrative Director to adopt a Medical Treatment Utilization Schedule (MTUS) that is "scientific and evidenced-based, peer-reviewed, and nationally recognized." The Administrative Director conducted formal rulemaking and the MTUS was adopted effective June 15, 2007.

This notice addresses the following specific sections of the MTUS: section 9792.20 revises and adds regulatory definitions, section 9792.21 describes how the MTUS is based on the principles of Evidenced-Based Medicine (EBM) and constitutes the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions. This section sets forth the scientific process used to determine when medical care is reasonable and necessary when the MTUS is silent on a particular medical condition or diagnostic test or when the MTUS is successfully rebutted pursuant to Labor Code section 4604.5. The scientific process begins with a medical literature search sequence to guide those making treatment decisions find recommendations applicable to the injured worker's medical condition. Section 9792.25 adds additional regulatory definitions for terms used in determining the strength of medical evidence that supports a recommendation, section 9792.25.1 explicitly sets forth a systematic methodology to determine the strength of evidence used to support the recommendations of a medical condition, and finally, section 9792.26 addresses the role and duties of the Medical Evidence Evaluation Advisory Committee (MEEAC). All other MTUS sections remain unchanged and are not the subject of this notice of rulemaking.

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 9792.20 Medical Treatment Utilization Schedule – Definitions**

• This section defines key terms used in the MTUS regulations.

- This section is re-lettered to accommodate additional definitions.
- Definitions for the terms "Evidenced-Based Medicine" and "ODG" are added to ensure that its meaning, as used in the regulations, will be clear to the public.
- Subdivision (e) the definition of "Evidence-Based" is deleted and replaced with the definition for "Evidence-Based Medicine (EBM)" to provide a term that describes the broader systematic approach to making clinical decisions which allows the integration of best available research evidence with clinical expertise and patient values.
- Subdivision (f) the definition of "Functional improvement" is amended to delete the phrase "evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to section 9789.10–9789.111" and replaced with the phrase "medical evaluation and treatment" to provide a more comprehensive definition.
- Subdivision (j) the definition of "Nationally recognized" is amended to delete the phrase "; or currently adopted for use by one or more U.S. state governments or by the U.S. federal government;" for clarity and precision to the definition.
- Subdivision (k) the definition for "ODG" is added to clarify the Official Disability
  Guidelines published by the Work Loss Data Institute contains evidence-based medical
  treatment guidelines for conditions commonly associated with the workplace. The street
  address and website address are included to inform the public where guidelines may be
  obtained.
- Subdivision (l) is re-lettered from (k) and the definition of "Peer reviewed" is amended to delete the specific reference to "medical" study's and broadening the term to include any study's content, methodology, and results that have been evaluated and approved prior to publication by an editorial board of qualified experts.
- Subdivision (m) is re-lettered from (l) and the definition of "Scientifically based" is amended to delete the phrase "in MEDLINE" because a literature search involves more than literature found in MEDLINE. In addition, the phrase "for the guideline" is deleted and replaced with the phrase "to support a recommendation" for accuracy because scientific literature can be used as the basis for a guideline and to support a recommendation in a peer-reviewed published study.
- Subdivision (n) is re-lettered from (m).

# Proposed Amendments to Section 9792.21 – Medical Treatment Utilization Schedule; Medical Literature Search Sequence

• This section sets forth the role of the MTUS in providing a framework for the evaluation and treatment of injured workers and the process to follow when the MTUS is silent on a particular medical condition or diagnostic test or when the MTUS is successfully rebutted. This section also provides a minimum standard when conducting a medical literature search. The title of the section is amended to add "Medical Literature Search Sequence".

