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 9792.20 – 9792.26

1. Introduction.

This Initial Statement of Reasons ("ISOR") describes the purpose, rationale, and necessity of the Division of Workers' Compensation's (DWC) proposed revisions and new regulations to the existing Medical Treatment Utilization Schedule (MTUS) regulations.

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.

The proposed regulations explain and clarify the scientific process by which evidence-based clinical decisions are made for injured workers. The role of the MTUS as the standard for the provision of medical care in accordance with Labor Code section 4600 for all injured workers is established. The proposed regulations set forth the 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. Recommendations shall be evaluated according to the explicit, systematic, strength of evidence methodology set forth in the proposed regulations to determine which recommendation is supported with the best available evidence. The recommendation supported with the best available medical evidence shall be used to determine what is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Finally, the proposed regulations add two additional members to the Medical Evidence Evaluation Advisory Committee (MEEAC) and address the role and duties of MEEAC.

DWC welcomes comments on the ISOR and on the proposed regulations that the ISOR describes. Please see the accompanying Notice of Rulemaking for instructions on how to submit comments electronically, on paper, and orally at the DWC hearing on the proposed regulations.

2. Technical, Theoretical, or Empirical Studies, Reports, or Documents.

The Division relied upon:

(1) Appraisal of Guidelines for Research & Evaluation (AGREE) II Worksheet (May 2009) (www.agreetrust.org)

(2) Akobeng AK, "Evidence-based child health. 1. Principles of evidence-based medicine" *Arch Dis Child,* 2005; Volume 90, 37-40.

(3) Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L. for the "AGREE Next Step Consortium. AGREE II: Advancing guideline development reporting and evaluation in healthcare" *Can Med Assoc J.,* 2010. Dec 2010; 182:E839-842; doi:10.1503/090449.

(4) Higgins JPT, Green S (editors). "Cochrane Handbook for Systematic Reviews of Interventions" Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from: www.cochrane-handbook.org

(5) Institute of Medicine (IOM). 2011 "Clinical Practice Guidelines We Can Trust" Washington DC: The National Academies Press.

(6) International Association of Industrial Accidents Boards and Commissions (IAIABC). 2011 Report on Guidelines Used by Various States. Available from: www.iaiabc.org/files/public/ResearchandReports_MedicalTreatmentGuidelines_StateIndex_IAIABC_2011.pdf

(7) Last JM, "A Dictionary of Epidemiology" (4th edition), Oxford University Press.

(8) Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009). Available from: www.cebm.net

(9) Sackett DL, Rosenberg WM, Gray JA, Haynes RB, and Richardson WS, "Evidence based medicine: what it is and what it isn't" *BMJ,* 1996; January 13, Volume 312, 71-72.

3. Specific Technologies or Equipment.

None.

4. Duplication or Conflicts with Federal Regulations (Gov. Code section 11346.2(b)(7)).

The proposed regulations do not duplicate or conflict with any federal regulations. There are no federal regulations that prescribe rules for Medical Provider Networks.

5. 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)(6)(A)).

The Acting Administrative Director has determined that the proposed regulations will not have a significant, statewide adverse economic impact directly affecting business. The proposed regulations will explain and clarify the scientific process by which evidence-based clinical decisions are made for injured workers. They update the grading criteria for weighing scientific evidence when deciding the appropriate medical treatment for an injured worker. This process currently exists but the grading criteria are limited in scope because it only allows for the evaluation of randomized controlled trials and does not provide a methodology for evaluating other types of evidence. Moreover, the current strength of evidence methodology is complicated and burdensome. The effect of this rulemaking is clearer guidance for medical decision-makers in situations where the scientific evidence on a particular treatment question is in dispute.

Although there may be minor costs to disseminate the amended criteria to serve as reference material in the medical decision making process, those costs will likely be offset by the savings from avoidance of inappropriate medical treatment, 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.