- Subdivision (b) clarifies the MTUS provides a framework for the most effective treatment of work-related illness or injury to achieve functional improvement, return-to-work, and disability prevention.
- Subdivision (c) describes EBM as a systematic approach to making clinical decisions which allows the integration of the best available research evidence with clinical expertise and patient values. EBM requires the evaluation of medical evidence by applying an explicit systematic methodology to determine the strength of evidence used to support the recommendations for a medical condition. The best available evidence is then used to guide clinical decision making.
- Subdivision (d) is re-lettered from (c). The previous subdivision (c) is deleted and replaced with the clarification that the MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services and that the MTUS constitutes the standard for the provision of medical care in accordance with Labor Code section 4600.
- Subdivision (e) is added to acknowledge the MTUS does not address every medical condition or diagnostic test and the MTUS's presumption of correctness may be successfully rebutted.
- Subdivision (e)(1) is added to specify the MTUS' presumption of correctness may be rebutted if medical evidence is cited that contains a recommendation applicable to the specific medical condition or diagnostic test requested by the injured worker and the recommendation is supported with a higher level of evidence than the medical evidence used to support the MTUS' recommendation.
- Subdivision (f) is added to clarify when the MTUS is silent on a particular medical condition
  or diagnostic test or when the MTUS is successfully rebutted, medical care shall be in
  accordance with the best available medical evidence found in scientifically and evidencedbased medical treatment guidelines and/or peer-reviewed published studies that are nationally
  recognized by the medical community.
- Subdivision (g) requires a medical literature search be conducted by medical reviewers making treatment decisions and should be conducted by the requesting provider to find the recommendation supported with the highest level of evidence that is applicable to the injured workers' specific medical condition when there is a situation described in subdivision (f).
- Subdivision (h) acknowledges a comprehensive medical literature search is resourceintensive. For purposes of this section and in the interest of efficiency and consistency, the medical literature search sequence set forth in subdivision (i) shall be sufficient.
- Subdivisions (i)(1-3) set forth a medical literature search sequence that, at a minimum, shall be followed: (1) Search the most current version of ACOEM or ODG to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. Continue to step two if the current version is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported

by a higher level of evidence (2) Search the most current version of other evidence-based medical treatment guidelines that are recognized by the national medical community and are scientifically based to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1. Continue to step three if the current version is more than five years old, or if no applicable recommendation is found, or if the medical reviewer or treating physician believes there is another recommendation supported by a higher level of evidence (3) Search for current studies, five years old or less, that are scientifically based, peer-reviewed, and published in journals that are nationally recognized by the medical community to find a recommendation applicable to the injured worker's specific medical condition. Choose the recommendation that is supported with the highest level of evidence according to the strength of evidence methodology set forth in section 9792.25.1.

- Subdivision (j) requires that Utilization Review decisions and Independent Medical Review decisions shall cite the medical treatment guideline or peer-reviewed published study that contains the recommendation supported with the highest level of evidence. Treating physicians may cite the medical treatment guideline or peer-reviewed published study with the recommendation supported with the highest level of evidence in the chart notes or Request for Authorization, particularly if barriers to getting authorization are anticipated.
- Subdivision (j)(1) clarifies that the citation shall include information that clearly identifies the source of the recommendation.
- Subdivision (k) makes clear when there is a discrepancy between recommendations cited; the underlying medical evidence supporting the differing recommendations shall be evaluated by using the explicit systematic methodology set forth in sections 9792.25.1 to determine which recommendation is supported with the highest level of evidence. Medical care shall then be in accordance with the recommendations supported by the best available medical evidence.