6. Economic Impact Analysis ((Gov. Code section 11346(b)(1)(A)-(D)).

<u>The Creation or Elimination of Jobs within the State of California</u>

The Acting Administrative Director has determined that the proposed regulations will not have a significant impact on jobs within the State of California. The proposed regulations will explain and clarify the scientific process by which clinical decisions are made for injured workers. The MTUS Hierarchy of Evidence for Different Clinical Questions will replace the strength of evidence methodology that was limited in scope and will provide clearer guidance for medical decision-makers and treating physicians. Although businesses, particularly physicians and other medical providers, may incur 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. Therefore, the proposed regulations will neither create nor eliminate jobs within the State of California.

<u>Creation of New Businesses or the Elimination of Existing Businesses within the State of California</u>

The Acting Administrative Director has determined that the proposed regulations will not significantly create or eliminate businesses within the State of California. The proposed

regulations clarify and improve the way medical treatment decisions are made but it is not expected to create new businesses or 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 because a methodology to evaluate the strength of medical evidence already exists. Those who are making medical treatment decisions, namely physicians and other medical providers are already required to apply the current methodology when deciding appropriate medical treatment. The proposed regulations will clarify and improve the medical decision making process but it is not expected to expand businesses currently doing business within the State of California.

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

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

7. The Specific Purpose, Rationale, and Necessity of Each Section of the proposed revisions and proposed new MTUS regulations (Gov. Code section 11346.2(b)(1)).

The Specific Purpose, Rationale, and Necessity of Each Section of the proposed new or proposed revised MTUS regulations, in accordance with Government Code section 11346.2(b)(1) is provided below.

Section 9792.20 Medical Treatment Utilization Schedule - Definitions.

Specific Purpose:

This section lists and defines key terms used in these regulations. The purpose of the definitions is to ensure that the meanings of these terms, as used in the regulations, are clearly understood by the public.

The section has been changed to: (1) add a new definition for "evidenced-based medicine" to provide a term that describes the broader systematic approach to making clinical decisions and delete the narrower term "evidenced-based" that merely describes the literature that must be used to support recommendations; (2) amend the definition for "functional improvement" to make it more comprehensive by deleting the limiting phrase "evaluation and management visit billed under the Official Medical Fee Schedule (OMFS)"; (3) amend the definition for "nationally recognized" for clarity to delete the option that two or more U.S. state governments or the U.S. federal government" adopt it for use because there are guidelines being used in states or the

federal government that are not evidenced-based; (4) add a new definition for "ODG" to describe the Official Disability Guidelines because this is a guideline that contains evidenced-based recommendations for conditions commonly associated with the workplace and parts have been incorporated into the MTUS; (5) amend the definition for "peer-reviewed" to delete the reference to "medical" studies to broaden the definition because other useful studies can be reviewed other than medical studies; and (6) amend the definition for "scientifically based" to delete the reference to "MEDLINE" to make the definition more comprehensive. The reference to "for the guideline" is deleted and replaced with "to support a recommendation" for accuracy because literature can be used as the basis for a guideline and to support a recommendation in a peer-reviewed published study.

The subdivisions have also been renumbered to reflect the deletion and addition of definitions.

Necessity:

It is necessary to define each of the key terms used in the MTUS regulations to ensure that their content and meaning, as used in the regulations, are clearly understood by the public. New definitions have been added and existing definitions are amended to ensure consistency of interpretation to terms being used in order to provide clarity and to ensure proper compliance with the regulations.

Consideration of Alternatives:

No more effective alternative to any of the definitions, nor equally effective and less burdensome alternative, has been identified by the Acting Administrative Director at this time. The public is invited to submit such alternatives during the public comment process.

Section 9792.21 Medical Treatment Utilization Schedule

Specific Purpose:

The purpose of this section is to make specific the systematic Evidence-Based Medicine approach to making clinical decisions in the workers' compensation system. This section clarifies the role of the MTUS as the standard for the provision of medical care in accordance with Labor Code section 4600. The MTUS is presumptively correct on the issue of extent and scope of medical treatment and diagnostic services for the duration of an industrial condition. However, since the MTUS cannot address every conceivable medical condition or if there is evidence to rebut the MTUS, these proposed amendments specify the procedure to evaluate medical evidence in order to determine the best available medical evidence. The process begins with a medical literature search sequence that shall be conducted by providers making treatment decisions and should be conducted by treating physicians. These proposed regulations instruct the regulated public to begin their search with the most current versions of ACOEM or ODG. Both of these guidelines are currently used in California as indicated in the International Association of Industrial Accident Boards and Commissions (IAIABC) "Report on Guidelines Used by Various States 2011". In addition, the Medical Evidence Evaluation Advisory