## **Proposed Amendments to Section 9792.25 – Strength of Evidence - Definitions**

- This section adds definitions specific to sections 9792.25-9792.26. The title of the section was originally "Presumption of Correctness, Burden of Proof and Strength of Evidence" and has been amended to "Strength of Evidence Definitions" to reflect the correct subject of the amended section. This section defines key terms to ensure that its meaning, as used in the regulations, will be clear to the public and to assist the regulated public in the understanding of the proposed methodology to evaluate the strength of evidence used to support the recommendations of a medical condition.
- This section is re-lettered and renumbered to accommodate the deletion of previous subdivisions and the addition of new definitions.
- Subdivision (a) specifies the additional definitions shall apply to sections 9792.25-9792.26.
- Subdivisions (a)(1) (29) sets forth the definitions for the following key terms "Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument," "Bias," "Biologic plausibility," "Blinding," "Case-control study," "Case report," "Case-series," "Cohort study,"

"Concealment of allocation," "Confounding variable," "Cross-sectional study," "Diagnostic test," "Disease incidence," "Disease prevalence," "Expert opinion," "Inception cohort study," "Index test," "Intention to treat," "Low risk of bias," "Meta-analysis," "Post-marketing surveillance," "Prognosis," "Randomized trial," "Reference standard," "Risk of bias," "Selective outcome reporting," "Systematic review," "Treatment benefits," and "Treatment harms".

# Proposed Adoption of Section 9792.25.1 – Strength of Evidence - Method for Evaluating the Quality of Evidence used to Support a Recommendation; MTUS Hierarchy of Evidence for Different Clinical Questions

- This section sets forth a systematic methodology to determine the strength of evidence used to support the recommendations of a medical condition replacing the Strength of Evidence methodology that was previously set forth in section 9792.25(c)(1)(A). The proposed strength of evidence methodology is called the MTUS Hierarchy of Evidence for Different Clinical Questions.
- Subdivision (a) requires the application of the MTUS Hierarchy of Evidence for Different Clinical Questions to evaluate the quality of evidence used to support a recommendation found in a medical treatment guideline or in a study published in the medical or scientific literature.
- Subdivision (a)(1) sets forth the first step in applying the MTUS Hierarchy of Evidence for Different Clinical Questions. Determine if the recommendation is applicable to the specific medical condition or diagnostic test requested by the injured worker. The recommendation that evaluates a population, setting or intervention most similar to the injured worker should be used and the reasoning documented.
- Subdivision (a)(2) requires the consideration bias may have had in the study used to support a recommendation. Bias factors include, but are not limited to, vested interests such as financial interests, academic interests, industry influence, and the methodological safeguards to protect against biases related to the generation of the randomization sequence, concealment of allocation, blinding, selective outcome reporting, early stopping, intention to treat, and confounding bias. A study that is determined to be of poor quality due to the presence of these factors shall not be used as justification for a medical treatment decision.
- Subdivision (a)(3) sets forth the third step in applying the MTUS Hierarchy of Evidence for Different Clinical Questions. Determine the design of the study used to support the recommendation. Study designs are categorized as systematic reviews of randomized controlled trials or prospective or cohort studies. Observational studies include prospective or cohort studies, cross-sectional studies, case-control studies, case series, uncontrolled or observational studies and case reports. Finally, published expert opinions may be used to support a recommendation.
- Subdivisions (a)(4)(A-D) sets forth the process to determine which of the four clinical questions is being answered by the study being evaluated as described in the MTUS Hierarchy of Evidence for Different Clinical Questions. The corresponding hierarchy of

evidence under Treatment Benefits, Diagnostic Test, Prognosis or Treatment Harms shall then be applied.

- Subdivision (a)(5) requires the levels of evidence shall be applied in the order listed from highest to lowest. Recommendations for or against medical treatment based on a lower level of evidence shall be permitted only if every higher ranked level of evidence is inapplicable to the employee's medical condition.
- Subdivision (a)(5)(A) requires the documentation of the level of evidence for each published study and the study's citation.
- Subdivision (a)(5)(B) requires a written statement when relying on lower levels of evidence that states higher levels of evidence are absent.
- Subdivision (b) sets forth the MTUS Hierarchy of Evidence for Different Clinical Questions.