Committee (MEEAC) recommended ACOEM or ODG to begin the medical literature search sequence because both guidelines are comprehensive and address conditions typically experienced by injured workers. The medical literature search sequence will continue to other treatment guidelines if no applicable recommendation is found or if the current version is more than five years old or if the medical reviewer or treating physician believes there is another recommendation supported with a higher level of evidence not found in either ACOEM or ODG. Finally, the medical literature search sequence will continue to current scientific studies, five years old or less, if no applicable recommendation is found or if the current version is older than five years old or if the medical reviewer or treating physician believes there is another recommendation supported with a higher level of evidence not found in other evidence-based medical treatment guidelines. After a medical literature search is conducted, the recommendation applicable to the injured worker that is supported with the highest level of evidence shall be cited in either the Utilization Review decision or the Independent Medical Review decision. In addition, treating physicians should cite the applicable recommendation in the chart notes or Request for Authorization. The purpose of these proposed regulations is to establish the process to evaluate medical evidence. If there is a discrepancy between the recommendations cited the underlying medical evidence supporting the differing recommendations shall also be evaluated according to the strength of evidence methodology set forth in section 9792.25.1.

Necessity:

This section is necessary to clarify the systematic Evidence-Based Medicine approach to making clinical decisions. The proposed regulations make clear the MTUS is the standard for the provision of medical care for all injured workers diagnosed with industrial conditions. They set forth the procedural process that should be followed if the MTUS is successfully rebutted or when a medical condition is not addressed by the MTUS. The procedural process begins with a medical literature search to find a recommendation applicable to the injured worker's specific medical condition. The medical literature search sequence is necessary to make the resource-intensive process of conducting a medical literature search more efficient. In addition, the medical literature search sequence ensures consistency when searching for medical evidence.
Providing a citation of the recommendations source in Utilization Review decisions and Independent Medical Review decisions is necessary to ensure transparency. In addition, it is necessary to determine if there is a discrepancy in the recommendations. The differing recommendation will be evaluated according to the strength of evidence methodology set forth in section 9792.25.1 to determine which recommendation is supported with the best available medical evidence. The proposed regulations are necessary because they provide the regulated public with a clear step-by-step process to determine how to evaluate medical evidence and results in more consistent decisions proven to be beneficial. Medical care shall be in accordance with the recommendation supported with the best available medical evidence.

Consideration of Alternatives:

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

Section 9792.25 Strength of Evidence - Definitions

Specific Purpose:

This section lists and defines key terms used to apply the MTUS Hierarchy of Evidence for Different Clinical Questions as set forth in section 9792.25.1 to ensure that the meanings of the terms, as used in the regulations, are clearly understood by the public.

The original text in subdivisions (a) through (c) and the corresponding Tables A and B have been deleted as unnecessary because the text and tables relate to a methodology to determine the strength of evidence that will no longer be used.

Necessity:

It is necessary to define each of the key terms used in the MTUS regulations to ensure that their content and meaning, as used in the regulations, are clearly understood by the public. New definitions have been added and existing definitions are amended to ensure consistency of interpretation to terms being used in order to provide clarity and to ensure proper compliance with the regulations.

Consideration of Alternatives:

No more effective alternative to any of the definitions, nor equally effective and less burdensome alternative, has been identified by the Acting Administrative Director at this time. The public is invited to submit such alternatives during the public comment process.

Section 9792.25.1 – Method for Evaluating the Quality of Evidence used to Support a Recommendation; DWC/MTUS Hierarchy of Evidence

Specific Purpose:

This section sets forth a systematic methodology to determine the strength of evidence used to support the recommendations for a medical condition found in a medical treatment guideline or in a study published in the medical or scientific literature. This section clarifies that the MTUS Hierarchy of Evidence for Different Clinical Questions shall be used to determine the best available medical evidence. The proposed amendments provide step-by-step instructions on how to apply the MTUS Hierarchy of Evidence for Different Clinical Questions. Once it is applied, the proposed amendments require the public to use the evidence with the highest level of evidence. The proposed amendments then set forth the MTUS Hierarchy of Evidence for Different Clinical Questions.

Necessity:

It is necessary to set forth a clear, systematic methodology for evaluating medical evidence. The Strength of Evidence methodology in our current regulations is adopted from ACOEM and is limited in its application because it merely provides a methodology to evaluate medical evidence supported by randomized controlled trials. ACOEM takes the position that evidence other than randomized controlled trials is not scientific and cannot be used as the basis to support a recommendation, particularly an intervention. However, DWC takes the position that the MTUS shall be supported by the current best available evidence in making clinical decisions. Therefore, the proposed regulations are necessary to specify the process to evaluate medical evidence.

Consideration of Alternatives:

Alternative #1: No need for a strength of evidence methodology because the MTUS shall always constitute the standard of care.

Analysis: Although it would be ideal if the MTUS always constituted the standard of care, this alternative is not feasible because it fails to acknowledge the ever evolving nature of medical evidence. New studies may be published that changes a medical recommendation. If this alternative were to be implemented, DWC would need to constantly update its regulations to keep up with the changes brought about by new medical evidence. In addition, the rulemaking process usually takes about one year to complete, at best, the rulemaking process will take a few months. No regulatory process will be in place to accommodate changes to a medical recommendation during the rulemaking process.

Alternative #2: Maintain the current strength of evidence methodology, as adopted from ACOEM, because randomized controlled trials are usually considered scientific evidence of the highest quality.

Analysis: Although randomized controlled trials are generally considered scientific studies of the highest quality, many medical interventions have not been rigorously evaluated with randomized controlled trials. Medical recommendations supported by medical evidence considered to be of a lower quality should not be automatically discredited or in this alternative precluded from supporting medical interventions. For example, there are randomized controlled trials that are flawed and deficient that they should not be considered better evidence than a study considered to be a lower level, such as a large, well-designed observational study. Accordingly, the process to evaluate and rank various study designs should be included in the strength of evidence methodology in order to determine the best available medical evidence.

Alternative #3: Incorporate a strength of evidence methodology that quantifies differences in applicability, consistency, study design and quality to evaluate medical evidence in more detail then what is currently proposed.

Analysis: Although there is clearly more room to evaluate the nuanced differences between the medical evidence supporting recommendations, DWC is balancing the need for evaluation of

medical evidence with the practical limitations faced by a medical provider in the workers' compensation system. This alternative would be ideal for epidemiologist but would not be practically applicable for many medical providers in the workers' compensation system due to limitations in time and costs.

Section 9792.26 – Medical Evidence Evaluation Advisory Committee

Specific Purpose of Section 9792.26

This section expands the Medical Evidence Evaluation Advisory Committee (MEEAC) by two additional members to include a pharmacologist and a representative from the nursing community to provide the Medical Director with advisory input from these important medical fields. In addition, the methodologies to be used by MEEAC to evaluate medical evidence are specified. MEEAC shall use the Appraisal of Guidelines for Research & Evaluation II (AGREE II) Instrument to narrow its choice of guidelines. MEEAC may still use a guideline with a low AGREE II overall score provided that the recommendation is the best available medical evidence. Consistent with the stakeholder public, MEEAC shall apply the DWC Hierarchy of Evidence for Different Clinical Questions to determine the best available medical evidence from which it will base its recommendations. The purpose of this section is to make clear to the stakeholder public the process MEEAC will use to formulate its advisory recommendations to the Medical Director.

Necessity:

It is necessary to specify the process MEEAC will use to formulate its advisory recommendations to the Medical Director to ensure that the regulated community understands MEEAC's recommendations are based on the principals of Evidence-Based Medicine.

Consideration of Alternatives:

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