# Proposed Amendments to Section 9792.26 - Medical Evidence Evaluation Advisory Committee

- This section addresses the role and duties of the Medical Evidence Evaluation Advisory Committee (MEEAC).
- Subdivision (a) re-numbered from (a)(1) by deleting "(1)" as this is a mistake in the numbering of the current regulations. The lower case first letters for the Medical Evidence Evaluation Advisory Committee has been deleted and replaced them with capital letters. MEEAC is then set forth in parenthesis to indicate for expediency this acronym will be used in latter references to the Medical Evidence Evaluation Advisory Committee.
- Subdivision (a)(1) is re-lettered from (a)(1)(A) by deleting "(A)" as this is a mistake in the lettering of the current regulations.
- Subdivision (a)(2) is amended by deleting "medical evidence evaluation advisory committee" and replacing it with the acronym "MEEAC" for expediency. The number "17" has been deleted and replaced with the number "19" to accommodate the two additional proposed members of MEEAC, a "Pharmacologist (PharmD)" and a "Nurse Practitioner (NP) or Registered Nurse (RN) or equivalent".
- Subdivision (a)(2)(P) is added to state "One member shall be from the pharmacology field."
- Subdivision (a)(2)(Q) is added to state "One member shall be from the nursing field."
- Subdivision (a)(2)(R) is re-lettered from (a)(2)(P).
- Subdivision (a)(3) is amended by deleting "seventeen" and replacing it with "nineteen" members and the acronym "MEEAC" replaces "the medical evidence evaluation advisory committee" twice for expediency.
- Subdivision (b) is amended by deleting "the medical evidence evaluation advisory committee" and replacing it with the acronym "MEEAC" for expediency.

- Subdivision (c) is amended by deleting the phrase "To evaluate evidence when making recommendations to revise, update or supplement the MTUS, the members of the medical evidence evaluation advisory committee shall:" and replacing it with the phrase, "Members of MEEAC shall make advisory recommendations to the Medical Director or his or her designee to revise, update or supplement the MTUS" to better match the structure and flow of changes to subsequent subdivisions.
- Subdivisions (c)(1-3) are deleted as these processes are no longer necessary because they have been deleted and changed.
- Subdivision (d) is added to replace former (c)(1) and clarifies MEEAC's advisory recommendations shall be supported by the best available medical evidence found in scientifically and evidenced-based medical treatment guidelines or peer-reviewed published studies that are nationally recognized by the medical community.
- Subdivision (e) is added to replace former (c)(2) and clarifies MEEAC shall use a modified version of the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument to assess the quality and methodological rigors used to develop a medical treatment guideline.
- Subdivision (e)(1) is added to clarify the modified AGREE II consist of the same six domains and two global rating items as the original AGREE II Instrument but includes two additional domains and additional key items.
- Subdivision (e)(1)(A) is added to clarify the additional domain in the modified AGREE II Instrument is Conflict of Interest.
- Subdivision (e)(1)(A) 1. Is a key item and is added to clarify that all conflicts of interest of each guideline development group member were reported and discussed by the prospective group prior to the onset of his or her work.
- Subdivision (e)(1)(A) 2. Is a key item and is added to clarify that each panel member explains how his or her conflict of interest could influence the clinical practice guideline development process or specific recommendations.
- Subdivision (e)(1)(A) 3. Is a key item and is added to clarify that the chairperson of the guideline development group had no conflicts of interest.
- Subdivision (e)(1)(B) is added to clarify the other additional domain in the modified AGREE II Instrument is Currency of Guideline.
- Subdivision (e)(1)(B) 1. Is a key item and is added to clarify that the guideline is being updated in a timely fashion, typically at least every three years and, if the guideline is more than five years old, it should be considered out of date.
- Subdivision (f) is added to clarify those recommendations in guidelines that have a low AGREE II overall score may still be considered by MEEAC provided that the evidence supporting the recommendation is the best available medical evidence.

- Subdivision (g) is added to clarify the process to be followed by MEEAC to determine the best available medical evidence is the strength of evidence methodology set forth in section 9792.25.2. MEEAC shall choose the recommendation supported by the best available medical evidence.
- Subdivision (h) is re-lettered from (d) and is amended by deleting the phrase "the medical evidence evaluation advisory committee" and replacing it with the acronym "MEEAC" for expediency. The phrase term "of two year period" is deleted and replaced with a "two-year" term for grammar and stylistic purposes. The minimum number of MEEAC meetings per year is amended from "four (4)" to "three (3)" times a year.
- Subdivision (i) is re-lettered from (e).

# Objective and Anticipated Benefits of the Proposed Regulations:

The objective of the proposed regulations is to improve the way in which medical evidence is evaluated in order to clarify the process in which clinical decisions are made for injured workers diagnosed with industrial conditions. The proposed MTUS Hierarchy of Evidence for Different Clinical Questions sets forth a methodology for the evaluation of medical evidence supported by various study designs. The current strength of evidence methodology is limited because it only provides a methodology to evaluate scientific evidence supported by randomized controlled trials.

The proposed regulations will be beneficial to the health and welfare of California residents by providing clearer guidance for medical decision-makers in situations where the scientific evidence on a particular treatment question is in dispute. Better informed treatment decisions are expected to produce improved health outcomes for affected injured workers and non-quantifiable savings in disability costs and treatment utilization.

# **Determination of Inconsistency/Incompatibility with Existing State Regulations:**

The Acting 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 Acting Administrative Director has concluded that these are the only regulations that provide a systematic methodology to evaluate the strength of evidence supporting a medical treatment recommendation.

## DISCLOSURES REGARDING THE PROPOSED ACTION

The Acting Administrative Director has made the following initial determinations:

- Mandate on local agencies and school districts: None.
- Cost or savings to any state agency: None
- 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 Acting 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 physicians and other medical providers. Although there may be minor costs to disseminate the revised criteria to serve as reference material in those processes, those minor costs will likely be offset by the savings from the clearer guidance for medical providers making treatment decisions. Better-informed treatment decisions should save costs with the avoidance of inappropriate medical treatment.
- Statewide adverse economic impact directly affecting businesses and individuals: Although the proposed action will directly affect business statewide, specifically physicians and other medical providers, the Acting 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.
- Significant effect on housing costs: None.

#### **Results of the Economic Impact Analysis/Assessment:**

- The Acting Administrative Director concludes that it is (1) unlikely the proposal will create some 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 business currently doing business within the State of California.
- Benefits of the Proposed Action: The benefit anticipated from the regulations is clarification of the scientific process in which clinical decisions are made for injured workers resulting in clearer guidance for medical providers making treatment decisions. Better-informed decisions are expected to produce improved health outcomes for affected injured workers, the delivery of state-of-the-art treatment when appropriate for the patient, and reduced overall cost of caring for chronic conditions, and non-quantifiable savings in disability costs and treatment utilization.
- Small Business Determination: The Acting Administrative Director has determined that the proposed regulations will not affect small businesses to a significant degree. Physicians and other medical providers may incur minor costs to disseminate the revised criteria to serve as reference material in those processes but those minor costs will likely be offset by the savings from the clearer guidance for medical providers making treatment decisions. Better-informed treatment decisions should save costs with the avoidance of inappropriate medical treatment.

#### CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Acting Administrative Director must determine that no reasonable alternative considered or brought to the attention of the Acting 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 Acting 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 <a href="https://www.dir.ca.gov">www.dir.ca.gov</a>. 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, 17<sup>th</sup> 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 Acting Administrative Director may adopt the proposed regulations substantially as described in this notice. If the Acting Administrative Director makes modifications which are sufficiently related to the originally proposed text, the Acting Administrative Director will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Acting 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 form 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 Acting Administrative Director's mailing list.

If adopted, the regulations as amended, will appear in California Code of Regulations, title 8, commencing with section 9792.25. The text of the final regulations also may be available through the website of the Office of Administrative Law at www.oal.ca.gov.